Anatomy of a License Agreement

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Author's note: Most of the examples in this chapter are taken from Stanford University's standard license agreements. Stanford takes no responsibility for this language and any use of the language is done at the user's own risk.

Introduction

A license agreement is a contract between parties to allow one party the right to something that is owned or controlled by another party. The owning/controlling party usually receives some sort of consideration for granting this right.

Before delving into the substance of the agreement itself, a note on the use of plain language. If you keep the language clear, concise, and as simple as possible, anyone reading the agreement will understand your intentions. Clear, concise, and simple language is important in order that:

a) when starting the relationship with the other party, you both have the same understanding of the contract and to what you've each agreed;
b) if you or your licensing counterpart leave your respective entities, anyone else can pick up the agreement and will have the same interpretation as the two of you did; and
c) if the agreement becomes part of a legal action, any third party will interpret the agreement in the way you intended, including a judge or jury of your peers.

If you are not sure if something is clear, it likely isn't. Run the language by your colleagues (without providing any interpretations!) before signing as at least one test to make sure you are understood.

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The Beginning

In the opening words of a license agreement, you meet the parties entering into the agreement. Like being formally introduced to someone for the first time, you are told the who, where, and what about the party—its full legal name, address, place of business, and type of entity. The licensee is the party attaining rights under the agreement, and the licensor is the party granting the rights.

Following the introductions, some background (often called *recitals*) may be provided on the entities. What is the topic of the agreement? Are there others involved of whom to be aware? Why are the parties working together? The background frames the agreement and provides support for the subsequent sections. However, some entities may choose not to include a background section since it is purely informational and not usually a substantial part of the agreement.

Definitions

Definitions is often the next section of a license agreement because it defines words that you will use throughout the agreement. It is important to define any word or phrase that could be open to interpretation or to create a definition for any phrase you will use repeatedly in the agreement. Definitions also ensure that both parties have the same intent when using a particular word or phrase. Even the word *exclusive* is important to define, as exclusive may have certain caveats—particularly in the university technology transfer world in which inventions are sponsored by the government (nonexclusive license to the government required under Bayh-Dole) and retained rights are of increasing importance (See Point 1 of the "Nine Points to Consider in Licensing," on the AUTM Web site at http://www.autm.net/AM/Template.cfm?Section=Nine_Points_to_Consider).
Example words and phrases to define in your license agreement follow:

Exclusive/Nonexclusive

If including any exclusivity in the agreement, you should define the term *exclusive*. How exclusive is the relationship between the parties? By stating there is exclusivity, what does that allow or prohibit each party from doing?

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An example definition:

> *"Exclusive" means that, subject to Articles X and Y, Licensor will not grant further licenses under the Licensed Patents in the Licensed Field of Use in the Licensed Territory.*

In this example, exclusivity is defined by the university agreeing it will not grant any more licenses to the patent falling under the agreement (licensed patent) in the area the company will use the patent (licensed field of use), with the exception of two instances named in the articles X and Y (in Stanford's case, these articles are (a) the licensee retains for itself and all other academic research institutions and (b) any rights the government may have to the technology per Bayh-Dole).

If granting a nonexclusive license, the licensor can license the licensed patent to other parties.

Licensed Field of Use

The licensed field of use states the area in which the licensor is allowing the licensee to use the licensed patent. For example, if the licensed patent covers a compound that may be useful in the treatment of certain central nervous system diseases, but the licensor only wants to develop the compound to treat Alzheimer's, the licensed field of use would be "therapeutics for Alzheimer's disease."

When possible, carefully define the field of use and provide diligence for each part of the licensed field of use, especially in exclusive licenses. (More on diligence is in another section of this article.) If the licensed field of use is not carefully defined, the licensor may find it has unintentionally granted rights beyond the scope of what it intended. This is particularly important when granting multiple licenses on a single technology.

Licensed Patent

The licensed patent rights are often the core of what is granted to the licensee by the licensor. The licensed patent definition should encompass all of the patents that fall under the agreement.

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A sample definition for the licensed patent is:

> *"Licensed Patent" means Licensor's U.S. Patent Application, Serial Number _____, filed _____, any foreign patent application corresponding thereto, and any divisional, continuation, or reexamination application, and each patent that issues or reissues from any of these patent applications. Any claim of an unexpired Licensed Patent is presumed to be valid unless it has been held to be invalid by a final judgment of a court of competent jurisdiction from which no appeal can be or is taken."Licensed Patent" excludes any continuation-in-part (CIP) patent application or patent.*

A list of the known licensed patents may be included in this definition or in an appendix of the license agreement. However, not all licensed patents may be known at the time of licensing, especially in cases where only a provisional patent application has been filed at the time of licensing.

Different institutions have different philosophies on granting rights to continuation-in-parts (CIPs) and improvement inventions. Be careful to assess what those CIPs or improvements may be—has the value already been accounted for under the license? Does the licensor even have the right to be able to grant rights to such improvements (for example, what if the improvement is sponsored by a third party)?

Licensed Product

The licensed product is the eventual product made using the technology licensed under the agreement. The definitions of licensed patent, technology, or whatever is being licensed under the agreement are needed under this licensed product definition since the use of the licensed intellectual property or other matter defines whether the eventual product is something that falls under the license agreement.

A sample definition:

> *"Licensed Product" means a product or part of a product in the Licensed Field of Use:*
>
> *(A) the making, using, importing, or selling of which, absent this license, infringes, induces infringement, or contributes to infringement of a Licensed Patent; or*
>
> *(B) which is made with, uses or incorporates any Technology.*

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Licensed Territory

The licensed territory is where the licensee can use the rights granted under the license agreement. The majority of license agreements from institutions define the licensed territory as worldwide, but some license agreements restrict where the licensee may practice the licensed patent and/or sell licensed product. A licensor could also grant to a party exclusive rights for certain territories and nonexclusive rights in others.

Net Sales

If, as part of the consideration for granting the license agreement, the licensor is receiving payments based on sales of the licensee's licensed products, a definition is needed for those sales. The definition of sales can range from a simple statement to something more complex. For example, it could simply be the gross sales of the licensed product by the licensee (or any sublicensees). Or it could be the gross sales minus an agreed-upon percentage (e.g., 5 percent). However, the majority of license agreements have more complex net sales definitions, allowing for the deduction of certain items from the gross sales before any calculation is made on the payment to licensor.

A sample net sales definition:

> *"Net Sales" means all gross revenue derived through Licensee or sublicensees from Licensed Product. Net Sales excludes the following items (but only as they pertain to the making, using, importing, or selling of Licensed Products; are included in gross revenue; and are separately billed):*
>
> *(A) import, export, excise and sales taxes, and custom duties;*
>
> *(B) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises or point of installation;*
>
> *(C) costs of installation at the place of use; and*
>
> *(D) credit for returns, allowances, or trades.*

Grant

The grant is the main purpose of the agreement, outlining exactly what the licensor is allowing under the agreement.

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Grant of Rights to Licensee

The grant section explains what the licensor (the party granting the rights) is allowing the licensee (the party receiving the rights) to do. Note that patents are a negative right, therefore a nonexclusive license really is the licensor granting the licensee permission to infringe the licensed patent in the development and sale of a licensed product.

A sample grant clause is:

> *Licensor grants Licensee a license under the Licensed Patent in the Licensed Field of Use to make, have made, use, import, offer to sell, sell, and have sold Licensed Product in the Licensed Territory.*

The licensees often want to include all of these ways to use licensed patent (make, have made, use, import, offer to sell, sell, and have sold licensed product) because licensees may not actually make or sell the product themselves, but instead contract this work out to third parties.

Exclusivity and Term of the Agreement

All right, so the licensor has told the licensee that it is getting a grant of certain patent rights. But is the licensor restricting itself at all from granting other licenses? If so, how? And for how long will the license last?

For example, if the licensor wants to grant only the license to the licensee in a certain field of use and only for 10 years from date of first commercial sale, the next section of the agreement would state:

> *Said license is Exclusive, including the right to sublicense under Article 4, in the Licensed Field of Use beginning on the Effective Date and ending on the 10th anniversary of the first date of commercial sale of a Licensed Product.*

The license could either terminate thereafter or could be nonexclusive. This may depend on the type of technology and the life left on the licensed patent.

Be sure to include a section in the license agreement under which the licensee must tell the licensor when the first commercial sale occurs (see the “Diligence and Reporting” sec-

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tion). Not only may it be important for the term of the license, but if the invention is sponsored by the government, the government requires institutions to obtain this information.

Retained Rights and Government Rights/Provisions

As mentioned previously in this article, retained rights have increased in importance to academic institutions, especially in light of the *Duke v. Madey* decision. Therefore, most institutions now recommend some version of retaining rights to technologies such that academic researchers are free to do academic research without fear of a lawsuit for infringing a patent. For more on *Duke v. Madey*, see Volume 1 of the AUTM Technolgy Tranfer Manual)

The "Nine Points to Consider in Licensing" contains three sample retained rights clauses in the Appendix, Part 1. It is available on the AUTM Web site at http://www.autm.net/AM/Template.cfm?Section=Nine_Points_to_Consider.

The federal government also often has certain rights to inventions based on its sponsorship of those inventions. Stanford includes the following clause in exclusive licenses to notify the licensee of those rights and references this clause in its definition of exclusive:

> *This Agreement is subject to Title 35 Sections 200-204 of the United States Code. Among other things, these provisions provide the United States Government with nonexclusive rights in the Licensed Patent. They also impose the obligation that Licensed Product sold or produced in the United States be "manufactured substantially in the United States." Licensee will ensure all obligations of these provisions are met.*

In nonexclusive licenses, the third sentence regarding substantial manufacture is not needed since the licensee still has the right to grant other licenses in the U.S. All other provisions in the above paragraph are included, though. (To review the provisions of Bayh-Dole, visit the Cornell University Web site at http://www4.law.cornell.edu/uscode/35/200.html. Press "next" in the upper right-hand corner to review sections 201-204.)

As a brief overview (and not all-inclusive), the Bayh-Dole act stipulates the following:

1) Nonprofit organizations and small businesses are allowed to own the inventions created with the use of federal funds, but in order to do so they must abide by other provisions of the Bayh-Dole Act.

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2) The funded entity must disclose the invention to the government within a reasonable time.
3) The funded entity must elect to retain title of the invention within a certain period of time.
4) The government has a nonexclusive right to use the invention for its own purposes.
5) If the funded entity does not decide to pursue the invention, it needs to notify the government in a timely manner in order that the government may pursue the rights, if it chooses to do so.
6) If the funded entity is a nonprofit, then:
   a) it cannot assign rights to the invention without prior approval from the federal agency;
   b) it must share royalties with the inventors;
   c) after payments of expenses and royalties to inventors, the balance must be used for the "support of scientific research or education;" and
   d) a preference should be shown for licensing to small businesses.
7) The government has march-in rights for federally funded inventions, meaning that if the technology is exclusively licensed and the federal agency that funded the invention finds that the licensed entity is not meeting certain requirements or needs, the government can use the rights in the technology to meet the requirements or needs.
8) For any exclusive licensing, the licensee must agree "that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States" unless the licensee receives a waiver from the U.S. government.

Financials

In consideration of granting the license, the licensee will pay certain amounts to the licensor. The financials of a license agreement are a balancing act. Whereas one licensor may be willing to pay more on the license product, another licensor may prefer to pay more upfront and less on the product made in the future. Below are several typical types of licensing payments, but certainly not an exhaustive list. For example, some licenses may only require a one-time payment or simply an annual renewal fee. Be sure to appropriately customize the types of payment to the type of license being granted.

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Upfront Payment (aka Issue Fee)

An upfront payment (or issue fee) is made in consideration of the grant of the license. Typically upfront payments are not creditable towards any other payments and are not refundable once made.

An upfront can reflect:

- a part of the value of the technology that is being licensed, including the resources already devoted to producing the licensed technology
- a consideration for the time and effort to enter into the license
- a diligence payment for the upcoming work to be done on the technology
- payments already made by licensor for licensed patent's expenses

An upfront payment can be in the form of cash and/or stock. Upfront payments can also potentially be spread out over time, especially in the case of startup companies that are low on cash in the beginning.

Annual Minimum/Annual Maintenance Payment

An annual maintenance payment reflects:

- the licensee's diligence in continuing to pursue the technology
- a minimum amount the licensee will pay to licensor for that year to keep the license

Annual payments are often creditable toward earned royalties. They can either be cumulatively creditable or only creditable for the year in which the payment was made. In order to ensure both parties understand how the credit operates, an example may be used in the license agreement. Following is sample language for the example in the case of an annual minimum that is only creditable for one year, taken from Stanford's boilerplate agreement:

For example:

> *(A) if Licensee pays Stanford a $10 maintenance payment for year Y, and according to Section 7.4 $15 in earned royalties are due Stanford for Net Sales in year Y, Licensee will only need to pay Stanford an additional $5 for that year's earned royalties.*

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(B) if Licensee pays Stanford a $10 maintenance payment for year Y, and according to Section 7.4 $3 in earned royalties are due Stanford for Net Sales in year Y, Licensee will not need to pay Stanford any earned royalty payment for that year. Licensee will not be able to offset the remaining $7 against a future year's earned royalties.

Earned Royalties

When a licensee sells products or services based on the technology licensed from the licensor (licensed products) the company often pays an earned royalty on the product to the licensor. The most common form of this earned royalty is a percent of net sales (defined above). However, it can also be a fixed amount per unit sold (e.g., $1 per widget sold) or a fixed amount depending on the total sales (e.g., $10 if sales are below $100, $25 if sales are between $100 and $1,000, and $100 if sales are over $1,000).

If a percentage of net sales is used as the earned royalty, the percentage may also vary depending on the total net sales, the type of licensed product (e.g., is it a diagnostic or a therapeutic), what earned royalty payments the licensee must make to third parties (which often means a stacking clause is included in the license agreement), and/or if the licensed product is sold in combination with other products that are not licensed products. This last type of alteration to the earned royalties is defined under a combination products clause.

A sample of such a clause follows:

It is recognized that Licensed Product(s) may be sold in combination with other therapeutically active substances (hereinafter referred to as "Combination Product[s]"). "Therapeutically active" shall mean biologically active in achieving a clinical therapeutic objective in concert with, or supplementary to, a Licensed Product(s). In determining the Net Sales of Combination Product(s), Net Sales shall first be calculated in accordance with the definition of Net Sales in Paragraph X.X and then multiplied by the percentage value of the Licensed Product(s) contained in the Combination Product(s), such percentage value being the quotient obtained by dividing (a) the cur-

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rent market value of the Licensed Product(s) by (b) the sum of the separate current market values of the Licensed Product(s) and the other components which are contained in the Combination Product(s). The current market value of each therapeutically active ingredient and of the Licensed Product(s) shall be for a quantity comparable to that contained in the Combination Product(s) and of the same class, purity, and potency. When no current market value is available for a component other than the Licensed Product(s) of a Combination Product(s), LICENSEE shall calculate a hypothetical market value for such component, allocating the same proportions of costs, overhead, and profit as are then allocated to similar components made by LICENSEE and having an ascertainable market value. If, however, the parties determine that the above formula does not adequately and fairly reflect the contribution of each component in a particular Combination Product(s), then the parties shall negotiate in good faith a modification of the formula for the determination of Net Sales of that Combination Product(s).

A sample stacking clause may be:

In the event that Licensee incurs royalty obligations to any third party in order to make, have made, use or sell a Licensed Product within the Field Of Use, then Licensee shall be entitled to set off as a credit against earned royalty payable to Licensor under Section X.X on Net Sales of such Licensed Product, fifty percent (50%) of the amount actually paid to such third parties under such licenses for sales of Licensed Product; provided, however, that in no event shall the earned royalty payable to Licensor under section X.X for Net Sales be reduced by more than 50%.

However, note that stacking should be negotiated when discussing the financial terms of the agreement. If you have already agreed on your well-balanced financial terms, stacking can be an unwelcome additional deduction.

Another area to note under earned royalties is sales by sublicensees. Will the earned royalty also apply for sublicensees' sales or is remuneration from sublicensees accounted for in

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a different manner? An example may be that the licensor receives a certain percentage of all sublicensing income the licensee receives from the sublicensee (not a separate earned royalties amount). Another route is for the licensor to receive a certain percentage of sublicensing income the licensee receives from the sublicensee, except for earned royalties. In the case of earned royalties, the licensor could be paid on what is called a pass-through basis, meaning the licensor receives what it would have received if the direct licensee had sold the product.

Milestone Payments

Milestone payments may also be part of the consideration for the license. These payments reflect the proven and increased value of the licensed technology. Milestone payments are more common in field exclusive or fully exclusive licenses than nonexclusive licenses, but can be included in any license to gain the balanced financial consideration.

Types of milestone payments include:

- therapeutics (upon investigational new drug filing; initiation of Phase I, II, and/or III clinical trials; nondisclosure agreement filing; Food and Drug Administration approval)
- prototype
- first commercial sale
- strategic partner signed
- funding (e.g., $1,000,000 total received by licensee from outside sources)
- first issuance of patent in a certain country
- issuance of certain types of patent claims
- proof of concept
- number of years of survival of agreement

Typically the amount of the milestone payment reflects the increased value of the technology following the achievement of the milestone.

Patent Expenses

In most exclusive licenses, the licensee reimburses the licensor for patent expenses. These expenses may or may not include expenses incurred prior to the effective date of

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the license agreement. When drawing up a term sheet for an exclusive license, include reference to patent expenses and be as explicit as possible regarding which expenses the licensee will reimburse.

Sometimes in nonexclusive licenses a portion of patent expenses may also be reimbursed by the licensee to the licensor, or the licensor may include consideration of the patent expenses in the upfront and annual payments.

Discussion of Most Favored Nations

Some nonexclusive licenses may include a most favored nations (MFN) clause. A sample MFN clause may read:

> *If Licensor grants a license for the Licensed Patent(s) to a third party to make, use, or sell the Licensed Product(s) on terms more favorable than the terms of this Agreement, Licensor will immediately notify Licensee and, at Licensee's option, this Agreement will be amended so that Licensee will receive the benefit and burdens of the terms granted to such third party. The remaining terms of this Agreement will continue in force.*

Be careful when including such provisions—the institution may not have an easy mechanism by which to remember when it granted a MFN. It may also be difficult to determine which are more favorable terms for a license. For example, a license may be more financially back-loaded vs. front-loaded. Other provisions may need to be in alignment as well, such as the licensed field of use, for the MFN clause to apply.

Diligence and Reporting

No one wants to grant a license simply to see a technology collect dust on a shelf. Licenses from institutions are granted so that products can be made to better the world. Therefore, diligence requirements for the licensee are included in agreements to help assure that progress will be made, and the invention hopefully developed into a product.

Both general diligence clauses and specific diligence milestones are typically found in license agreements. In a nonexclusive license agreement, milestones may or may not be included, depending on the technology and the institution's practices. Some sort of diligence should be included even under nonexclusive licenses, though. Otherwise, a licensor could license

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the technology simply to bar the institution from granting an exclusive license.
A sample diligence clause is:

> *Because the invention is not yet commercially viable as of the Effective Date, Licensee will diligently develop, manufacture, and sell Licensed Product and will diligently develop markets for Licensed Product. In addition, Licensee will meet the milestones shown in Appendix A, and notify Licensor in writing as each milestone is met.*

In order to know whether the licensee is being diligent, the licensor will ask for progress reports. Typically such reports are submitted annually. Information contained in these reports may also be required by the government, particularly the date the first commercial product is sold using a technology funded in part by the federal government.

If the licensee is not fulfilling its obligations of diligence or reporting, usually the licensor is allowed to terminate the agreement with sufficient notice to the licensee.

Warranties and Indemnities

A warrant is a written guarantee of the integrity of something. When considering warranties, the licensor and licensee must determine what risks they are willing to take. An institution is not often willing to warrant anything with regard to the licensed technology (e.g., whether the technology will work and if the licensor can commercialize it). In other words, the licensee takes the license and uses the invention at the licensee's own risk. The practices of your institution for warranties may be regulated by your risk management and/or general counsel's offices. Check with appropriate staff regarding what terms are acceptable for your institution or company.

Indemnity is security against hurt, loss, damage, liability for the licensed technology. In general, institutions want to be indemnified by the licensee for any claims or actions resulting from the use of the licensed technology. The exception on this may be the gross negligence or willful misconduct of the institution (licensor) or the researcher at the institution.

In general, the licensees of institutional technologies take on the technologies at their own risk. Certain exceptions can apply, but it is important to know what exceptions an institution is willing to make.

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Patent Prosecution and Protection

Patent Prosecution

In an exclusive license, the exclusive licensee may request to have involvement with the prosecution of the licensed patent. The involvement may range from being copied on all patent correspondence to use of licensee's own in-house counsel. Each licensor must decide for each technology where its comfort level is for the transfer of control of the patent prosecution to the licensee. The licensor should at least retain review rights of prosecution as well as the final decision on matters regarding the substance and national filings of the patents. There should be a clear understanding by the licensee and attorney of record as to who (licensee or licensor) is the attorney's client.

A sample clause under which the licensee is responsible for patent prosecution is:

> *Following the Effective Date and subject to Stanford's approval, Licensee will be responsible for preparing, filing, and prosecuting broad patent claims (including any interference or reexamination actions) for Licensor's benefit in the Licensed Territory and for maintaining all Licensed Patents. Licensee will notify Licensor before taking any substantive actions in prosecuting the claims, and Licensor will have final approval on how to proceed with any such actions. To aid Licensee in this process, Licensor will provide information, execute and deliver documents, and do other acts as Licensee shall reasonably request from time to time. Licensee will reimburse Licensor for Licensor's reasonable costs incurred in complying with such requests.*

In a nonexclusive license, in general the licensor retains all control of the patent prosecution.

Suspected Infringement

If it is suspected that a third party is infringing the licensed patent, license agreements often address how to proceed against the suspected infringer. In nonexclusive licenses, typically the licensee will inform the licensor of any suspected infringement, and the licensor will then have full decision authority on how to pursue the suspected infringer.

In the case of an exclusive license, the licensor and licensee arrange which party can pursue the suspected infringer, the notifications required by one party to the other, who will pay what costs, and how the outcome of any action will be split.

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Sample clauses on suspected infringement:

1.1 Licensor Suit. Licensor has the first right to institute suit, and may name Licensee as a party for standing purposes. If Licensor decides to institute suit, it will notify Licensee in writing. If Licensee does not notify Licensor in writing that it desires to jointly prosecute the suit within 15 days after the date of the notice, Licensee will assign and hereby does assign to Licensor all rights, causes of action, and damages resulting from the alleged infringement. Licensor will bear the entire cost of the litigation and will retain the entire amount of any recovery or settlement.

1.2 Joint Suit. If Licensor and Licensee so agree, they may institute suit jointly. If so, they will:

(A) prosecute the suit in both their names;
(B) bear the out-of-pocket costs equally;
(C) share any recovery or settlement equally; and
(D) agree how they will exercise control over the action.

1.3 Licensee Suit. If neither Section 1.1 nor 1.2 apply, Licensee may institute and prosecute a suit so long as it conforms with the requirements of this Section and Licensee is diligently developing or selling Licensed Product. Licensee will diligently pursue the suit and Licensee will bear the entire cost of the litigation, including expenses and counsel fees incurred by Licensor. Licensee will keep Licensor reasonably apprised of all developments in the suit, and will seek Licensor's input and approval on any substantive submissions or positions taken in the litigation regarding the scope, validity, and enforceability of the Licensed Patent. Licensee will not prosecute, settle, or otherwise compromise any such suit in a manner that adversely affects Licensor's interests without Licensor's prior written consent. Licensor may be named as a party only if

(A) Licensee's and Licensor's respective counsel recommend that such action is necessary in their reasonable opinion to achieve standing;
(B) Licensor is not the first named party in the action; and

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(C) the pleadings and any public statements about the action state that Licensee is pursuing the action and that Licensee has the right to join Licensor as a party.

1.4 Recovery. If Licensee sues under Section 1.3, then any recovery in excess of any unrecovered litigation costs and fees will be shared with Licensor as follows:

(A) any payment for past sales will be deemed Net Sales, and Licensee will pay Stanford royalties at the rates specified in Section X.X;

(B) any payment for future sales will be deemed a payment under a sublicense, and royalties will be shared as specified in Article Y.

(C) Licensee and Licensor will negotiate in good faith appropriate compensation to Stanford for any non-cash settlement or non-cash cross-license.

1.5 Abandonment of Suit. If either Licensor or Licensee commences a suit and then wants to abandon the suit, it will give timely notice to the other party. The other party may continue prosecution of the suit after Licensor and Licensee agree on the sharing of expenses and any recovery in the suit.

Although lengthy, these clauses address each type of situation that could occur with the suspected infringement.

Termination

There may come a point when either party to the license agreement wishes to terminate the license. The licensee may determine the technology is no longer of interest or may change research directions. The licensor may find that its licensee is not fulfilling the licensee's obligations under the license agreement.

The termination section of the license agreement outlines how and when each party can terminate the agreement. Often, the licensee is allowed to terminate at any time upon a certain number of days notice to the licensor. However, this may not be the case when the license agreement is tied to sponsored research or collaboration contracts.

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The licensor is only allowed to terminate the license in certain situations such as:

- delinquency on payments or reports
- missing diligence milestones or not diligently developing the licensed technology
- other material breaches of the license agreement
- providing false reports

The licensee does not want to enter into the license agreement with the risk that the technology could be pulled away at any point. At the same time, the licensor needs to ensure that its technology is being developed and it is receiving the consideration agreed upon.

If the licensor does send a notice of termination to the licensee, usually there is a period in which the licensee can cure the breach or work out a settlement with the licensor for the breach. Note that the period to respond to the termination and the cure periods are separate, therefore these periods can add up to quite a bit of time if the licensor is not careful on limiting the total time for these periods.

Sublicensing

Particularly in exclusive licenses, sublicensing privileges may be granted to the licensee. The licensee can then further license the technology to other parties.

In nonexclusive licenses, sublicensing isn't generally allowed or needed. Instead, the new party wishing to take a license can come back to the licensor to take a license. However, certain exceptions may be practical for some technologies. The licensor should consider what is in the best interests of the technology.

If the licensor does allow the licensee to sublicense, areas to consider are:

- Can a sublicensee then further sublicense? How many layers of sublicensing are allowed? Note that unlimited layers of sublicensing are not a good idea as the licensor may quickly lose control over what is happening with the technology.
- What provisions from the license agreement between the licensee and licensor should also be included in the sublicense? Items the licensor may want the licensee to include in the sublicense are the warranties, indemnification, reporting, and auditing provisions.
- Does the licensor receive a copy (perhaps redacted) of the sublicense?

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- How much remuneration should the licensor receive of the payments received by the licensee from the sublicensees?
- What happens to the sublicenses if the license agreement between the licensee and licensor terminates?

Sublicensing can also be required by the licensor in cases of unmet markets or needs for the technology.

A sample clause on required sublicensing is:

> *If Licensee is unable or unwilling to serve or develop a potential market or market territory for which there is a company willing to be a sublicensee, Licensee will, at Licensor's request, negotiate in good faith a sublicense with any such sublicensee. Licensor would like licensees to address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics, and agricultural technologies for the developing world.*

Other Provisions

There are many other provisions that are also important to include in certain types of license agreements. Some are noted below and samples can be found in the boilerplate license language of many institutions (for Stanford's standard agreements, visit the Web site at http://otl.stanford.edu/industry/resources/industry_res.html. Examples also might be found on the AUTM Web site in the AUTM Toolkit at http://community.autm.net/AUTM/AUTM/Resources/LibraryDocuments/Default.aspx?LibraryKey=e6f054bc-45cb-42ff-8c77-a8e76942091d. Some of these provisions are also covered in several *AUTM Technology Transfer Practice Manual* chapters available on the AUTM Web site at http://www.autm.net/TTP_Manual_Third_Edition/4304.htm).

- exports
- accounting/audits
- names and marks
- assignment
- arbitration and governing law

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- marking of licensed product
- notices
- severability, force majeure, entire agreement, electronic signatures

Conclusion

A license agreement is a relational document. One part affects other parts of the agreement. Negotiate the agreement knowing how each change affects other provisions. Keep the agreement language clear such that anyone reading the agreement would interpret the clauses the same way. This will help avoid ambiguities that could strain the relationship between licensor and licensee and ultimately could help some of the cutting-edge technologies from institutions make it to market.

One final note: Stanford lists all of its boilerplate agreements on its Web site at http:/otl.stanford.edu/industry/resources/industry_res.html?headerbar=2. With the new AUTM Toolkit, which can be found on the AUTM Web site at http://community.autm.net/AUTM/AUTM/Resources/LibraryDocuments/Default.aspx?LibraryKey=e6f054bc-45cb-42ff-8c77-a8e76942091d I hope other universities will also share their boilerplate agreements for review by their AUTM colleagues.

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Comparison of National Innovation Systems in China, Taiwan, and Singapore: Is Bayh-Dole One-Size that Fits All?

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Abstract

National innovation system (NIS) is an analytical tool to evaluate a country's technological development that focuses on institutional actors creating and diffusing technologies. Examining the policies shaping NIS in China, Taiwan, and Singapore reveals dramatic differences in the types of institutional actors in each country and their roles overseeing and performing research and development (R&D). These differences further exist in university-industry linkages (UILs). As an example of contrasting UIL governing transfer of public research assets to the private sector, the operation of each country's Bayh-Dole style legislation is described to illuminate indicators of technology transfer and preview future obstacles. It is finally suggested that legislation implementing innovation policy should be crafted within the context of a country's specific needs.

Introduction

One leading approach in analyzing a country's technological development is the concept of national innovation system (NIS). First proposed by economist Christopher Freeman to evaluate Japan's rapid postwar development, NIS focuses on institutional actors (public and private) and their activities (creating, importing, modifying, and diffusing new technologies). Legislation promoting the creation and transfer of technology, such as Bayh-Dole (BD), falls within a narrower slice of NIS that is the university-industry linkage

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(UIL). A UIL broadly describes how basic R&D activities interact, diffuse, and transfer to the commercial sector. Because NIS varies drastically, it is easy to imagine similarly dramatic variations in UIL.

The following evaluation of NIS in China, Taiwan, and Singapore reveals dramatic differences in the structure and function of institutional actors overseeing and performing research and development (R&D). Because the role of institutional actors in different countries varies significantly, it is suggested that legislation implementing innovation policy, such as those governing UIL, should be crafted within the context of a country's specific needs.

The first section of this paper analyzes the NIS of China, Taiwan, and Singapore, looking in particular at how they shaped and defined institutional actors. The second section evaluates UIL, using the specific example of BD-style legislation in each country to illuminate existing indicators of technology transfer and preview potential obstacles.

National Innovation System (NIS): An Analytical Tool Focused on Institutional Actors' Activities and Interactions

There is no universal definition of NIS, but competing interpretations share the core principle that the function and interactions of actors are significant forces in shaping a nation's scientific and technological development.[1] The Organization for Economic Cooperation and Development (OECD) provides one framework for detailing a country's NIS, suggesting six primary roles for institutional actors. This includes: (1) performing R&D, (2) financing R&D, (3) human resource development, (4) diffusing technology, (5) promoting entrepreneurship, and (6) formulating technology and innovation policy.[2] This broad definition encompasses everything from administrative agencies coordinating and conducting public research (e.g., the National Institutes of Health), private-sector research enterprises (e.g., Genentech), higher education (e.g., Stanford University), and bridging institutions (e.g., Biotechnology Industry Organization).

Focusing on these specific roles of institutional actors provides a useful analytical tool in characterizing activities beyond rough function-based definitions. An administrative agency in one country may vary drastically from an analogous agency in another county

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in terms of function. As an example, the Chinese Academy of Science (CAS) in mainland communist China and Academia Sinica (AS) in nationalist Taiwan are the analogous scientific academies in each country. Both academies serve key roles in governing public research institutes and even share a common origin (with AS being relocated to Taiwan after the 1949 Chinese civil war).

However, CAS directly establishes and invests in high-technology enterprises, starting nearly 400 spinoff companies to date.[3] In contrast, AS does not directly foster such private commercialization, but rather, promotes adoption of new technologies by existing private enterprises.[4]

To provide further context in understanding the role of institutional actors in each country, this paper first summarizes the underlying technology policies shaping their creation. A brief discussion of NIS follows, first beginning with China, turning next to Taiwan and Singapore.

China: Shifting away from a Legacy of Central Planning, the Rise and Fall of the University-Research Enterprise

After the founding of the People's Republic of China in 1949, research was conducted primarily at specialized public research institutes (RIs), with universities involved in only a limited number of research activities. Adopting the central planning approach of its Northern neighbor, the Soviet Union, the Chinese government was the principle source of science and technology (S&T) funding. The government allocated specific, defined tasks to RIs through administrative orders, with the majority of science research focused on military-related applications. In contrast, "Universities did undertake research, but their most important priority was pedagogy."[5]

Furthermore, this central planning structure erected a wall, divorcing S&T innovation from industrial activities fixated with production. "As a result of this system, public research institutes had no incentive to understand the needs of enterprises for technology… state-owned enterprises were supposed to concentrate on production activities, without proper incentive systems for innovation..."[6] This artificial decoupling of research and industry eviscerated innovation incentives, causing China to lag behind other Asian nations in technology development.

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Establishing Western-style economic reforms in the 1980s was coupled with an emerging emphasis on scientific research and education for economic development. The first of three major policy shifts occurred in 1985 by winnowing away the prior Soviet-style research structure through creation of new incentives. Specifically, RI and university budgets were slashed to spur increased collaboration with industry for alternative funding resources. "For URIs, the only option was to search for alternative source of funds."[7]

In concert with changing the funding landscape, new innovation incentives were offered through adoption of the landmark 1985 Chinese patent law. Together, these initiatives attempted to traverse the gap separating research and industry, providing new types of innovation incentives to spur development of new technologies.

The second step began during the early 1990s, laying the foundation for much of China's current technology landscape through creation of university and research institute-based enterprises (UREs). "The unique feature of the Chinese NIS is the URI-owned enterprises."[8] At the initial stages, the Chinese government encouraged not only strong links between universities and emerging enterprises, but direct creation of high-technology companies. Guidelines for administering UREs were promulgated, and faculty could occupy both teaching roles in a university/RI and research positions in the URE. Nearly ten years after spurring their creation, more than 2,000 UREs were founded with a combined worth of $3.8 billion.[9]

The third and most recent step, beginning in 2001, shifted the focus away from UREs. Critically, unlike Western spinoff companies, UREs were endowed with substantial control over the mother institutions' assets, including manpower, facilities, research results, and resources.[10] Earlier reforms bridging research and industry may have reached too far as "[S]ome universities might go bankrupt because of the losses their affiliated firms were suffering."[11] Furthermore, there was increasingly trenchant criticism that UREs were merely importing and adopting technology, rather than innovating. As a result, "The government began to examine the efficiency of UREs in 2001. Since then, a 'delinking' of URIs from their affiliated enterprises has been under way."[12]

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Through three major phases, the overall trajectory of Chinese innovation policy has migrated away from central planning, although this further necessitated fine-tuning of the resource allocation between research and industrial activities. Nevertheless, the Soviet-style central planning legacy remains a pervasive and strong influence on modern Chinese innovation policy. "Each national S&T plan outlines the *main direction* of S&T development… The performers of S&T activities *fulfill the tasks assigned to them from above* and *depend upon official allocations* for necessary resources. These performers of S&T activities do not need to suffer the full losses resulting from failure in innovation activities, but nor do they benefit fully from success."[13]

Taiwan: Driving Policy through Consensus, Promoting Autonomy of Institutional Actors in Implementation

After the founding of the Republic of China in 1949, Taiwan's main economic areas were agriculture and exports. However, by the late 1960s, economic policy "relied heavily on labor-intensive manufacturing exports," and there was little or no R&D or innovation policy to speak of.[14] Continuing into the 1970s, R&D activities in both industrial and academic areas remained low. By this time, Taiwan's economy was studded with many small and medium enterprises (SMEs), which were ill-equipped for R&D or had no concept of R&D altogether.[15]

To address the lack of a formal R&D policy, the first National Conference on Science and Technology convened in 1978 and continues to meet every four to five years.[16] Because Taiwan's economy was dominated by SMEs with small R&D capacity, "It was decided that government research organizations should play the role of bridge between academic research and commercialization. This allowed the formation of a preliminary system of industrial innovation."[17] In short, policy-makers sought to make public research assets and resources widely accessible to a variety of existing private businesses.

Due to a generous population of SMEs and the desire to empower them with strong, accessible public research resources, Taiwanese policy-makers drove innovation policy primarily through consensus-building. Rather than orchestrating strong top-down national policy initiatives, relevant actors were tapped to shape national policy initiatives, thereby obtaining significant autonomy in implementing specific approaches.

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As an example, the National Conference on Science and Technology, "brings together relevant experts from industries, universities, government, and foreign S&T advisers and generates *long-term plans that articulate the basic direction* of national S&T policies." With the larger guideposts in view, the specific execution of these S&T plans "in Taiwan follows principles of integrated planning and decentralized implementation."[18]

While the Taiwanese consensus-building approach creates variability in executing the overall national innovation policy, two hallmarks are sector-targeting and industrial-clustering. First, was the creation of public research institutes (RIs) and science parks to house RIs alongside private enterprises.[19] In 1973, the Industrial Technology Research Institute (ITRI) was created, focusing on semiconductor chips, computers, and opto-electronic products.[20] One of Asia's first scientific parks, Hsin-Chu Science Park (HSP) was unveiled a few years later in 1980.

Second, was the creation of strong incentives to lure private enterprises to these locations. Enterprises setting up shop in HSP were met "With several adequate incentives including abundant supply of technology and skilled engineers, tax credits, excellent infrastructure, and convenient official services…"[21,22]

Together, this approach propelled Taiwan to first-rank production volume of desktop computers and notebooks, along with becoming the third largest exporter of computer products, behind only the United States and Japan.[23] With these results in hand, "Taiwan's PRIs continue to play the role of R&D agencies for Taiwan's SMEs—as they have done for decades—to meet their technological and resource insufficiency."[24]

Perhaps due to remarkable successes with ITRI and HSP, Taiwan continues to replicate industrial-clusters for new technologies in different geographical locations.[25,26] Again, a variety of actors furnish execution details, including SMEs, local county governments, and even city municipalities. As an illustrative example, "[T]he Taiwan *national* innovation system is starting to encompass targeted technology developments within the country's capital, Taipei, *under the control of the city administration*."

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However, merely replicating more industrial clusters across Taiwan has raised concerns about redundancy in R&D efforts, thereby handicapping the overall quality and level of innovation. First, as one commentator noted, "The advantage of one park cannot be easily completely duplicated to other areas. This in turn raises an important policy issue: The science-park development mode may not be implemented without limit."[28]

One additional weakness of this approach was revealed in overexposing Taiwan to global market fluctuations, such as falling demand for computer technologies after implosion of the dot-com bubble. Limiting this exposure has further required a shift in focus from rapidly gaining expertise in foreign technology to creating new technologies. Taiwan's national policy was a sophisticated strategy of fast followership—first beginning with identification of key technologies and later building expertise and capabilities in those technologies.[29] This reliance on foreign technology has meant Taiwan is "extremely dependent on inflows of foreign technologies… and so are easily influenced by global economic fluctuations. Consequently, Taiwan often suffers from the lack of R&D of original pioneering and self-contained technologies."[30]

Taken together, Taiwan faces a challenge of climbing up the technology ladder by spurring innovation, but must avoid the track of merely adopting "more of the same" policy approaches that captured initial successes. One strong point of the current approach is that, by allowing a variety of actors to implement the overall national policy, this encourages desirable heterogeneity in execution. Taiwanese policy-makers should continue the decentralized planning approach by embracing input from relevant actors, while also enhancing in-house SME R&D activities.

Singapore: Economic Planning Attracting Foreign Enterprises and Investment, Coupled with Highly Focused Intervention through State-Owned Enterprises and Research Institutes

The Republic of Singapore was founded in 1965 as an island city-state with few natural resources at its disposal. The Singaporean government initially had "little option but to turn decisively outward to export domestically made manufactures."[31] Capitalizing on its strategic location as a historic port of trade, Singapore also eventually developed a thriving professional and financial services center.

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At each stage, the hallmark of Singapore development policy has been focused on long-term strategic planning to attract foreign investment, punctuated with decisive government intervention. Innovation policy has followed suit with the government maintaining a strong hand guiding R&D activities, although there are emerging views suggesting the need for a lighter touch.

Among the earliest export domestic manufactures, Singapore moved immediately into electronic and electrical products. One critical enabling factor was not R&D policy, but rather, control of labor costs by leveraging Singapore's specific geography as an island city-state. By closing the nation's borders, managing labor inflow, and regulating wages, the government "pegged wage rises at or below productivity gains [which] was essential in safeguarding this required rate of profit."[32] Creating a profitable enclave for Western companies further promoted an influx of high foreign investment and foreign enterprises.[33] "[S]ound economic planning and concerted efforts by the government to attract foreign investments were key factors behind its phenomenal growth pace…"[34]

As some commentators have highlighted, strong links with the global marketplace actually favored an overall hands-off approach to allow the Singapore government to act decisively in response to swift global trends, rather than being encumbered by formal planning documents. "Planning in Singapore never involved detailed blueprints, because of the priority accorded to reaction to the international market, impossibility of predicting its course, and need for flexibility to ensure a quick and competitive response."[35] Further illustrating this approach is the surprising fact that "[Singapore's] first formal science and technology plan was only implemented in 1991."[36]

That is not to say that the Singapore government did not strongly promote R&D within its borders during earlier years. Rather, Singapore encouraged R&D through direct funding and creation of incentives in three primary vehicles: foreign enterprises, universities, and state-owned enterprises. "Tax incentives were given to manufacturing companies that undertook R&D in Singapore. The level of public commitment to R&D was confined largely to scientific research in public universities and defense R&D…"[37] Furthermore, while educational and manpower training was offered through local institutions, later efforts

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included overseas training for select workers and grants and subsidies for foreign companies providing specific skills to employees.[38]

Finally, a variety of state-owned enterprises were created for sectors unattractive to foreign investors. "[T]he Singapore government began as nonstatutory undertakings, a range of enterprises…the government retains a majority holding in profitable and key undertakings like Singapore Airlines and Singapore Telecom."[39] Critically, Singapore "had the advantage that public enterprise began afresh rather than through the nationalization of already loss-making firms."[40]

However, as Singapore approaches a current level of economic development on par with many leading Western nations, the focus is shifting away from attracting foreigners and importing technologies to strengthening local institutions through new technology creation. "Lately, however, there have been concerns that the development strategy that Singapore had adopted for the past few decades may no longer be sufficient…."[41] And it is in this context that Singapore's most expansive and decisive innovation policy measures have been deployed. In 1991, the first National Technology Plan was enacted, focusing on the construction of technology infrastructure, further incentives for private sector R&D, and enhanced technical manpower training. This was followed by a second plan in 1996, funding the establishment of thirteen public research institutes in sector-specific areas.[42]

Despite these efforts, Singapore is confronted by a somewhat unique challenge of promoting creativity and entrepreneurship within a highly skilled workforce, but one ranking near the bottom in entrepreneurial propensity among developed nations.[43] Addressing this concern, educational policy evolved toward "increasing creativity in schoolchildren," through migration away from exam-based educational assessment toward encouraging project-based skills systems. Nevertheless, it is necessary for Singapore policy-makers "to change the social and cultural attitudes toward entrepreneurship, acceptance of nonconformity, and tolerance of failure."[44]

As Singapore grapples with obstacles in scaling the technology value-chain, policy-makers must balance a remarkably successful model of attracting foreigners to its shores, with an

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increasingly interventionist approach empowering local institutions. Nevertheless, with the guiding hand of government acting nimbly in response to the country's needs, Singapore may continue to carve a unique path in reaching future successes.

Comparison of NIS Reveals Stark Differences in Types of Institutional Actors and Their Roles

From this whirlwind tour of NIS, stark differences between each country are apparent. First, the overall policy approach adopted by central government and the role of institutional actors in each country is very different. The Chinese government retains a strong central planning structure. In the midst of propelling massive institutional reform, the government must strike an effective balance between research and industrial relationships to eliminate obstacles previously hampering the country's economic development.
In contrast, Singaporean innovation policy has shifted away from being focused intensely on creating attractive incentives for foreign investment and R&D to buttressing these efforts with growing investment in local institutions under the direction of government planners. At the furthest end of decentralized planning, the Taiwanese government formulated innovation policy by building consensus and granting significant autonomy to local actors in execution, although emerging limitations in expanding this approach to new technological and territorial areas may require stronger central guidance.

Second, the result of each country's NIS has spawned markedly different *types* of institutional actors. The Chinese R&D landscape is populated by universities/research institutes and their closely associated high-technology enterprises, UREs, while Taiwan possesses many domestic SMEs empowered through broad access to public research resources. Further contrasting these two nations, Singapore is predominated by foreign and state-owned enterprises interfacing with expanding university and research institute resources.

Nevertheless, a common goal is enhancing the efficiency of innovation through creation of new technologies, while reducing mere importation and application of foreign technologies. Proper formulation of incentives is a common theme and appears to be a critical enabling factor in rising up the technology ladder. For example, in China, transformation of RIs was accomplished through funding cutbacks coupled with new opportunities to form UREs.

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In Taiwan, a variety of financial, technological, and infrastructure incentives were provided to enterprises setting up shop in science parks and engaging specific technology sectors. In Singapore, strong profit incentives attracted foreign investment, with additional benefits provided to those businesses conducting R&D and manpower training. This brief summary of incentives deployed in each country's NIS highlights that the specific types of incentives varies drastically, but that formulating a proper incentive scheme is a critical balancing act in defining institutional actors and their roles.

University-Industry Linkages: The Wide Embrace of Bayh-Dole Style Legislation in Asia

Given that the earlier evaluation of NIS in China, Taiwan, and Singapore reveals dramatic differences in the structure and function of institutional actors, it is remarkable that each nation has nevertheless adopted BD-style legislation as a keystone in its modern innovation policy governing the diffusion and transfer of public research assets into the private sector. As an illustrative example of university-industry linkages (UIL) in different countries, Bayh-Dole (BD) is particularly attractive because of its widespread adoption around the globe.

As has been noted, "[C]ountries from China and Brazil to Malaysia and South Africa, have passed laws promoting the patenting of publicly funded research…"[45] This wide embrace provides opportunity to compare and contrast the variable impact of BD-style legislation in circumstances composed of divergent cultural, social, political, historical, and economic conditions.

Thirty Years of the American Bayh-Dole Experience Shows Good Successes Coupled with New Obstacles

Prior to Bayh-Dole's adoption in 1980, discoveries in American public research institutes were commercialized in murky legal waters. Specifically, there were few bright-line rules governing ownership of research products originating from public research funding. One of the key roles of BD was clarifying ownership and administrative rules, providing a framework for individual researchers and their universities to patent and license research products—a key step in starting university spinoff companies. In short, American policymakers fashioned a *novel incentive scheme* to encourage innovation and spur commercial adoption, which is an important formulation in NIS.

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Bayh-Dole has been effusively praised for spurring innovation in providing individual researchers and universities with potentially lucrative royalties or with opportunities to privately commercialize their technologies. In 2002, *The Economist* called BD, "possibly the most inspired piece of legislation enacted in America over the past half century."[46]

Routinely highlighted as indicators of BD's success are patent and licensing metrics demonstrating rising numbers of patent application filings, license grants, and royalty revenues. As an example, patent application increased from below 2,000 filings in 1991 to more than 11,000 in 2004. During this same period, royalty income spiked from approximately $200 million to $1.4 billion.[47]

Despite these remarkable numbers, there has been criticism that BD has gone too far in actually erecting new barriers in university-industry research collaborations in the United States. As one commentator recently highlighted, "The broad discretion given to public funded research institutions to patent upstream research raises concern about patent thickets, where numerous patents on a product lead to bargaining breakdowns and can blunt incentives for downstream research and development."[48]

Furthermore, technology transfer practices in patenting and license negotiations may have "contributed to a change in academic norms regarding open, swift, and disinterested scientific exchange."[49] In short, impressive patent and licensing metrics may mask significant chilling effects on American research and industry relationships.

This criticism that BD may have led to undesirable consequences in creating new barriers provides basis for additional criticism that BD may not be workable in different countries. "[W]ithin the United States, the effects and desirability of the BD Act remain controversial…it is necessary to explore *under what conditions* the U.S. approach to UILs can serve as a useful framework for policy elsewhere."[50]

Among these important conditions necessary for fostering successful BD-style legislation, one commentator has noted that BD's "success" in the United States was highly dependent on the specific nature of actors in American NIS. "[I]t is unclear whether any of the positive impacts of BD in the U.S. would arise in developing countries following similar

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legislation, absent the *multiagency federal pluralism, the practically oriented universities, and other features of the U.S. research system…*"[51]

Considering that there is at least reasonable disagreement about BD's positive impact, the discussion turns to an analysis of BD-style legislation in each country. Evaluating the prospects for success in any given country certainly cannot be conclusive, given that even thirty years of the American experience with BD is still under considerable debate. However, the prior analysis of NIS describing institutional actors in each country provides informative waypoints for evaluating how BD-style legislation could operate in different countries.

China's "De Facto" Bayh-Dole Regime

China's version of BD-style legislation was adopted only very recently in 2008, accompanied by a visit by former U.S. Senator Birch Bayh himself.[52] While the legislation enacted a framework for establishing intellectual property rights (IPRs) developed from publicly funded research, the potential role of BD legislation in China is perplexing, considering the expansive powers that Chinese UREs already possess in claiming ownership over public research assets.

Unlike an American-style spinoff company where academics may use private capital funds to commercialize an invention, "UREs are usually endowed with the de facto right to exclusively take advantage of the mother institutions' various assets including research outcomes or resources, such as financial resources, physical spaces, manpower, social links, and even the title of the university as a commercial brand."[53] In short, in China "there has long been a de facto Bayh-Dole regime (even before the Chinese patent law was legislated in 1985)."

As provided in the earlier description of China's NIS, the most recent policy focus has been to move away from UREs, which are increasingly seen as merely importing and applying technology, rather than truly innovating. As an example of this delinking of research and industrial relationships, 6,634 UREs existed in 1997, dropping to 5,451 in 2000, and 4,563 in 2004.[54] Perhaps it is envisioned that redefining these relationships will be a new slate of American-style spinoff companies relying on newly adopted BD-style legislation to commercialize promising research technologies through private finance investment.

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Nevertheless, it is easy to imagine that Chinese BD legislation is a severely limited tool in redefining the current Chinese R&D landscape. The mere presence of several thousand UREs across China argues strongly that they will remain a significant force in implementing Chinese R&D policy. Stakeholders in the current URE scheme are unlikely to easily relinquish their current roles in exchange for the potentially arduous and risky road of an American-style spinoff company.

If Stanford University researchers had significant control over the university's facilities, research results, and could even adopt the Stanford name for their own private companies, it is hard to imagine they would eagerly embrace a more challenging commercialization model requiring pursuit of private financing to practice entrepreneurial activities. Together, it appears China is embarking on a long campaign in altering the scope and relationship of research and commercialization activities, and BD is only one piece of this massive puzzle.

Taiwan Adopted Bayh-Dole in Lockstep with IP Manpower Training, Education, and Promotion of Technology Adoption

In 1999, Taiwan first adopted BD-style legislation in the "Basic Law on Science and Technology."[55] Notably, a multipronged approach was adopted in facilitating and promoting technology transfer practices. First, the government spurred creation of technology transfer offices in universities and RIs by imposing stricter research funding criteria, while encouraging patenting and licensing of technology as an alternative funding resource.[56] Second, for Taiwan's many SMEs, the government fostered competence in "intellectual property management, including aspects, such as law, patent engineering, licensing, and negotiation."[57] An example of early success is National Taiwan University's (NTU) growing collection of licensing and royalty fees. Beginning in 2001, NTU collected only about $100,000 in fees, rising to nearly $1 million by 2004.[58]

One evaluation of patenting rates has highlighted that Taiwan "has arguably been the East Asian country that has made the most progress in shifting from imitation to innovation."[59] A significant number of Taiwanese patents arise from Taiwan's leading research institute, ITRI, with more than 3,000 patents.[60]

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Further analyzing ITRI's activities, an increasingly critical patent portfolio established learning opportunities for strategic IP management. Rather than simply nurturing a propensity for patenting, ITRI *assigned specific patents to multiple SMEs* to "develop a stronger position in patent negotiations and [they could] take the lead in developing new technologies and setting standards."[61] This hands-on experience in IP portfolio management is "now seen as a key contributor to the enhancement of the country's innovative capacity."[62]

Taken together, the Taiwanese experience with BD, while recent, indicates some good predictors of future success. If anything is in common with the United States, it is a strong entrepreneurship capacity in the creation of SMEs. However, this is where any similarities end, as it appears that adoption of BD-style legislation was coupled with dedicated campaigns to further educate and train manpower in IPR management. At least some of this experience was gained through strategic portfolio management at leading RIs, such as ITRI, with precise efforts to strategically position patent portfolios through assignments to specific companies, thereby maximizing IPR benefits.

Thus, while BD-style legislation in Taiwan may prove to be significant in shaping that country's innovation capacity, it is notable that any successes may take on a markedly different path than the American experience.

Singapore Bayh-Dole-Style Practice Promulgated through Agency Rules Has Led to Mixed Results

Singapore promulgates BD-style practice through internal agency rules at leading public research institutes such as the National University of Singapore (NUS) and the Agency for Science, Technology, and Research. As an illustrative example, "Since the early 1990s, NUS has implemented an intellectual property (IP) policy whereby all IP created by NUS staff are assigned to NUS with INTRO [NUS' tech transfer office] tasked to license the IP and distribute any return from commercialization…"[63]

Despite these early pioneering efforts, technology transfer at leading institutions in Singapore, such at NUS, has seen mixed results. As an example, NUS collected $116,000 in 2001, rising to only $290,000 in 2003. "[T]he propensity for technological collaborations between universities and private industry was still relatively low and that universities were

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not highly regarded by industry as an important source of technology."[64] However, one encouraging result was that prior to 1999, only one issued U.S. patent was jointly owned between private industry and NUS. By 2001, more than 40 percent of patents were jointly owned.

Perhaps taking a cue from the Taiwanese experience, some recent initiatives in Singapore have focused on IP manpower training. Recognizing that "Singapore suffers greatly from a lack of expertise in various fields of IP and technology transfer," policy-makers established an IP educational academy in 2003 to provide professional training in IP management.[65]

Together, it appears too early to tell if Singapore's efforts in encouraging technology transfer through adoption of BD-style practices will lead to better and more consistent results in patenting and licensing. However, it appears that the country is at least being informed by the earlier experience in Taiwan, providing IP manpower training with educational programs to promote technology adoption.

Comparison of BD-Style Legislation Suggests There Is No One Size Fits All

Perhaps the only thing in common between BD legislation in these countries is that they are very recent. China enacted legislation within the past two years and is in the paradoxical position of using modern BD-style incentives to chisel away at an existing regime where public resources are already expansively exploited for commercial use. Taiwan and Singapore are more relevant examples for comparison with the American experience and even these two countries show remarkable differences.

Taiwan can claim some early successes through rising royalty revenues and patenting rates. However, the illustrative example of ITRI's strategic IP portfolio is remarkable, given that a public research institute strategically assigned patents to private companies to maximize IPR benefits. This is akin to the National Institutes of Health handing off patents to Amgen and Genentech to ward off disfavored competitors or provide them with better leverage in negotiations for standard setting or litigation settlements.

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In contrast, Singapore appears to be delivering mixed results, although as described, some initial results are encouraging. Rising numbers of jointly owned university and industry patents are a strong sign of increased collaboration. Unlike the earlier ITRI example, this appears to be a more earnest approach in building relationships (albeit a potentially more challenging one).

However, Singapore may merely be in the earlier stages of patenting, as ITRI only adopted increasingly sophisticated and aggressive IP techniques after amassing more than 3,000 patents, including key technologies to ward off competitors. Further contrasting Singapore is that BD-style technology transfer is promulgated through agency rules. Again, this is akin to the NIH unilaterally deciding that its technologies can be commercialized under its direction.

Together, it is clear that stark differences existing between each country's NIS further extends into the specific example of UIL governing technology transfer practices. As one leading commentator has noted, "There is a widespread perception that U.S. leadership in industrial innovation owes much to the capacity of its higher education system to provide multiple and dense interlinkages between university research and innovation in enterprises…Unfortunately, very little scholarly research is available to guide policy debates in the Pacific Rim on this important issue…."[66]

Recognizing that Asian nations, including the discussed examples, have diverse development trajectories propelled by markedly different institutional actors is a good first step in crafting effective technology transfer legislation for developing nations.

Notes

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The Intersection of Intellectual Property and Bankruptcy Law

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As the worldwide economy expanded over the past decade, intellectual property assets have increased dramatically in value and become an ever-increasing share of a company's balance sheet. Now, as the economy contracts and many companies are facing bankruptcy, a key question concerns the status of the intellectual property that may have been assigned, transferred, sold, or licensed if one of the parties to the transaction declares bankruptcy. The answer may be critically important to any company that may lose rights to manufacture a licensed product because the licensor declared bankruptcy, as well as to any licensor who may be faced with a totally new competitive landscape because the debtor-licensee sold its rights to the licensor's primary competitor.

Intellectual Property Licenses as Executory Contracts

The filing for bankruptcy under Chapters 7 and 11 creates a separate legal entity, the bankruptcy estate, comprising the debtor's assets at the moment of filing, as well as the proceeds of such property and additional property interests the estate may acquire later.[1] In a Chapter 7 proceeding, the court appoints a trustee to collect the debtor's nonexempt property, sell it, and equitably distribute the proceeds to the creditors. In Chapter 11, the debtor in possession (DIB) serves as the bankruptcy trustee, with a fiduciary duty to maximize value for the estate's creditors. The DIB retains possession of the company's assets to continue operating the business while developing a plan of reorganization.

Section 365 of the bankruptcy code gives the bankruptcy trustee or DIB the authority to assume, assign, or reject a debtor's executory contracts based on whether the action is

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in the best interests of the debtor, notwithstanding any contrary provisions appearing in such agreements and subject to certain other limitations as described below.[2] The bankruptcy court will only reject a decision by the trustee if it is "manifestly unreasonable."[3] Upon the court's approval of the debtor's assumption of an executory contract, the prepetition contract is reinstated and becomes fully binding.

The so-called Countryman definition generally accepted by courts defines a contract as executory where the obligations "of both the bankrupt and the other party are so far unperformed that the failure of either to complete performance would constitute a material breach excusing the performance of the other."[4] As applied to the intellectual property context, an ongoing obligation to account for and pay royalties for the life of the agreement meets the Countryman test for an executory contract.

Other considerations in determining whether a contract is executory include material ongoing licensee obligations such as sharing of technology with the licensor, reporting on problems with the technology, and marking all products sold under the license with proper statutory patent notice. From the licensor's prospective, courts have held providing a nonexclusive licensee notice of any patent infringement suit or any other use or licensing of the process, refraining from licensing the technology to anyone else at a lower royalty rate, approving grants of sublicensees under reasonable standards, indemnifying licensees for losses, and defending claims of infringement are considerations in determining whether the agreement is executory. Several courts recognize the licensor's duty to forbear from suing the licensee for infringement as, in and of itself, a material ongoing performance obligation that makes the agreement executory.[5]

The bankruptcy code recognizes, however, that because intellectual property law involves goals that may be very different and even contrary to the goals of bankruptcy laws, it includes limitations on the assumption, assignment, and rejection of executory intellectual property agreements and affords additional protections to nondebtor parties to intellectual property licenses and contracts.

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Limitations on the Right to Assume and Assign Intellectual Property Licenses

The bankruptcy code expressly prohibits the assignment of a license, without the consent of the nondebtor party, if applicable law excuses such nondebtor party from accepting performance from or rendering performance to an entity or person other than the debtor. In general, the federal policy designed to protect the limited monopoly of intellectual property owners and restrict unauthorized use constitutes applicable law.

Whether patent licenses are assignable depends on whether they are nonexclusive or exclusive. Federal law has long held that nonexclusive patent license agreements are personal to the licensor and are not assignable unless expressly made so in the agreement.[6] Accordingly, courts have unanimously applied section 365(c) to prohibit the assignability of nonexclusive patent licenses absent consent of the nondebtor licensor.[7]

Similarly, because a nonexclusive copyright license is personal to the licensee and nondebtor licensor cannot be forced to accept performance from or render performance to a party, other than the debtor, section 365(c) also prohibits the assumption and assignment of a nonexclusive copyright license absent consent of the nondebtor licensor.

In contrast, because patent law specifically regards exclusive licenses as conferring property and not merely personal rights, section 365(c) generally has been held not to preclude assumption and assignment of an exclusive patent license by the debtor-licensee.

However, at least one court has barred the licensee from assigning its interest under an exclusive patent license.[8] The court reasoned that to permit the assignability of exclusive licenses "would create a situation where a patent holder loses control over the identity of its license holders whenever the license agreement provides a licensee with an exclusive right. Such a result, which effectively treats the grant of an exclusive license as the equivalent of an outright assignment of the patent, is inconsistent with federal case law."[9]

Courts are split on the assignability of exclusive copyright licenses where the contract is silent on this issue. The Ninth Circuit has held the copyright act does not allow a copyright licensee to transfer its rights under an exclusive license, without the consent of the

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original licensor.[10] On the other hand, a number of courts have expressly disagreed with the Ninth Circuit and determined that the holder of an exclusive license is entitled to all the rights and protections of the copyright owner to the extent of the license, as well as the right to transfer such rights, and accordingly an exclusive licensee may freely transfer his rights.[11] Therefore, section 365(c) does not prohibit a debtor-licensee from assigning an exclusive copyright license.[12]

Finally, with regard to trademark law, although it is generally not in the interest of the trademark owner to have the license transferred to a third party without consent, section 365(c) will not necessarily excuse a trademark holder, in the absence of a contract provision barring assignment of the trademark, from accepting performance from or rending performance to a party other than the debtor in accordance with the terms of a license. Thus, a number of courts have permitted trademark licenses to be assumed or licensed.[13] However, at least one court agreed that, as with patent and copyright licenses, a trademark licensor has a significant interest in a licensee's identity, which flows from the trademark owner's need to protect its mark's good will, value, and distinctiveness.[14]

Limitations on the Assumption of a Nonassignable Intellectual Property License

A related issue is whether a DIB may assume a license even when no assignment is contemplated. This is obviously an important question because it may be critical for many DIBs to be able to continue to have access to licensed intellectual property. Section 365(c)(1) states that "a trustee may not assume or assign any executory contract [if applicable nonbankruptcy law excuses the nonbankrupt party] from accepting performance from or rendering performance to an entity other than the debtor or the debtor in possession." Courts have split on the meaning of this subsection with a majority relying on the literal language finding that it prevents a debtor from even assuming a license if the applicable law prohibited assignment.[15]

In contrast, a minority of courts has rejected the hypothetical test in favor of an alternative actual-test approach that allows assumption of contracts that are nonassignable and nondelegable under applicable law.[16] The test focuses on whether or not the nondebtor

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party would actually be forced to accept performance under the executory contract from someone other than the party with whom it originally contracted.[17]

Rights of Nondebtor Licensee upon Rejection

Prior to the passage of the Intellectual Property Bankruptcy Protection Act of 1988,[18] which amended section 365 of the bankruptcy code, licensees faced the real possibility that where the debtor-licensor rejected an executory contract, the licensee would lose its right to continue to use the licensed intellectual property and would be left with a prepetition claim for contract damages even in cases in which the licensee may have built a business or product line upon use of the licensor's intellectual property.[19]

Section 365(n) addressed this issue by providing a nondebtor intellectual property or technology licensee with two options in the event that a licensor seeks to reject a license falling within the bankruptcy's definition of *intellectual property*. First, the licensee can treat the rejection as a breach, giving rise to a potential claim for money damages under section 365(g). Alternatively, the licensee can elect to retain the rights to the intellectual property covered by the license. Where the licensee elects to retain rights to the intellectual property, the debtor-licensor is required to (1) provide the licensee with access to the subject intellectual property or technology, (2) not interfere with the exercise of licensee's rights under the license, and (3) comply with any exclusivity provision in the license agreements. In return, the licensee must continue to pay royalties due under the licensing agreement and must waive all rights to set off or any claim for administrative expenses.

Section 365(n) permits the licensee to enforce only the passive obligations of the licensor such as adhering to confidentiality agreements and, in the case of an exclusive license, not licensing the technology to others, that are necessary for the licensee to enjoy the continued use and exploitation of licensed intellectual property. In other words, by rejecting the licensing agreement, the debtor is relieved from performing any affirmative duties under the contract. Thus, while the code permits a licensee to retain its rights to intellectual property that existed prepetition, it does not permit postrejection enforcement of the debtor-licensor's ongoing obligations to update or improve such intellectual property.

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This potential problem is exacerbated by the fact that under bankruptcy law, the parties cannot contract around this situation. This can create problems for the licensee who may be left with no means to gain access to critical technological updates and is left with outdated or obsolete technology. Thus, companies that are considering entering into a licensing agreement with financially strapped but technology rich companies should weigh the advantages of access to the technology with the risk that that they may not have continued access to latest technology should the licensor declare bankruptcy. One solution under such circumstances would be for the licensee to acquire the technology outright from the licensor with the means to improve upon it.

Section 365(n) specifically includes licenses to patents, copyrights, and trade secrets, but does not encompass trademark licenses.[20] Thus, the rejection by a debtor-licensor of a trademark license extinguishes the licensee's right to use the mark and leaves the licensee with only a claim for breach of contract. Indeed, one court confirmed the rejection by the debtor-licensor of a trademark license agreement over the objections of the licensee that rejection would result in damages of $67 million.[21]

Conclusion

The intersection of intellectual property and bankruptcy law presents real challenges to both intellectual property and bankruptcy lawyers. While Congress has enacted amendments to the bankruptcy code, such as section 365(n), that has clarified certain areas and provided increased protection to licensees and licensors in the event of a bankruptcy, several areas remain open to questions.

Accordingly, it is critical that intellectual property lawyers, who are involved in drafting intellectual property licensees, have an understanding of the consequences that a bankruptcy filing would have on the rights and obligations of the respective parties to the licensing agreement. It is equally important for bankruptcy attorneys to have a basis understanding of intellectual property law, or at a minimum, to know when they should be consulting with their intellectual property colleagues about a bankruptcy estate that includes a large amount of intellectual property.

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Notes

1. 11 U.S.C. § 541.
2. 11 U.S.C. §§ 365 (a), (c) & (f).
3. See e.g., *In re Sandman Associates, L.L.C.* 251 B.R. 473 (Bankr. W.D. Va. 2000).
4. Very Countryman, *Executory Contracts in Bankruptcy: Part I,* 57 MINN.L.REV. 439, 446 (1973)
5. *In re Access Beyond Technologies, Inc.* 237 B.R. 32, 43 (Bankr. D. Del. 1999).
6. See e.g., *PPG Indus., Inc. v. Guardian Indus. Corp.* 597, F.2d 1090, 1093 (6th Cir. 1979).
7. See e.g., *In re CFLC, Inc.,* 89 F.3d 673, 679 (9th Cir. 1996); *In re Catapult Entertainment, Inc.,* 165 F.3d 747 (9th Cir. 1999).1
8. *In re Hernandez,* 285 B.R. 435 (Bankr. D. Ariz. 2002).
9. Id. at 439.
10. *Nike v. Gardner,* 279 F.3d 774 (9th Cir. 2002).
11. *In re Golden Books,* 269 B.R. 311, 318 (Bankr. D. Del. 2001).
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16. The debtor would have to cure any existing monetary defaults and provide adequate assurance of future performance in order to assume (and in order to assume and assign) the contract. So even if, for example, an anti-assignment clause may not be enforceable, the nondebtor party may still have a basis to challenge the assumption in the event the debtor (or the assignee as the case may be) cannot cure and/or cannot demonstrate the ability to perform the obligations going forward.

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17. See e.g., *Institut Pasteur v. Cambridge Biotech Corp.*, 104 F.3d 489, 493 (1st Cir. 1997).
18. 11 U.S.C. 365(n).
19. See e.g., *Lubrizol Enterprises, Inc. v. Richmond Metal Finishers, Inc.*, 756 F.2d 1043 (4th Cir. 1985), cert. denied, 475 U.S. 1057 (1986).
20. *In re Centura Software Corp.* 281 B.R. 660, 670 (Bankr. N.D. Cal. 2002)
21. *In re Exide Technologies,* 340 B.R. 222 (Bankr. D. Del. 2006).

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Use of Consultants in Technology Transfer

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Technology Transfer Professionals: Multitasking Gurus

The broad mandate of university technology transfer offices (TTOs) is to evaluate and selectively nurture early-stage technologies through the developmental stages of maturity. In the process of taking ideas to market, the technology transfer professional has to play several roles—friend (or foe), philosopher, investor, board member, and mediator. This is in addition to being a willing graduate student in every discipline in which the university performs research, with the purpose of becoming an expert in the given field of the disclosure in less than a week.

From Concept to Commerce: The Consultant's Role

Consultants as a breed bring their own jargon, baggage, and approach. In addition though, consulting firms pride themselves on having a team of highly motivated, focused, well-trained, and experienced problem-solvers. The daily routine of a consultant involves solving multidimensional problems ranging from technology to market challenges. Often, these challenges are layered within organizational, systemic, and team issues. These solutions are as applicable to a TTO as any corporate entity.

Consulting firms, by virtue of their professional environs, are forced to keep a close ear to the ground and diligently track emerging trends in the technology markets. The value of early-stage technologies in shaping the future can never be underestimated. As a consultant, the value attached to technology innovation is clearly evident across the array of companies of various sizes and stature, irrespective of whether they are year-old startups or corporate behemoths. Market differentiation is a key motivating factor for companies to continuously hunt for novel technologies and develop new products and features to stay ahead in the highly competitive environment.

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There are other factors, such as regulatory pressures, that can greatly impact industry's need for innovation. The clean-tech arena is one such segment. Consultants with in-depth understanding of market and technology dynamics together with a pulse of the technology maturation curve are positioned as key allies of the technology transfer professional. The approach of "build it and they will come" seldom succeeds and has few takers. The understanding of customer need is rated a paramount factor for success by most business consultants. Consultants with this understanding may often provide the required reality check on the technology gap and market opportunity for a given early-stage idea or technology.

Justifying the Cost: TTOs Can Afford to Hire Consultants

Following the lead of many executives in private industry, universities today are not shy about hiring consultants to assist them in reducing redundancy and administrative costs. The question is, How are TTOs justifying to their university senior leadership spending dwindling resources on consultants who perform commercial and patent assessments for new or existing invention disclosures?

Investment in Initial Evaluation May Prevent Unnecessary Patent Costs

In today's environment where patent fees on provisional patent applications can top the $10,000 mark, spending a fraction of that amount to have a consultant look into whether or not there is even a market for the subject of the invention disclosure appears to be reasonable path to take. This may be particularly true if the TTO is a one-person shop and/or has a nominal number of disclosures in a certain discipline/industry submitted each year. But what about larger technology transfer offices? Say for example, technology transfer offices that have multiple full-time employees and 50-plus invention disclosures submitted each year. In that case, it could be argued that engaging a consultant to perform a commercial or patent assessment on every case may become cost-prohibitive. These larger offices may first want to consider engaging a consultant to perform an initial, overall triage of these inventions to rank them using agreed-upon criterion.

Another example of when consultants are useful is when a TTO is sitting on a large backlog of cases (which have accumulated over many years and have not been patented) or a large portfolio of patent applications and patents that are not licensed. Engaging a consultant to prune these cases in a relative short period of time can not only help reduce costs but also avoid the perception that the technology transfer office is the perennial black hole.

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Early-Stage Technology Commercialization: Call for Help to Understand Licensee's Perspective

Knowledge of technology markets is essential to understand the relative position of an early-stage technology in the given industry landscape. The knowledge of technology markets is important but not sufficient for successful technology commercialization. Developing an understanding of customer needs and challenges is paramount to any successful business, including the business of technology transfer. For any TTO it is critical to understand the forces shaping and motivating potential licensees in the corporate research and development (R&D) environment. The knowledge of technology markets when viewed in the context of challenges being faced by potential licensees presents a clear and realistic picture. TTOs may have limited access to this knowledge and must pay to acquire this experience.

Consultants fact gather in many ways, often having access to information a TTO does not. Leading consulting firms advise an array of clients ranging from small startups to Fortune 100 companies. Consultants often help and troubleshoot or help to develop and implement corporate strategy. Thus, consultants have an insider's view of how things function or, more importantly, where the challenges arise.

For many businesses in diverse verticals, technology development and innovation are crucial to keep up with customer demand, competition, and, more importantly, achieve overall growth objectives. As a standalone perspective, technology is important, but in conjunction with six other perspectives—customer, economic, global, integrated industry, competitive, and best practices—it provides a critical focal point for technology-driven or technology-based companies. In good economic times or bad, technology innovation fuels growth and sustainability of organizations. Companies that continue to invest in development of innovative products, services, and solutions tend to do better than those that cut back on R&D programs.

The key for any organization is to identify the most potent projects and take them through a systematic process of development and go/no-go decision milestones. Whether the projects are homegrown or externally sourced via in licensing or an open innovation platform, they eventually enter the new product development platform and are governed by the same forces and parameters.

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In this regard, it is critical to view some of the external and internal challenges that are typically faced by any R&D organization. The organization's technology and R&D executive team is faced with numerous internal and external challenges. Internal organizational challenges include issues related to company vision, executive sponsorship, team-building, and maintaining funding for R&D projects, while external challenges are related to factors impacting adoption and commercialization of new technologies and realizing return on investment (ROI) on product development efforts. Consulting firms undergo years of learning dealing with a variety of circumstances and industry segments. Thus, consulting firms are well-placed to provide a 360-degree understanding of these challenges. The table provides a list of external and internal R&D challenges commonly faced by organizations.

Table 1: External and Internal Research and Development Challenges

Key Internal Challenges	Key External Challenges
Evaluating open innovation for co-development: Reviewing the available open innovation options to optimize innovation strategy in pursuit of efficient product development.	Negotiating the intellectual property (IP) jungle: It is critical to map the IP landscape to identify whitespace and IP-dense areas to guide the innovation strategy and ensure freedom to practice.
Implementing customer-driven innovation management: Integrating customer feedback to guide the innovation process for product development.	Matching innovations to applications (unmet needs): Focused and purposeful innovation based on a rigorous process of evaluating existing and future applications.
Aligning ideation with the strategic vision (including interdepartmental communication): Ideation must include mechanisms to channel inputs from multiple functional groups within the organization to align innovation with the strategic vision.	Mining the whitespace to inform innovation strategies: It is imperative to scan the technology/application whitespace to identify novel target opportunities.
Defining innovation timeframes: The process of demarcating stages of innovation based on time to market.	Tracking the competitive technology landscape: Real-time monitoring of technologies and applications targeted by incumbent and potential competitors.
Build vs. buy for innovation: Balancing internal technology innovation with external sourcing.	Monetizing innovation: The ultimate objective of innovation success is to productize innovation to maximize profitability and sustainability.

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Addressing Your Internal and External Stakeholders

One of the most difficult tasks at hand for a technology transfer professional is managing expectations, both at the internal and external levels. Dealing with external expectations involves understanding the needs of the market and potential licensees, managing the relationship with venture capitalists and angel investors, engaging with law firms and accounting firms, and dealing with the patent office amongst others.

Internally, the challenge can be much bigger. The key internal constituents of a TTO include faculty inventors, student inventors, student interns, deans and administration officials, the grants management and contracts offices, as well as the senior-most offices in the university focused on economic development.

A diverse list of external and internal constituents, each with its own agenda, presents a complex maze to navigate. The sponsors of a TTO are internal and, hence, the first part of this discussion will be internally focused. Interacting with inventors, encouraging and motivating them to file disclosures before publishing, preventing public disclosure at conferences before appropriate safeguards, or dealing with unrealistic expectations are all key components of the internal challenge matrix. There is a constant struggle to manage a portfolio of very early-stage technologies that need in-depth assessment from multiple viewpoints. Often, inventors are more amenable to an unbiased external opinion as opposed to what is perceived as biased internal positions or narrower field of expertise.

Perceived Expert

Consultants can bring a great deal to the table given the direct, strong, and long-term established understanding and relationships with the industry. The TTO can gain high regard and credibility with its internal constituents by leveraging the contacts of the consulting firms for pursuing avenues in sponsored research, technology marketing, brand creation, and projection of capabilities to a large pool of potential licensees. This value proposition when conveyed in the appropriate context can potentially generate a great deal of good will for the TTO.

Process Efficiencies

Consultants also focus on process efficiency, whether it is a supply chain or a disclosure analysis and management system. Cleaning up the processes can generate substantial

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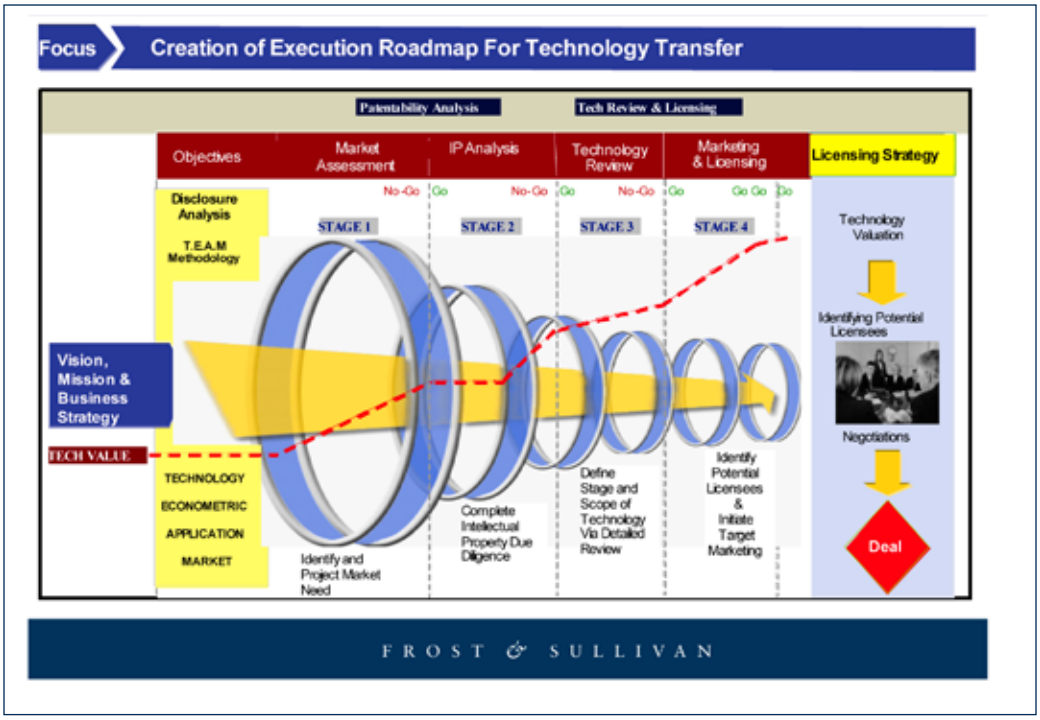
time and cost savings. In addition, gaining valuable firsthand market feedback on an inventor's technology can provide that added level of confidence, for which, the inventors often look. The answer could be negative, and an external unbiased opinion can make it easier to digest and perhaps a little more palatable.

Similarly, an encouraging response from the market can go a long way in boosting the morale of the inventor and the entire research team. Leveraging their relationships with consulting firms, TTOs can help brand their faculty inventors, position their cutting-edge technologies in the market, and help get the required attention to the game-changing research that goes on in the labs. TTOs can demonstrate in several ways the value of developing a close relationship with a consulting firm. The consulting firms, on their part, have to look at this as a relationship-building and partnership-building endeavor and not merely as a route to near-term profits as illustrated in Figure1.

Figure 1: The Technology Transfer Roadmap: Where Can a Consultant Add Value?



At each step of due diligence indicated in Figure 1, a consulting firm can bring in a very market-based approach focused on commercializing an early-stage technology. This can range from obtaining market feedback on early-stage ideas through primary research,

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identifying target licensees, and facilitating early discussions, as well as providing necessary support during negotiations when needed. The negotiations could involve potential investors or licensees, sponsored research agreements, or the more frequent discussions with faculty inventors to help fine-tune their inventions or convey a market reality that may not be the most desirable outcome for faculty.

The integrated approach of intellectual property (IP), technology, and market due diligence together with inputs from primary research can be invaluable in uncovering the future potential of an early-stage idea or technology. The TTO should stay in contact with the consulting firm during the due-diligence process to track the direction of the project to ensure the best results.

Garnering Investor and Venture Capital Support

TTOs can engage consulting firms to present the value proposition of a notable technology to potential investors. Angels and venture capitalists (VCs) alike recognize the name-brand consulting firms and will likely see as favorable any data or analysis that is supported or presented by leading global consulting firms. This attitude stems from the fact that often, the VC firms themselves rely on some limited external due diligence and opinions. One such source of external opinion would be a consulting firm that has in-depth technology expertise in the given area.

Selecting a Good Consulting Firm

Considering the myriad consulting firms available to a technology transfer professional, what features should the technology transfer professional or TTO look for in a prospective firm?

One of the most critical features is flexibility of turnaround time. Under the U.S. IP-process flowchart, commercial/patent assessment occurs before filing a provisional patent application. That means to ensure that overseas patent rights are not compromised due to premature publication, the faculty member/inventor must delay publishing of research results until a patent application is filed. This can become a problem if the assessment takes months instead of weeks.

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Another feature that is important when seeking to engage a consulting firm is the nature of the data being gathered by the consultant firm for the assessment. In many instances, the consultant in effect gathers publically available data, for example, market data characterizing yearly sales for a specific industry. The value added is it takes the consultant much less time to identity and collect this publically available data compared to the technology transfer professional attempting to do this internally.

However, there are some instances where it is necessary for the assessment to drill deeper and seek out very specific nonpublished data, for example, to determine the market share of a potential licensee in a particular industry. Although all consulting firms have access to the published data via the Internet, only select, generally larger firms (with many clients willing to provide this data in an unidentifiable manner) have the capability to produce this type of market data.

Last, but not least, flexibility in pricing is critical to any technology transfer professional. Having a variety of offerings, including low-cost options, is essential for consulting firms looking to be engaged by TTOs in today's economy. Many TTOs are under tremendous pressure by senior university management. This is particularly true for state universities struggling to maintain or increase services in an environment of reduced funding. Many consulting firms may lose the ability to break into the university arena. Some of this flexibility may take the form of discounts of fees, but more desirable (from a technology transfer perspective) is a tiered, stage-gate approach.

The Disclosure Number Game: Too Little or Too Much?

TTOs globally typically have either of two problems with regards to disclosure throughput: too little or too much. There could be a problem of receiving too few disclosures and hence motivating their faculty inventors to engage in frequently presenting their potentially patentable ideas to the TTO. Alternatively, for some TTOs, there is a problem of plenty.

The TTOs that receive a deluge of invention disclosures often can have a large backlog spanning several years. In both instances, consulting firms can be engaged to provide much-needed support. Where there is a need to motivate faculty, consulting firms can be engaged to demonstrate the cutting-edge commercial applications that are being brought

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to market globally in the field of the concerned faculty inventor's research focus area. This will serve to motivate the faculty member and provide an impetus for higher disclosures. In addition, a consulting firm may be engaged to structure workshops that can increase faculty participation in the technology transfer and commercialization process.

The problem of plenty is a relative one and depends on the prevalent throughput of disclosure review in an individual TTO. For example, for a technology transfer office having only one full-time employee (FTE), plenty could range from 35 to 55 invention disclosures. Whereas for a technology transfer office having five or ten times as many FTEs, plenty could take the form of hundreds of invention disclosures.

Regardless, for those TTOs that have a problem of plenty, it is well-worth considering engaging with a consulting firm that can deliver on large-scale projects consisting of hundreds of cases in a span of months. This kind of throughput is achievable only if the consulting firm has the necessary bandwidth in terms of a large number of highly qualified subject specialists or technology, market, and IP analysts in addition to extremely efficient processes in place.

The consulting firms that are routinely engaged by industry to perform such a function would perhaps be best-positioned for such types of projects owing to their well-established protocols and years of experience dealing with these projects. It is critical for TTOs to ensure that the backlog is cleared quickly so as to enable the licensing managers to devote time to the newer disclosures coming in that can have a potentially higher value.

It is also important to consider that technology waits for no one and, hence, some of the older cases may be made obsolete just due to the passage of time for the lack of finding a licensee or for the mere lack of a revisit to the backlog. This problem is compounded by the fact that patent maintenance costs can be alarmingly high and could pose a huge drain on resources. Hence, both for process efficiency reasons and for resource considerations, it is imperative that this problem be addressed sooner, rather than later. The problem does not go away with time, and the pain only gets more severe.

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Successful TTO-Consultant Relationships: Case Studies

A unique partnership model was developed between the University of South Alabama and Frost & Sullivan. Here, a large number of disclosures were presented to the consulting firm via established confidential mechanisms for a preliminary review. After completion of this review within the timeframe of a few weeks, the consulting firm sent in its recommendations on cases that were deemed fit for a thorough analysis. The TTO evaluated these recommendations and, in approximately 85 percent of the cases, was in good agreement with the consulting firm.

Once the scope of the analysis and selected cases had been well-defined, the consulting firm then undertook complete due diligence including a detailed technology review, technology-market fit analysis, as well as an IP landscape assessment. The final recommendations were made to the university TTO based on all of the above criteria.

Figure 2: Partnering Schematic

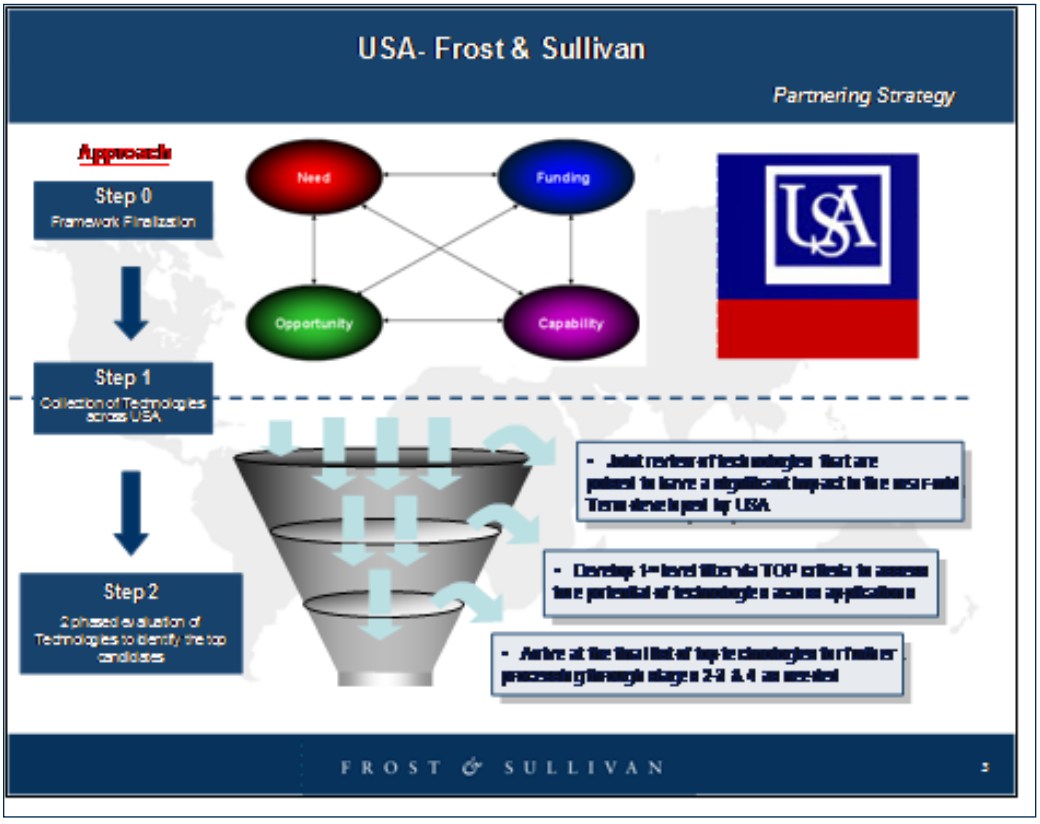

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Figure 2 shows a model that allows for a second opinion from a well-established consulting firm, while maximizing the return on investment for the TTO by investing in due diligence for only those cases that have been preselected through a funnel process.

The preceding case study was based on a real-life scenario. But to illustrate the point further, the following examples provide two hypothetical case studies.

Case Study No. 1

James Rockstar, a serial inventor working at the University of FlorBama (UFB), has a successful record of working with UFB's Office of Technology Transfer (OTT) to license the first stage of a cutting-edge, platform technology to the aerospace industry. As a result, Rockstar's reputation in the industry soars. Under these licenses, the licensees must reimburse OTT for worldwide patent expenses relating to this first-stage technology. The total reimbursement amounts to more than $250,000.

Based on the successful track record of the first-stage technology and Rockstar's worldwide reputation as a leader in his field, OTT makes the decision to file Rockstar's second-stage technology around the world with the hope that licensees will be forthcoming and the patent fees will be reimbursed. Three years go by, at an average worldwide patent prosecution average cost of $40,000 per year, and still no licenses. Should UFB's OTT office pull the plug on these second-stage patents/applications and risk alienating Rockstar?

UFB's OTT decides to first engage a consulting firm to get a better handle on the market parameters for this second-stage technology. The firm concludes that, unlike the first-stage technology, this second-stage technology has fewer benefits for the industry segment, is highly likely to be impacted by regulatory constraints, slow growth rates, and, as result, has very limited market potential, if any. UFB's OTT shares these results of this commercial assessment with Rockstar. They both agree to pull the plug on this technology, thereby resulting in a savings of more than $40,000 per year. The consultant charges were less than 20 percent of the annual expenditure on the average yearly maintenance costs.

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Case Study No. 2

John Newhire, a new, industry-savvy professor of engineering at the University of National Football Championship (UNFC), submits a new invention disclosure relating to an electronic device for use in the telecommunication industry. Since Newhire spent ten years working for an electronics manufacturer, the commercial assessment performed by a consulting firm (hired by UNFC's OTT) was extremely positive, indicating a large market potential for the invented device. Newhire is so confident that his device is a game-changer, he builds a prototype in short order and presents the working prototype to UNFC's OTT with the request that OTT pay to have the device patented. OTT decides to hire the same consulting firm to perform a patent assessment on the invention.

In the process of conducting this patent assessment, the consultant's technical expert confirms that the invention may be too broad in view of the fact that there are many patents issued in this area and, therefore, the prior art is very tight. As the interview continues, Newhire becomes very agitated and defensive about his device. He insists that his device must be patentable because it is not commercially available in the industry. The consulting firm finishes the interview and produces a patent assessment for UNFC's OTT.

After discussing the patent assessment with Newhire, it becomes clear that not only is the patent prior art saturated, but one patent in particular, identified by the consultant firm, discloses Newhire's invention exactly. As a result, UNFC's OTT decides not to file a patent application on Newhire's invention disclosure. Newhire is relieved that he did not have to spend his time and effort working on a patent application for a device disclosed in the prior art that was very likely to be rejected by the patent office.

Conclusion

In view of the case studies discussed above, it is clear that there are likely to be specific circumstances under which consulting firms can provide value to TTOs through their due diligence. The models described in this analysis present select examples and are meant only to serve as guidelines for TTO-consultant relationships. TTOs may further explore the best strategy that suits their relevant contexts, budgets, and specific requirements. It is also advisable for consultants to develop a deep understanding of the workings and

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challenges faced by university TTOs to better serve their clients. In the larger scheme of things, it would serve both the TTO and the consulting firm well to keep the big picture in mind: that of taking innovation to market to serve unmet needs in an efficient manner.

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Data Security and Privacy: Into the Breach

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In 2007, an attack against the computer systems of the TJX Co. potentially exposed credit card and other personal information of 45 million T.J. Maxx customers. The 2008 intrusion into Heartland Payment Systems' processing system—the fifth largest in the United States[1]—compromised more than 100 million credit and debit card transactions. And in an ignominious end to 2009, a malicious attack against RockYou.com's user database compromised the user names, passwords, and e-mail addresses of more than 32 million accountholders.

Stolen confidential business and personal information may be disseminated over the Internet in a matter of minutes. Even if personal data are not compromised, the loss of even one computer may mire an institution in a tangled web of international data security and privacy laws and regulations. And the resulting financial cost pales when compared to the damage to reputation, customer wrath, and loss of trust.[2] Still, rarely a day goes by without a data breach being reported by an academic institution, health-care organization, or other business or government agency.

Data breaches increased as much as 47 percent in 2008, exposing as many as 35 million records.[3] While academic, governmental, and military institutions reported a decrease in breaches, business breaches climbed from 21 percent to 41 percent between 2006 and 2009.[4] Still, breaches continue to be reported by organizations of all types. For example, it was reported that:

- Binghampton University in New York kept information for every student, possibly dating back at least 10 years, in a storage room next to one of the most heavily trafficked lecture halls on campus. The storeroom door was taped open to prevent it from locking. The information, which included Social Security numbers, credit card numbers, scans

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of tax forms, employee salary and immigration asylum information, was disorganized and haphazardly maintained in boxes sprawled throughout the two-story room and in unlocked filing cabinets.[5]

- The University of Hawaii notified people who conducted business with one of its parking offices for 13 years that an unauthorized access to its database server occurred on May 30, 2010. Of the 53,000 affected records, 41,000 Social Security numbers and 200 credit card numbers were exposed.
- University of Florida officials notified more than 2,000 people that in May 2010 their Social Security or medical identification numbers were included on address labels affixed to letters mailed through the U.S. Postal Service, inviting them to participate in a research study. The same information was also shared with a telephone survey company.
- The compromise of a University of Maine database exposed names, Social Security numbers, and medical information of every student who visited the university's counseling service between 2002 and 2010.[6]

Contrary to common thought, the overwhelming majority of breaches results from information mishandling or insufficient (or failing to follow) privacy processes and procedures, not cyber attacks or hackers. For instance, simply wiping data from a defective hard drive returned to its vendor for repair would have prevented the breach of up to 76 million records about U.S. military veterans, including Social Security numbers dating as far back as 1972.[7] Studies indicate that of all reported breaches for 2008, only 2.4 percent of the data were encrypted or secured by other strong protection mechanisms (decreasing to 1 percent in 2009[8]), and only 8.5 percent of the data were even password protected.[9]

Social Security numbers of several hundred alumnae of Armstrong Atlantic State University's nursing school were compromised when a portable hard drive was stolen from the campus, despite the fact that use of portable devices to store confidential information violated university policy.[10] Historically, institutions have spent more on cyber security prevention although, until very recently, only a small percentage of breaches occur as a result of malicious attacks.

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Malicious attacks exceeded human error for the first time in 2009, with hackers and insider theft accounting for 36.4 percent of all breaches and human error accounting for 27.5 percent,[11] a trend that continued in 2010 with hacking accounting for 17.1 percent and insider theft at 15.4 percent.[12] While the total number of reported breaches declined in 2009, 60 percent of those reported represented system breaches affecting almost 222.5 million records.[13] And, although academic and health-care organizations generally have experienced fewer breaches than their commercial counterparts, it may be due more to kismet than conscious choice.

Indeed, their exposure risk is exceedingly high in light of the sensitivity of the collected data. And yet, a 2009 survey found that while 98 percent of health-care organizations have implemented information security and privacy policies, fewer than half use encryption or data anonymization technology.[14] What will it take for U.S. organizations[15] to make data security as second nature as issuing identification cards/security badges and locking their doors? And what role should technology transfer managers play with respect to data security and privacy issues?

An overview of privacy and data security basics follows, distinguishing the laws of Canada and the European Union (EU) from those of the United States. This overview will illustrate the differing approaches and cross-border privacy issues confronting academic institutions with respect to their faculty; students generally and in connection with clinical trials and other research; health-care providers with respect to their patients; and all organizations with respect to their existing and prospective customers, employees, and suppliers.

Canada and the EU treat privacy of personal information as a fundamental human right to be controlled by the individual and, therefore, address security and disclosure of private information through comprehensive laws and regulations. Canada protects the privacy of its residents through its Personal Information Protection and Electronic Documents Act (PIPEDA).[16] The EU governs protection, processing, sharing, and transborder flows of personal data through the EU Privacy Directive, which directs each EU member state to enact its own local law. The EU Directive serves as a blueprint for each member state's local privacy statutes, most of which are enforced through each member state's Data Protection Authority.[17]

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Neither Canada nor the EU Privacy Directive permits use or sharing of personal information without first obtaining the subject individual's explicit and informed consent and providing individuals with the ability to access and update their data and a complaint process. The information must also be used or disclosed only for the purposes for which it was collected. This is commonly referred to as the *opt-in approach.*

Canada, the EU, and its individual member states aggressively and proactively protect individual privacy.[18] Although it was originally thought that Canada's PIPEDA only applied to entities having a physical presence in Canada, a 2007 court decision held otherwise. In *Lawson v. Accusearch Inc.*,[19] the Federal Court of Canada determined that Canada's Office of the Privacy Commissioner (OPC) had the authority to investigate complaints against businesses that collect, use, or sell personal information of Canadians, even if the entities have no physical infrastructure within Canada. The EU and its members have also determined that its data protection legislation applies to social networking site operators, even if their headquarters are not located in the EU.

Similarly, the EU Privacy Directive has been expansively interpreted by the Article 29 Data Protection Working Party (Working Party), applying EU data protection law to non-EU Web sites that set cookies or use JavaScript that runs on their residents' computers.[20] This position was reaffirmed by the Working Party's opinion on search engines, endorsing the view that an Internet protocol (IP) address or unique cookie identifier, in and of itself, may be personal data and reiterating that setting cookies or other activities locally on a user's PC is sufficient to trigger applicability of EU data protection law, as is having ad sales in connection with the search engine.[21] Having a local office, local customer support, or a third-party agent within a member state would also suffice.

Online advertisers are finding that their behavioral targeting practices are being closely scrutinized. An amendment to the EU's Privacy Directive requires that consumers give prior, explicit consent before cookies may be placed on the computers of EU residents. The U.S. Federal Trade Commission (FTC) issued its Self-Regulatory Principles for Online Behavioral Advertising[22] providing for transparency, consumer control, and reasonable security for consumer data similar to the EU requirements, exhorting companies to use the principles as a catalyst to developing industrywide self-regulatory practices.

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In response to high-profile data breaches by EU companies, EU members continually address gaps in their laws. For example, Germany's Data Protection Act has been expanded to reach to all collection, processing, and use of personal data, requiring that personal data be anonymized unless cost prohibitive and that, absent an existing relationship, marketing and research firms obtain consumer permission to use even address data. Germany has also introduced U.S.-style data breach notification obligations, the one area in which the EU still lags behind the United States.[23]

Having undergone a five-year review in 2010, Canada's PIPEDA was amended in 2010 to include breach notification to the OPC and affected individuals, enforcement of which began immediately. (The FTC's efforts to align the interests of the United States and the EU generally and in connection with behavioral advertising and data breach notification laws of individual states are discussed more fully below.)

Additional examples of aggressive regulation outside the United States include the Scottish government's Identity Management and Privacy Principles for public service organizations aimed at increasing public confidence in the handling of private data, including guidance on identity verification, audit trails, data sharing, and risk management.[24] Canada's OPC required that Bell Canada make more transparent its practice of using deep-packet inspection technology to tie users' online activities to their IP addresses.[25]

Facebook found itself in the crosshairs of the OPC and privacy advocates when modifications to its privacy policy made information located on user pages more available. In response, Facebook implemented safeguards designed to better protect the personal information of its users and their online friends on deactivation and from third parties, such as application developers.[26] And, citing the failure of social networking sites to adequately protect user data as reflected in their online privacy statements, Germany's data protection commissioner has proposed an independent ratings agency to alert users to the risks of the various social networking Web sites.

Proximity and more familiarity with language and culture often lead U.S. businesses to test the global market by expanding internationally to Canada first and then to the EU. But Canada's comprehensive framework is not the approach taken by U.S. privacy laws and regulations. The Privacy Act of 1974[27] regulates the collection and use of records by

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U.S. federal agencies and affords individuals the right to access and correct their personal information. Information disclosed for any "routine use" compatible with the agency's purpose in collecting the information is excluded. The law does not apply to state and local agencies or the private sector.

In contrast to the broad umbrella approach to data security and privacy reflected by EU and Canadian law, no overarching U.S. federal law governs the private sector's use and protection of personal information.[28] Rather, in addition to endorsing industry self-regulation through technology and privacy statements (the *opt-out standard*), to date the U.S. government has approached privacy from an information use/sector-specific perspective, focusing on information misuse. As a result, federal data security and privacy laws in the United States have developed in patchwork fashion, geared toward the regulation of targeted types and uses of information, i.e., consumer credit information,[29] health and medical information,[30] financial information,[31] personal information of children,[32] driver's license information,[33] and e-mail.[34] A law even protects against disclosure of video rental information. [35]

That said, the U.S. privacy approach is shifting. Following public hearings and roundtable discussions on consumer privacy, in December 2010, the FTC proposed a comprehensive framework for protecting personal information, including a privacy-by-design approach through which organizations would build privacy protections into their everyday business practices.[36] Believing the advertising industry's self-regulatory efforts to support transparency and choice—as set forth in its Self Regulation Principles discussed above—have fallen short, the FTC included a do-not-track program for online advertising, advocating a uniform, comprehensive choice mechanism such as a persistent cookie-like browser setting through which consumers would be able to choose whether to allow the collection and use of data regarding their online searching and browsing activities. The consumer's selected settings would be conveyed to sites visited by the consumer's browser to signal whether or not the consumer has consented to be tracked or receive targeted advertisements. In response, Microsoft announced[37] it will include functionality in its Internet Explorer Web browser that would limit the ability of advertisers and analytics providers to collect and use a user's online browsing data.

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On the heels of the FTC's issuance of its proposed framework, the Department of Commerce issued its policy recommendations for promoting online privacy that include the creation of a Department of Commerce National Program Office to coordinate federal activities needed to implement the National Strategy for Trusted Identities in Cyberspace.[38]

Many U.S. states, following the same informal/sector-specific approach, stepped into the chasm created by the lack of comprehensive federal legislation by regulating consumer credit, driver's license, Social Security, supermarket club, and credit card information. In 2000, California set the gold standard by establishing the Office of Privacy Protection within its Department of Consumer Affairs. From then on, California statutes have served as the foundation for a proliferation of laws enacted by a majority of states, mandating that policies be implemented to secure information to prevent unauthorized use and identity theft and recommending action to be taken in the event of a data breach.

A New York statute, enacted in 2009, prohibits employers from posting, displaying, or otherwise communicating personally identifiable information of employees, such as Social Security numbers, home addresses, telephone numbers, or e-mail addresses to the general public.[39] Massachusetts enacted a first-of-its-kind data security law requiring that businesses not only develop and maintain a security program with administrative, technical, and physical safeguards for personal records, but also encrypt all personal information transmitted wirelessly, stored on laptops or other portable devices, and, if feasible, personal information transmitted across public networks. All businesses that own, license, store, or maintain personal information about a Massachusetts resident, regardless of whether that organization is itself present in the state, must comply.[40] Until the U.S. Congress enacted the Health Information Technology for Clinical Health Act (HITECH) in 2009,[41] the first significant national reporting statute, California's laws obligating health organizations to safeguard patient data and its state enforcement office provided the most comprehensive protection of patient data.[42]

Although U.S. state laws vary in their specifics, they generally require that organizations (1) protect personal information from unauthorized access, use, modification, or disclosure; (2) maintain reasonable security procedures appropriate to the nature of the personal information and the nature and size of the organizations and their operations; (3)

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destroy records containing personal data under certain circumstances to prevent inappropriate access; (4) mandate in writing that their third-party service providers implement appropriate procedures in compliance with law; and (5) take certain action upon learning of a personal data breach, including prompt notice to affected individuals, law enforcement, and consumer credit-reporting agencies. Violations of state statutes tend to be characterized as unfair or deceptive practices subject to civil and criminal penalties.

With the exception of the individual states' data breach notification laws, protections afforded U.S. residents by law and the opt-out approach fall short of those afforded to residents of the EU. As a result, the EU restricts the flow of its residents' personal data to the U.S., absent the recipient's compliance with *adequate* privacy laws or explicit consent by the individual. In an effort to bridge the differing approaches to privacy and data security, the U.S. Department of Commerce, in consultation with the European Commission, developed a safe-harbor framework.

By complying with the following seven principles, organizations may avoid prosecution by European authorities under European privacy laws:

1. Individuals must be advised of the purpose for which the information is being collected, to whom it may be disclosed, how to restrict use and disclosure, and how to address inquiries and complaints.
2. Individuals must be given the opportunity to consent to disclosure of their personal data to a third party or use in a manner other than that for which it was initially collected.
3. The notice and choice principles (items 1 and 2 above) must be applied before disclosing information to third parties. Third-party service providers should be required in writing to comply with EU privacy protection principles.
4. Individuals must be able to access their information to correct, amend, or delete it.
5. Reasonable precautions must be taken to protect personal information from loss, misuse and unauthorized access, disclosure, alteration, and destruction. This would include reasonable steps to ensure that data is accurate, complete, current, and reliable for its intended use.
6. Personal information collected must be relevant to the purpose for which it is collected.
7. Finally, procedures should be implemented to verify compliance and investigate and resolve complaints.

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In an effort to move the U.S. toward a more unified approach, the FTC developed its Fair Information Practice Principles, a collection of reports, model codes, and guidelines with common core principles that more closely match EU requirements. These include: (1) notice/awareness, (2) choice/consent, (3) access/participation, (4) integrity/security, and (5) enforcement/redress.[43] And to address the burgeoning problem of misuse and loss of personal information, the FTC[44] developed additional rules and safe-harbor guidelines, including the creation of its Division of Privacy and Identity Protection, to assist the private sector in its efforts to protect personal data and comply with the varying federal data protection statutes.[45]

For example, the FTC's Financial Privacy Rule requires that financial institutions give clear privacy notices explaining their privacy and data-sharing policies and disclose to their customers how to limit information sharing, i.e., how to opt out. If a consumer does not opt out, then his or her personal data may not only be used by the financial institutions but also by his or her third-party service providers with which it is shared, including further disclosure if permitted by the financial institution's privacy policy.

The FTC's Safeguards Rule obligates companies subject to the Graham-Leach-Bliley Financial Services Modernization Act (G-L-B) [46] to have and implement written security plans appropriate to their size and complexity, the nature and scope of its activities, and the sensitivity of the information being handled to protect the confidentiality and integrity of personal information collected. The Safeguards Rule requires that businesses designate a plan coordinator to identify and assess risks to information in each area of operations; evaluate the effectiveness of current safeguards; design, implement, monitor, and regularly test the efficacy of the plan; and evaluate and adjust the plan in light of not only the test results but also changes in business operations and other relevant circumstances.

The FTC's Disposal Rule requires that businesses take reasonable steps to prevent unauthorized access to or use of sensitive information derived from consumer reports and to properly dispose of it (e.g., by shredding, burning, destroying electronic media, etc.). The Disposal Rule applies to not only consumer reports but also information derived from consumer reports (such as credit scores, background information, insurance claims, check writing, and medical history). The FTC encourages those who dispose of *any* records

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containing personal or financial information to take similar measures, taking the position that *anyone* accessing consumer reports for business purposes, not just those subject to G-L-B, is subject to the FTC Disposal Rule. In view of this, the Disposal Rule casts a much wider net, ensnaring less sophisticated users such as landlords, automobile agencies, personnel departments, and even families seeking nannies or other household help.

The FTC's standard for information security recognizes that information collected by organizations varies widely in its sensitivity, requiring only that reasonable procedures to protect sensitive information are maintained based on the nature and size of the organization, its resources, type and sensitivity of information collected, etc. The following are of particular import to the FTC with respect to compliance with its information security rules.

- Employee management and training
  -- Background/reference checks
  -- Employee buy-in via written agreements
  -- Limiting access to those with a need to access
  -- Controlling access via strong passwords that are regularly changed
  -- Password-activated screen savers that lock computers after a period of inactivity
  -- Policies addressing use of portable equipment such as laptops, personal digital assistants, or other remote devices capable of storing information
  -- Training employees to lock sensitive data, not share passwords, encrypt sensitive information, and report suspicious activity
- Information systems (include network and software design, information processing, storage, transmission, retrieval, and disposal)
  -- Ensure protection against physical hazards such as floods and fires.
  -- Store tangible sensitive data and/or the equipment housing the data in locked rooms.
  -- Back up records and archive off site.
  -- Avoid storing sensitive data on the Internet.
  -- Encrypt sensitive data for storage and transmission.
  -- Properly dispose of sensitive information.
- Deter, detect, defend: Detection and management of system failures
  -- Keep abreast of emerging threats and defenses.
  -- Keep systems/programs up to date via patches, antivirus software, firewalls, intrusion detection, and logs.

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-- Keep employees informed of risks and possible breaches.
-- Develop and implement oversight and audit procedures, i.e., monitoring in-bound and out-bound transfers, create dummy accounts to detect unauthorized hits.
-- Retain security professionals to test/stress security.

- Notify affected individuals, law enforcement, and related businesses in the event of a security breach.

Taking its cue from the recommendations of the 2006 Identity Theft Task Force and in an effort to address the increase in identity theft and discrepancies under the Fair and Accurate Credit Transactions Act of 2003,[47] the FTC and other federal regulatory agencies enacted the Red Flags Rule. The Red Flags Rule requires that financial institutions and creditors holding any consumer account (or other account for which there is a reasonably foreseeable risk of identity theft) develop and implement an identity theft prevention program by December 31, 2010.[48] Programs must identify and detect activities that may be red flags signaling possible identity theft and implement procedures to respond accordingly.

Who is subject to the Red Flags Rule? Any financial institution or *creditor* that offers one or more covered accounts must comply. Any entity extending credit to its customers is a creditor and may have consumer accounts subject to the rule. A creditor includes any entity that regularly defers payment for goods or services or provides goods or services and subsequently bills the recipient. It is an organization's *activities* and not its industry or sector that determines if it is a creditor subject to the rule. Therefore, academic institutions, health-care providers, and telecommunications companies may fall within the definition, depending on how and when they collect payment for services. Those who regularly grant or arrange for loans or the extension of credit or make credit decisions may meet the definition of a creditor. Anyone offering financing or assisting in the acquisition of financing from others, i.e., processing credit applications, are also included.

Current FTC guidelines[49] describe two relevant forms of covered accounts: (1) consumer accounts designed to permit multiple payments or transactions and (2) any other account that a creditor offers or maintains for which there is a reasonably foreseeable risk of identity theft to customers or to the safety and soundness of the creditor, including financial, operational, compliance, reputation, or litigation risks. Academic institutions maintain covered accounts through bookstore accounts, tuition and other financial accounts,

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employment applications, patient accounts (if not covered under the Health Insurance Portability and Accountability Act (HIPAA)), student and employee accounts receivable, parking offices, and the like.

In determining foreseeability, the FTC recommends that businesses consider how accounts are opened and accessed. The ability to remotely access the account may create a reasonably foreseeable risk of identity theft. Companies are also advised to consider any actual incidents of identity theft they have experienced involving such accounts. Because the test cited in item 2 above includes a determination of the reasonable foreseeability of identity theft, it requires an assessment of the extent and effectiveness of an organization's privacy and data security policies, practices, and procedures.

Covered entities must implement an identity theft program, conduct ongoing risk assessments, and regularly update their policies and training programs to reflect risk changes based on changes in their business processes, structures, etc., and the ever continuing sophistication of thieves and malware technology. Users of consumer reports must also develop reasonable policies and procedures to apply when they receive a notice-of-address discrepancy from a consumer-reporting agency.

Similarly, HITECH requires prompt notification of breaches of unsecured protected health information. The Department of Health and Human Services reported that between September 2009 and December 2010, health-care organizations suffered serious breaches of more than 6 million patient medical records necessitating the public reporting required by HITECH. The majority of these failures, including one involving almost 1 million records, resulted from simple, preventable security lapses such as stolen disks or laptops, not complex criminal schemes.[50]

At-risk organizations, such as academic institutions, their research sponsors, clinical trial teams, clinical/contract research organizations, and technology transfer licensees (especially those in the life sciences and pharma industries), must be keenly aware of and address privacy and data security issues generally, but especially before engaging in any clinical trial activities. Indeed, even use of digital photocopiers jeopardizes the security of sensitive information if steps are not taken to protect the data stored on the hard drives from remote access, misuse, or innocent disclosure when the photocopiers are retired

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from service. Acquisition of data of U.S. and foreign participants, sharing data among all interested parties, and safe storage and destruction must all be considered.

Consequently, all at-risk institutions must seriously consider and enact privacy security standards sufficient to safeguard personal medical data amassed during clinical trials and ensure that their third-party vendors, such as patient recruitment firms, have these capabilities. Medical data acquired in a clinical trial context creates complex privacy issues, requiring that the privacy rights of participants and research-and-information-access needs of trial sponsors and clinicians be sensitively balanced.

Safeguarding the collection, sharing, use, and storage of this sensitive information is as critical to the success or failure of a trial as other variables or events. As technology transfer managers continue to develop and expand the roles they, as agents of academic institutions, play in technology commercialization and startup activities, educating and monitoring their licensee performance in critical at-risk areas, such as data security and privacy, assumes greater importance.

Conclusion

More than ever before, academic and health-care institutions and businesses must not only be aware of the data collection, use, and privacy requirements of each jurisdiction in which they transact business or otherwise operate, but also prepare themselves for the challenges accompanying the inevitable data security breach. Academic institutions must safeguard not only faculty, student, and employee information, but also be keenly aware of HIPAA and the new HITECH rules to protect patient information in the context of research and clinical trials.

General counsel of these institutions address these issues every day as evidenced by the recent data security breaches at the universities of Hawaii, Florida, and Maine, previously discussed. University medical centers also face these issues not just with respect to patient information but also in connection with the conversion to electronic medical records required by HITECH. Many faculty and students of U.S.-based academic institutions are not U.S. residents. Many academic medical centers treat international patients both in the U.S. and international satellite facilities. Moreover, the success of university-industry relationships and technology transfer spin-outs depends, in no small measure, on ensur-

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ing that all parties understand and comply with privacy laws. Technology transfer departments are in an excellent position to educate their constituencies in this regard. Existing FTC, Commerce Department safe harbor and other agency rules, existing and proposed U.S. federal and state legislation governing the handling of personal information, as well as actions in the event of a security breach are clearly trending toward the EU model.

While the FTC's Red Flags Rule may not universally apply, U.S. state and international data protection laws do apply to entities if the personal data of their residents are affected by the entities' activities. In the event of a data breach, the notification requirements of each state (and more and more EU countries) apply even if the business is not in violation of law. Moreover, if a business must respond to a personal data breach, a court or regulator's determination that the business's actions are reasonable under the circumstances and the fines imposed may very well hinge on whether the business has policies and procedures in place—probably procedures similar to those mandated by the FTC generally and its Red Flags Rule.

To respond effectively to data breaches, all entities need significant preparation, processes, and systems that enable rapid identification and notification of the breach. The day an organization detects a breach is not the time to begin development and implementation of a plan. Responding to news media, regulatory bodies, and the public is time-consuming, resource intensive, and requires serious attention. It requires risk-based management decisions that should not be made in the heat of the moment or by untrained, untested personnel.

The costs of a security breach, in revenue, personnel resources, and expense, as well as loss of reputation, are far too great to ignore. That a breach will occur is certain. Organizations that meet, rather than ignore, the challenges of securing data save in the long run, on their bottom line, in preservation of good will, and most importantly, by retaining the trust of their faculty, students, patients, employees, and customers. Technology transfer managers are uniquely positioned to assist their employers and constituents with their privacy and data security compliance.

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Notes

1. The Nilson Report, Issue 922, March 2009.
2. Under a January 2010 settlement between Heartland and VISA, subject to certain conditions, issuers of Visa-branded credit and debit cards may recover losses incurred up to $60 million. Under a separate December 2009 settlement of consumer cardholder class action suits, Heartland agreed to pay a minimum of $1 million up to a maximum of $2.4 million to class members submitting valid claims. Pursuant to a separate December 2009 settlement with American Express, Heartland agreed to pay $3,538,380 to satisfy issuer losses. Several additional security holder class action suits are pending against Heartland.
3. Identity Theft Resource Center (ITRC), 2008 Data Breach Report.
4. ITRC 2009 Breach Synopsis and Report (January 8, 2010).
5. ITRC 2011 Breach Report List.
6. ITRC July 6, 2010 Breach Report List.
7. ITRC 2011 Breach Report List, supra note 4.
8. ITRC 2009 Breach Synopsis and Report, supra note 3.
9. ITRC 2008 Breach Report, supra note 2.
10. ITRC 2011 Breach Report, supra note 4.
11. ITRC 2009 Data Breach Report, January 2010.
12. ITRC 2010 Synopsis and Report (January 3, 2011).
13. ITRC 2009 Data Breach Report, supra note 10.
14. "Are Hospitals Ready for Meaningful use of EHRS?," *Computer Sciences Corporation Survey,* December 2009, Erica Drazen, and supra note 9.
15. References to *businesses* include academic and health-care institutions.
16. Personal Information Protection and Electronic Documents Act, R.S.C., ch. 5 (Can.), Effective January 1, 2001.
17. European Union Directive on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data. EU Directive 95/46 EC of the European Parliament and the Council of 24 October 1995, 1995 O.J. (L 281) 31 at http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf
18. The UK's Information Commissioner's Office has been authorized to impose fines of up to £500,000 beginning April 6, 2010.

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19. *Lawson v. Accusearch Inc.*, 2007 F.C. 125 (Can.)
20. Article 29 Data Protection Working Party Document (May 30, 2002) (WP56), at http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2002/wp56_en.pdf.
21. Article 29 Data Protection Working Party Opinion 1/2008 (April 4, 2008) (WP 148), at http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2008/wp148_en.pdf.
22. See http://www.ftc.gov/os/2009/02/P085400behavadreport.pdf.
23. See German Protection Act (BDSG) Section 42a.
24. See http://www.scotland.gov.uk/Publications/2010/12/PrivacyPrinciples.
25. See Personal Information Protection and Electronic Documents Act (PIPEDA) Case Summary 2009-010, http://www.priv.gc.ca/cf-dc/2009/2009_010_rep_0813_e.cfm.
26. See Personal Information Protection and Electronic Documents Act (PIPEDA) Case Summary 2009-08, http://www.priv.gc.ca/cf-dc/2009/2009_008_0716_e.cfm.
27. 5 U.S.C. § 552(a).
28. Online consumer data privacy issues are being discussed at the U.S. federal level, and bills introduced to Congress in 2011 may move the U.S. toward comprehensive federal privacy legislation.
29. See Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq. (1971) as amended by the Fair and Accurate Credit Transactions Act of 2003 (FACTA) Public Law 108-159.
30. See Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, amending 42 U.S.C. § 1301 et seq. (1996) (HIPAA).
31. See Graham-Leach-Bliley Financial Services Modernization Act of 1999, 15 U.S.C. § 6801 et seq. (1999).
32. See Children's Online Privacy Protection Act of 1998, 15 U.S.C. § 6501 et seq. (1999).
33. See Drivers Privacy Protection Act of 1994, 18 U.S.C. § 2721 et seq. (1994).
34. See Electronic Communications Privacy Act of 1986, 18 U.S.C. § 2721 et seq. (1994).
35. See Video Protection Act of 1988, 18 U.S.C. §§ 2710-11.
36. Protecting Consumer Privacy in an Era of Rapid Change: A Proposed Framework for Business and Policymakers. Preliminary FTC Staff Report, December 2010, http://www.ftc.gov/os/2010/12/101201privacyreport.pdf.
37. See http://www.microsoft.com/presspass/features/2010/dec10/12-07ie9privacyqa.mspx.
38. Commercial Data Privacy and Innovation in the Internet Economy: A Dynamic Policy Framework. The Department of Commerce: Internet Policy Task Force, December 16, 2010, http://ntia.doc.gov/reports/2010/IPTF_Privacy_GreenPaper_12162010.pdf.

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39. N.Y. Lab.Law Art 7 § 203-d.
40. M.G.L. c 93H as regulated by 201 CMR 17.00 effective March 1, 2010.
41. The Health Information Technology or Economic & Clinical Health Act amendment to HIPAA was enacted in 2009 as part of economic stimulus legislation, specifically the American Recovery & Reinvestment Act of 2009, Pub.L.No. 111-5, §13421, 123 Stat. 115, 276 (to be codified at 42 U.S.C. §17951).
42. U.S. Senator John Kerry (D. Mass) has introduced legislation in the 112th Congress to establish a federal regulation framework for the comprehensive protection of individuals' personal data following the framework suggested by the FTC.
43. FTC Fair Information Practice Principles, at http://www.ftc.gov/reports/privacy3/fairinfo.shtm.
44. The FTC authority under its charter to prohibit unfair and deceptive trade practices.
45. For example, the FTC's Financial Privacy, Safeguards and Disposal Rules, the Children's Online Privacy Protection Rule: Safe Harbor Program.
46. Supra note 23.
47. See FACTA, supra note 18, which amended the Fair Credit Reporting Act.
48. The FTC delayed to December 31, 2010, enforcement of the Red Flags Rule to enable Congress to issue clarifying legislation. It has also agreed not to enforce the rule on members of the American Medical Association and other professional organizations while their lawsuits, asserting that the inclusion of attorneys and physicians and other professionals within the definition of creditor is too broad, wend their way through the courts.
49. See http://www.ftc.gov/opa/2007/10/redflag.shtm. See also http://www.ftc.gov/os/fedreg/2007/november/071109redflags.pdf.
50. See Report of Office of Civil Rights of the Department of Health and Human Services at http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachtool.html.

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A Brief Overview of the Federal Regulatory Approval Process for Pharmaceuticals, Medical Devices, and Biological Products

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Background

Introduction

This chapter will provide the technology transfer professional with a basic overview of the U.S. federal regulatory approval process for pharmaceuticals, medical devices, and biological products. Please recognize that the laws and regulations that encompass this topic are vast and complex, especially those related to the conduct of human subject-based research. As such, this chapter is only meant to provide the most basic of overviews, while relying heavily on government-related sources.

The FDA's Role: Safety, Efficacy, and Security

Created in 1906, the U.S. Food & Drug Administration (FDA) is currently an agency within the U.S. Department of Health and Human Services and employs more than 11,500 full-time employees. It is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, medical devices, biological products, the U.S.'s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, as well as helping the public get accurate, science-based information to appropriately and intelligently use medicines and foods to improve health. Note that this chapter will only address the FDA's role in the regulation of pharmaceuticals, medical devices, and biological products marketed for use in human medicine.

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It is also important to recognize that the Federal Food, Drug, and Cosmetic Act (FD&C Act)—the basic food and drug law of the U.S. originally enacted in 1938—does not give the FDA responsibility to regulate the practice of medicine or to *develop* new drugs, medical devices, or biological products, but rather to oversee the *testing* of new drugs, medical devices, and biological products and their *introduction into interstate commerce.* So, one of the primary roles of FDA physicians, scientists, and other staff is to review test results submitted by drug, medical device, or biological product developers. The FDA then determines whether the drug, medical device, or biological product is safe enough to test in humans and, if so—after all human testing is completed—decides whether the drug, medical device, or biological product can be sold to the public and what its labels should say about directions for use, side effects, warnings, and the like.

The Drug Research Process

The drug research process is complicated, time-consuming, and costly; and the result is never known at the outset. Literally hundreds, and often thousands, of chemical compounds must be made and tested to find one that can achieve the desirable result without causing too serious side effects. Such a complicated process costs vast amounts of time and money. The FDA estimates that, on average, it takes eight-and-a-half years to study and test a new drug before the agency can approve it for the general public, while the cost to the sponsor may approach $1 *billion*. That includes early laboratory research and animal testing, as well as later clinical trials using human subjects.

Building on Good Science

New drug research often starts by studying how the body functions, both normally and abnormally, at its most basic levels. This is conducted via two primary modes of scientific inquiry: *in vitro* (in test tube) studies and *in vivo* (in living organism) studies. The pertinent question is, "If the body's functioning is changed, then will I have a useful drug?" That, in turn, leads to a concept of how a drug might be used to prevent, cure, or treat a disease or medical condition. Once the concept has been developed, the researcher has a target. Sometimes, scientists find the right compound quickly. More often, hundreds or even thousands must be tested. In a series of in vitro experiments (*assays*), compounds are added one at a time to enzymes, cell cultures, or cellular substances grown in a laboratory. The goal is to find which additions show some chemical effect. Some may not work

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well, but may hint at ways of changing the compound's chemical structure to improve its performance. The latter process alone may require testing dozens or hundreds of compounds.

A more high-tech approach is to use computers to simulate an enzyme or other drug target and design chemical structures that might work against it. A computer can show scientists what the receptor site looks like and how one might tailor a compound to block an enzyme from attaching there. Such scientific activity is called research *in silico*—meaning as being performed solely via computer simulation. However, although computers give chemists clues to which compounds to make, they do not give any final answers. That is, compounds made based on a computer simulation still have to be put into a biological system to determine whether they will actually work.

A fourth approach involves testing compounds made naturally by microscopic organisms. Candidates include fungi, viruses, bacteria, and molds, such as those that led to penicillin and other antibiotics. For example, scientists will grow microorganisms in a fermentation broth, one type of organism per broth. Sometimes, 100,000 or more broths are tested to see whether any compound made by a microorganism has a desirable effect.

Early-Stage In Vivo Testing of New Drugs

To this point, the search for a new drug has typically been confined to in vitro studies. Next, scientists have to test those compounds that have shown at least some desired effects in a living system. In initial in vivo testing, drug developers make every effort to use as few animals as possible and ensure their humane and proper care. Note that the clinical health and behavioral well-being of animals used in research and teaching are guaranteed by an interlocking set of state and federal laws, e.g., the Animal Welfare Act of 1966 and FDA requirements and standards (found at 21 Code of Federal Regulations Part 58). Usually, two or more species (such as mice or rats) are tested because a drug may affect one differently from another. Such tests show whether a potential drug has toxic side effects and what its safety is at different doses. The results point the way for testing in humans and, much later, product labeling.

So far, research has aimed at discovering what a drug might do to the human body (called a drug's *pharmacodynamics*). Now, it must also find out what the human body might do

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to the drug (called a drug's *pharmacokinetics*). So, in early-stage human clinical studies (usually in a small number of healthy volunteers and called a Phase I study, see description below), scientists measure how much of a drug is absorbed into the bloodstream, how it is broken down chemically in the body, the toxicity of its breakdown products (metabolites), and how quickly the drug and its metabolites are excreted from the body. Sometimes, such tests find a metabolite that is more effective than the drug originally chosen for development. Such early-stage human testing sets the stage for later human clinical studies in patients who have the disease or condition that the drug is meant to treat.

The Wrong Road

More often than many scientists care to admit, they just have to give up when a drug is poorly absorbed, is unsafe, or simply does not work. The Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that only 5 in 5,000 compounds that enter preclinical testing make it to human testing, and only 1 of those 5 may be safe and effective enough to reach pharmacy shelves. Occasionally, a tenacious scientist keeps looking and finds a usable compound after others had given up. In other cases, compounds may be put aside because they failed to work on one disease, only to be taken off the shelf years later and found to work on another disease.

The Clinical Trial and FDA Regulatory Process

Overview of Human Clinical Trials

As described above, the process of drug development begins in the laboratory, with years of in vitro and in vivo animal experiments. These stages are known as preclinical research. If successful, then FDA approval is sought to begin clinical trials that involve humans—with later-stage trials involving subjects who have the disease or condition that is to be treated. A description of the various phases of clinical experimentation follows.

Phase I Clinical Trials

Phase I clinical trials, which typically last several months, are primarily designed to determine safe doses and administration methods (i.e., orally, intravenously, inhaled, etc.). These studies investigate how the body metabolizes the drug and side effects that may result from increasing the dosage.

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Phase II Clinical Trials

About two-thirds of drugs tested in Phase I continue to Phase II clinical trials. At this stage, the drug is tested for efficacy, i.e., how well it works for its intended purpose. In most Phase II trials, one group of volunteers may be given the experimental drug while another control group of volunteers will receive a placebo. Safety and effectiveness are examined in these trials. They do not give a final assessment of whether or not a particular drug will successfully treat an illness in the general population, although many patients may report experiencing some therapeutic benefits.

Phase III Clinical Trials

Phase III clinical trials are broken into two segments: Phase IIIa and Phase IIIb. Phase IIIa clinical trials test the drug with several hundred to several thousand subjects to verify efficacy and safety on a larger scale. Generally lasting two to three years, Phase IIIa focuses on regulatory issues and is conducted at a variety of investigative sites.

Once Phase IIIa is complete, the drug's sponsor submits all preclinical, pharmacologic, efficacy, and safety data to local regulatory agencies. Information on the drug's composition and plans for producing, packaging, and labeling are also included. The resulting regulatory review can take up to thirty months to complete, sometimes more, depending on the country and type of drug.

Meanwhile, Phase IIIb clinical trials begin. Involving a large number of patients, Phase IIIb focuses on issues such as cost-effectiveness and efficacy compared with approved drugs in the same therapeutic class or that are used to treat the same disease.

Phase III clinical trials are only performed on the fraction of drugs that demonstrated favorable profiles in earlier trials. Since these studies measure how well a drug works in a large number of people, this helps fine tune dosage amounts and procedures to ensure a drug's safety and effectiveness. For most drugs, Phase III clinical trials involve many health-care centers (i.e., multicenter clinical trials) and hundreds, perhaps even thousands, of patients in the U. S. and around the world. As such, the majority of the funds expended for clinical trials by sponsors are consumed during Phase III. Once these studies are all successfully completed, the FDA can be asked to approve the therapy for the marketplace.

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Phase IV Clinical Trials

After the product has received regulatory approval, Phase IV clinical trials begin. Phase IV trials examine the long-term safety and effectiveness of a previously approved drug. This postmarket phase can include testing for an expanded use, e.g., in pediatric patients.

Investigational New Drug Application

The FDA's Center for Drug Evaluation and Researcher (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens are all considered drugs. CDER is the largest of the FDA's six centers and employs a staff of about 2,900.

Current federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states to conduct clinical trials of the drug, it must seek an exemption from that legal requirement from the FDA. Submitting an investigational new drug application (IND) to CDER is the means through which the sponsor technically obtains this exemption from the FDA; *however*, its main purpose is to detail the data that provide documentation that it is indeed reasonable to proceed with certain human trials with the drug. In many ways, the IND is the result or culmination of a successful preclinical drug development program.

During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

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Generally, this includes data and information in three broad areas:

- *Animal pharmacology and toxicology studies*: Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans.
- *Manufacturing information:* Information pertaining to the composition, manufacture, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed as to ensure the company can adequately produce and supply consistent batches of the drug.
- *Clinical protocols and investigator information:* Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators to assess whether they are qualified to fulfill their clinical trial duties.

There are different types of INDs. Commercial INDs are applications that are submitted primarily by companies whose ultimate goal is to obtain marketing approval for a new product. However, there is another class of filings broadly known as *noncommercial INDs* or research INDs. The vast majority of INDs are, in fact, filed for noncommercial research. These types of INDs include investigator INDs, emergency-use INDs, and treatment INDs.

An investigator IND is submitted by a physician, who both initiates and conducts an investigation and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.

An emergency-use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND using normal IND submission procedures. It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.

A treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

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New Drug Application (NDA)

When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet the FDA's requirements for marketing approval, the sponsor submits a new drug application (NDA) to the FDA. The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, then the product may be marketed in the United States. For decades, the regulation and control of new drugs in the United States has been based on the NDA. In fact, since 1938 (the year that the FD&C Act was passed), every new drug has been the subject of an approved NDA before U.S. commercialization. The data gathered during the in vivo animal studies and human clinical trials of an IND become part of the NDA.

Abbreviated New Drug Application

An abbreviated new drug application contains data that, when submitted to CDER's Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. A generic drug product is a drug that is shown to be comparable or *bioequivalent* to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Generic drug applications are called abbreviated because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness, just scientific proof of bioequivalence. Once approved, a generic drug manufacturer can then market the generic drug product to provide a lower cost alternative to the American public.

Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). This act expedites the availability of less-costly generic drugs by permitting the FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative clinical trials. The same act permitted the brand-name companies to apply for up to five additional years of patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process (called p*atent term extension*). Brand-name drugs are subject to the same bioequivalence tests as generics upon reformulation.

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Note that all approved products, both innovator and generic, are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is also called the Orange Book after its original distinctive orange-colored hard-bound cover.

Regulation of Medical Devices

The FDA's Center for Devices and Radiological Health (CDRH) develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices; to promote quality in mammographic services; and to control unnecessary human exposure to potentially hazardous radiation and to ensure the safe, efficacious use of such radiation.

The basic framework governing the regulation of medical devices was established in 1976, via specific medical device-related amendments to the FD&C Act.

CDRH's Office of Device Evaluation is responsible for the program areas through which medical devices are evaluated or cleared for clinical trials and marketing.

Device Classification

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as *panels*. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device, i.e., Class I, II, and III.

The class to which the device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. If the device is classified as a Class I or a Class II device, and if it is not exempt, then a 510(k) will be required for marketing (see discussion below). All devices classified as exempt (from the requirement to submit a 510(k)) are subject to the limitations on device exemptions. Limitations of device exemptions are covered under 21 CFR Parts 862-892. For Class III devices, a premarket approval application (PMA) is usually required (see discussion below).

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Device classification depends on the intended use of the device and also upon indications for use. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea." Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product.

In addition, classification is risk-based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

Note that the baseline requirements of the FD&C Act apply to all medical devices: Class I, II, and III.

Premarket Notifications (510(k)s)

This process is somewhat analogous to a generic drug concept in that premarket notification is used to obtain marketing clearance for a device that is substantially equivalent in safety and effectiveness to another lawfully marketed device or to a standard recognized by the FDA when used for the same intended purpose (e.g., if there is no available lawfully marketed comparator device). At least ninety days before placing a medical device into commercial distribution, the registrant must submit a premarket notification to the FDA, commonly known as a 510(k) in reference to the relevant section of the FD&C Act. The exception to this is if the device is exempt from the 510(k) requirements of the FD&C Act by separate statute or FDA regulation.

In addition to other information concerning the device, e.g., a description of the device (called a 510(k) summary or a 510(k) statement), the 510(k) submitter must include information to substantiate that the device is *substantially equivalent* to a legally marketed device (that is not subject to premarket approval) or otherwise compared to an FDA standard for similarly used devices. Such information may include a summary of the safety information related to the device. A substantially equivalent device is marketed subject to the same regulatory controls as the device or standard to which it is found to be substantially equivalent. A device may not be marketed pursuant to a 510(k) until the submitter receives written clearance from the FDA; that is, a successful submission is said to have been cleared, rather than *approved*.

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Premarket Approval Applications

Under the FD&C Act and FDA regulations, a manufacturer or others must submit a PMA for FDA review and approval before marketing certain new Class III devices. Class III devices are those that support or sustain human life; are of substantial importance in preventing impairment of human health; or which present a potential, unreasonable risk of illness or injury; or are new and present unknown safety or effectiveness issues or risks, e.g., an artificial heart or a hip or knee implant. The PMA submitter must provide reasonable assurance that (1) the device is safe and effective for its intended use and (2) that it will be manufactured in accordance with current good manufacturing practices. As to item (1), the data is usually collected first from preclinical animal studies and then from human clinical trials. PMA clinical studies are akin to drug studies in their complexity and expense, but not their size, i.e., a Phase III device-related clinical trial usually involves a much smaller number of study subjects, e.g., approximately 200 or less.

As part of the review process, the FDA may present the PMA to an expert advisory panel for its recommendations. After obtaining the panel's recommendations, the FDA makes a determination to (1) approve the PMA, (2) deny it, or (3) request additional information. When the FDA either approves or denies the PMA, it must publish a notice in the Federal Register to inform the public of the decision and make available a summary of the safety and effectiveness data upon which the decision is based. This publicly available summary does not include proprietary data or confidential information submitted by the applicant.

PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made. For example, it may request changes to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the PMA regulation, changes that affect the safety or effectiveness of the device require that the FDA's PMA process be followed again. The FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology. Some PMA supplements can be as complex as the original application. Although the statutory timeframe is 180 days for PMA supplements, the FDA is committed to reviewing these in shorter timeframes and has reduced review timeframes through the use of real-time supplement process, thirty-day notices, and expedited reviews.

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Investigational Device Exemptions

Under the FD&C and FDA regulations, an individual, institution, or company can sponsor the clinical investigation of a medical device to establish its safety and effectiveness. Before conducting such a clinical trial, however, the sponsor must first obtain the approval of an investigational review board (IRB), as well as informed consent from the study subjects at the time of their enrollment in the study. If the investigational device study presents a significant risk to the subjects (e.g., the study involves the testing of a Class III device), then the sponsor must also obtain the FDA's approval of an investigational device exemption application (IDE) pursuant to 21 CFR Part 812. The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject informed-consent form, device labeling, cost of the device, and other matters related to the study (also see the previous PMA discussion). The FDA has thirty calendar days from the date of receipt of the application to approve or disapprove an IDE submission. In sum, in the case of Class III medical devices, a sponsor would first need to file an IDE to facilitate obtaining the clinical data necessary to later file a PMA.

IDE Amendments and Supplements

Although not provided for in the IDE regulations, all submissions related to an original IDE that has been submitted, but not approved, are referred to as *IDE amendments.* After an IDE is approved, related submissions are called *supplemental applications* under the regulations. Identification of IDE amendments enables the FDA to track each IDE from the time it is originally submitted until the time it is approved.

The IDE regulation requires the sponsor of an investigation of a significant risk or Class III device to submit a supplemental application for any of several specified reasons. For example, a sponsor must submit a supplement if there is a change in the investigational plan when such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. Supplemental applications also are required for the addition of investigational sites. This regulation also requires the submission of various reports, which are logged in as supplements to IDE applications. These include reports on unanticipated adverse effects of the device; recall and device disposition; failure to obtain informed consent; and annual progress reports, final reports, investigator lists, and other reports requested by FDA.

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Product Development Protocols

The 1976 medical device amendments to the FD&C Act allows for two product approval pathways for a Class III (significant risk) device: the PMA (as described above) or, with *prior* FDA permission, the notice of completion of a product development protocol (PDP). The PDP process is based upon early consultation between the sponsor and the FDA leading to a device development and testing plan acceptable to both parties. It minimizes the risk that the sponsor will unknowingly pursue (with the associated waste of capital and other resources) the development of a device that the FDA will not approve. The PDP plan incorporates four discrete stages of FDA review during the device design process: (1) a PDP summary outline; (2) an FDA/advisory panel review of the full PDP; (3) consideration and, where appropriate, preapproval of design modifications and protocol revisions made during execution of the PDP; and (4) action on the sponsors notice of completion of the PDP. FDA review of the PDP summary may take up to thirty days, the review of the full PDP may take up to 120 days, and the FDA must declare the PDP completed or not completed within ninety days of receiving the notice of completion. If the FDA finds that the notice of completion—together with other information previously submitted—shows that the requirements of the PDP have been met, then the FDA will declare the PDP complete.

Humanitarian Device Exemptions

A humanitarian use device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. A humanitarian device exemption (HDE) application is essentially the same as a PMA in both form and content but is exempt from the effectiveness requirement of a PMA. Even though the HDE is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose, the application must contain sufficient information for the FDA to determine, as required by statute, that the device does not pose an unreasonable or significant risk of illness or injury to patients and that the probable benefit to health outweighs the risk of injury or illness from its use. A HDE application must also contain information that will allow FDA to make the other determinations required by the FD&C Act. An approved HDE authorizes marketing of the HUD.

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Regulatory Process Relating to Biologics

The FDA's center for biologics evaluation and research (CBER) regulates biological products for human use under applicable federal laws, including the FD&C Act. Note that CBER's activities also encompass medical devices associated with blood collection and processing procedures as well as those associated with cellular therapies. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

CBER regulates an array of diverse and complex biological products (biologics), both investigational and licensed as *not drugs,* including:

- *Allergenics*: Patch tests used to diagnose the causes of contact dermatitis; extracts used to diagnose and treat rhinitis (hay fever), allergic sinusitis and conjunctivitis, and bee stings.
- *Blood*: Blood and blood components used for transfusion, such as red blood cells, plasma, and platelets; pharmaceutical products made from blood and used as clotting factors and immunoglobulins.
- *Devices*: Medical devices and tests used to safeguard blood, blood components, and cellular products from HIV, hepatitis, syphilis, and other infectious agents; reagents used to type blood; machines and related software used to collect blood and blood components.
- *Gene therapy*: Gene therapy products used to replace a person's faulty or missing genetic material, such as treatments for cancer, cystic fibrosis, heart disease, hemophilia, diabetes, and infectious diseases such as AIDS.
- *Human tissues and cellular products:* Human tissues used for transplantation, such as skin, tendons, ligaments, and cartilage; and cellular products, such as human stem cells and pancreatic islets, used to treat cancer, Parkinson's disease, hemophilia, anemia, diabetes, and other serious conditions.
- *Vaccines*: Vaccines used for the prevention of infectious diseases, such as mumps, measles, chicken pox, diphtheria, tetanus, influenza, hepatitis, smallpox, and anthrax; vaccines used to treat HIV and to treat or prevent non-infectious conditions, including various cancers.

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- *Xenotransplantation products:* Xenotransplantation products, such as live animal cells, tissues, or organs, used to treat human diseases such as liver failure and diabetes, where human materials are not always available.

Biological Products

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research and may be used to treat a variety of medical conditions for which no other treatments are available.

In contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized. Biologics, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs.

Biologics often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.

Biologics Approval Process

Biologics are approved for marketing under provisions of the Public Health Service Act (PHS Act). However, because many biologics also meet the definition of drugs under the FD&C Act, those that do are also subject to regulation under FD&C Act provisions that relate to drugs.

The PHS Act requires individuals or companies who manufacture biologics for introduction into interstate commerce to hold a license for the products. CBER issues these licenses. Biological products intended for veterinary use are regulated under a separate

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law, the Virus, Serum and Toxin Act, which is administered by the U. S. Department of Agriculture.

Licensing of biologic products under the PHS Act is very similar to the new drug approval process for human drugs. Following initial laboratory and animal testing, a biologic is studied in clinical trials in humans under a biologics-related investigational new drug application (IND). If the data generated by the studies demonstrate that the product is safe and effective for its intended use, then the data are submitted to CBER as part of a biologics license application (BLA) for review and approval for marketing. The BLA is essentially a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. That is, the BLA serves the same purpose for biological products as an NDA does for (nonbiologic) drugs.

After a BLA is approved for a biological product, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot (or production run) of the product before it is released for distribution. If the product is subject to official release by CBER, then the manufacturer submits samples of each lot of product to CBER together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. CBER may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, CBER conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biologics.

In Vitro Diagnostic Devices

In vitro diagnostics (IVDs) are medical devices that analyze human body fluids, such as blood or urine, to provide information for the diagnosis, prevention, or treatment of a disease. IVD manufacturers are required to follow the same regulatory procedures as are followed by other manufacturers of medical devices, e.g., submission of IDEs, 510(k)s, etc.

Clinical Laboratory Improvement Act of 1988

In addition to FDA regulation under the FD&C Act, IVD devices are also subject to the Clinical Laboratory Improvement Amendments of 1988. This law established quality standards for laboratory testing and an accreditation program for clinical laboratories.

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The requirements that apply vary according to the technical complexity in the testing process and risk of harm in reporting erroneous results. The regulations established three categories of testing on the basis of the complexity of the testing methodology: (1) waived tests, (2) tests of moderate complexity, and (3) tests of high complexity. Laboratories performing moderate- or high-complexity testing or both must meet requirements for proficiency testing, patient test management, quality control, quality assurance, and personnel. These specific requirements do not apply to tests in the waived category.

CDRH Office of In Vitro Diagnostic Device Evaluation and Safety

The CDRH's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) regulates all aspects of in-home and clinical laboratory IVDs. The OIVD was formed November 17, 2002, in order to consolidate all regulatory activities for IVDs. The OIVD has a dual charge to foster the rapid transfer of new IVDs into the marketplace while preventing marketing of unsafe or ineffective devices. To accomplish this, the OIVD combines the functions of all the offices within CDRH into one organizational unit for cradle-to-grave regulation of IVDs.

Combination Products

Combination products are those containing a combination of drugs, medical devices, and/or biologics that are physically, chemically, or otherwise combined, e.g., drug-eluting stents or drug-infused bone implants. Clinical trials for combination products are more comprehensive, costly, and complicated than those required for individual drugs, medical devices, or biologics as the individual properties of each component must be investigated, as well as the properties of the components when used in combination. The FDA's Office of Combination Products assigns an FDA center (i.e., CDER, CBER, or CDRH) to have primary jurisdiction over the review of combination products and also coordinates reviews involving more than one FDA center.

Medical Products that Incorporate Nanotechnologies

In August of 2006, the FDA formed a Nanotechnology Task Force (NTF) that was charged with determining regulatory approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials.

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The NTF continues to identify and recommend ways to address any knowledge or policy gaps that exist so as to better enable the FDA to evaluate possible adverse health effects from FDA-regulated products that use nanotechnology materials.

In 2007, the NTF released a report that recommended that the FDA consider developing guidance and taking other steps to address the benefits and risks of drugs and medical devices using nanotechnology.

Then Commissioner of the FDA Andrew von Eschenbach, M.D., endorsed the *NTF Report* and its recommendations: "Nanotechnology holds enormous potential for use in a vast array of products," he said. "Recognizing the emerging nature of this technology and its potential for rapid development, this report fosters the continued development of innovative, safe and effective FDA-regulated products that use nanotechnology materials."

The *FTR Report* stated that FDA experts believed that nanotechnology products presented and would continue to present challenges similar to those FDA faces for products of other emerging technologies; however, product safety and effectiveness profoundly changed as size went up or down within the nanoscale, thereby adding additional complexity to product reviews.

The *NTF Report* also stated that many of the nanotechnology products that the FDA would regulate would span the regulatory boundaries between drugs, medical devices, and biologics and that these, then, would likely be regulated under the rules established for combination products (see previous discussion).

Summary and Exhibits

The field of regulatory oversight of pharmaceuticals, medical devices, and biological products is vast and complex. By design, this chapter has only provided the most basic of information. If a technology transfer professional finds himself or herself in a situation in which FDA oversight may be triggered, e.g., a spin-off wants to begin in vivo testing of a new medical device, then the author strongly recommends contacting a regulatory professional for advice.

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The appended exhibits are meant to provide additional educational information to assist the technology transfer profession in increasing his or her familiarity with the subject matter of this chapter. Exhibit A provides an stepwise listing of the drug review process, Exhibit B provides a description of the three regulatory classes of medical devices, Exhibit C provides a glossary of key terms and abbreviations, and Exhibit D provides additional sources of information. Note that the best starting point is the FDA's homepage (www.fda.gov).

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Exhibit A: Drug Review Steps

1. Preclinical in vitro and in vivo testing.
2. An investigational new drug application (IND) outlines what the sponsor of a new drug proposes for human testing in clinical trials.
3. Phase I studies (typically involve twenty to eighty people): In general, early-stage trials include several Phase I studies: (1) a single ascending dose study (or first dose in human study), (2) a multiple ascending dose study, (3) possible drug and/or food interaction studies, and (4) a proof-of-concept study, which is sometimes called a Phase I/II or Phase IIa study. The principal goals of early Phase I studies in human volunteers are usually safety, tolerance, and dose escalation, often to define the maximal tolerated dose.
4. Phase II studies typically involve a few dozen to about 300 people and are intended to preliminarily address efficacy.
5. Phase IIIa/Phase IIIb studies typically involve several hundred to about 3,000 people and are intended to address safety and efficacy under conditions mirroring how the drug will be used commercially.
6. The pre-NDA period, just before a new drug application (NDA) is submitted, is a common time for the FDA and drug sponsors to meet.
7. Submission of an NDA is the formal step asking the FDA to consider a drug for marketing approval.
8. After an NDA is received, the FDA has sixty days to decide whether to file it so it can be reviewed.
9. If the FDA files the NDA, then an FDA review team is assigned to evaluate the sponsor's research on the drug's safety and effectiveness.
10. The FDA reviews information that goes on a drug's professional labeling (information on how to use the drug). Such information is found primarily in what is termed the package insert.
11. The FDA inspects the facilities where the drug will be manufactured as part of the approval process.
12. FDA reviewers will approve the application or find it either approvable or not approvable.

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Exhibit B: Regulatory Classes of Medical Devices

Medical devices are divided into three classes, each with different regulatory requirements based on risk stratification as outlined below.

Class	Risk	Regulatory Requirements
Class I	Present minimal potential harm to the user.	Mostly exempt from testing. Does not require regulatory approval.
Class II	More complex, higher risk that are not life-sustaining.	Regulatory clearance required: 510(k). Based on demonstration of substantial equivalence to marketed devices or recognized FDA standards for devices used for a substantially equivalent (i.e., a standard-conforming purpose).
Class III	Support or sustain human life.	Regulatory approval required: premarket approval (PMA). Based on the results of clinical studies.

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Exhibit C: Select Glossary and Common Abbreviations

adverse event (AE): Any untoward medical occurrence in a patient or clinical-investigation subject administrated a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

biologicals license application (BLA): A set of documents submitted to the FDA to gain authorization to commercially market a new biological product for use in humans.

blinding/masking: A procedure in which one or more parties to a clinical trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the study subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor(s), and, in some cases, data analyst(s), being unaware of the treatment assignment(s).

case report form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the study sponsor on each study subject.

Center for Biologics Evaluation and Research (CBER): CBER's job is to ensure that biologics are safe and effective. CBER has a staff of about 950.

Center for Drug Evaluation and Research (CDER): CDER's job is to ensure that drugs are safe and effective. CDER is the largest of the FDA's six centers, with a staff of about 2,900. It has responsibility for both prescription and over-the-counter drugs.

clinically significant: Referring to a patient test result that is clinically important and should be brought to the attention of the patient's physician for decisions regarding treatment and/or evaluation.

compliance (in relation to clinical trials): Adherence to all the clinical-trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

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contract research organization (CRO): A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of the sponsor's study-related duties and functions.

clinical trial/study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product or products; and/or to identify any adverse reactions to an investigational product or products; and/or to study adsorption, distribution, metabolism, and excretion of an investigation's product or products with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

establishment inspection report (EIR): FDA inspector's letter documenting an inspection visit and his or her observation(s) regarding it that is sent to the principal investigator when an FDA Form 483 is not issued.

FDA Form 1572 (statement of investigator): A legal agreement between the FDA and the clinical investigator that must be signed prior to beginning a research study involving an investigational new drug. Form 1572 outlines the investigator's responsibilities for the study.

FDA Form 482: Notice of FDA inspection to assess study compliance with appropriate regulations and guidelines to determine whether the data submitted are accurate.

FDA Form 483 (notice of FDA inspectional observations): A list of inspectional observations and discrepancies found in the investigation at the conclusion of the FDA inspection of a clinical investigational site and followed by an exit interview to review findings. The principal investigator will be given a list of the findings.

FDA Guidelines: A set of recommendations that governs the FDA's interpretation of federal regulations.

federal wide assurance (FWA): A promise by institutions to federal agencies to protect research subjects participating in research.

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510(k): A 510(k) is a premarket submission made to the FDA to demonstrate that a medical device to be marketed is at least as safe and effective as, that is, substantially equivalent to, a legally marketed device that is not subject to a PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. 510(k) refers to Section 510(k) of the FD&C Act.

good clinical practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the right, integrity, and confidentiality of study patients are protected. Most often meaning the actual and documented compliance with the FDA's good clinical practice guidelines as specified in Title 21 of the Code of Federal Regulations (especially Part 312) and/or the ICH Harmonised Tripartite Guideline for Good Clinical Practice. Further, compliance with the regulations governing the protection of human subjects (45 CFR Part 46) should also be considered integral to good clinical practice.

good laboratory practice (GLP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of preclinical studies that provides assurance that the data and reported results are credible and accurate. Most often meaning the actual and documented compliance with the FDA's good laboratory practice guidelines as specified in Title 21, Part 58, of the Code of Federal Regulations.

human subject: Any individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A human subject may also be interchangeably called a *research patient* or a *study patient* or a *study subject* or a *trial subject* or a *research subject.*

Institutional Animal Care and Use Committee (IACUC, usually pronounced EYE-ah-cuck): A constituted body whose role is to protect the welfare of animals used in research.

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investigational device exemption (IDE): An IDE refers to the regulations specified in Title 21, Part 812, of the Code of Federal Regulations. An approved IDE means that the IRB (and FDA for significant-risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.

investigational new drug application (IND): A set of documents submitted to the FDA to gain authorization to test a new drug.

informed consent: A process by which a potential trial subject voluntarily confirms his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to his or her decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form (ICF).

institution: Any public or private entity or agency (including federal, state, or other agencies).

investigational (or institutional) review board (IRB): An independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a clinical trial by, among other things, reviewing, approving, and providing continued review of the clinical trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the clinical trial subjects.

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Globally recognized guidelines regarding the conduct of a clinical trial recognized by the FDA.

investigational drug: A drug permitted by the FDA to be tested on humans, but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing. An investigational drug is also referred to as a test article.

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investigator: An individual who conducts a clinical investigation.

investigator drug brochure (IDB or IB): Material and documents prepared by a sponsor that summarizes the preclinical (animal studies) and clinical results of trials using the investigational drug.

medical ethics committee: An entity made up of institutional officials, physicians, legal advisers, and patient advocates whose role it is to ensure that all interactions with patients are conducted in an ethical manner.

minimal risk: The probability and magnitude of harm or discomfort anticipated in the research is not greater in and of itself above that is ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

new drug application (NDA): A request for FDA approval to market a new drug.

open-label drug: A study drug or drugs whose administration in a research study is not blinded or hidden from the investigator and/or patient.

patient confidentiality: The legal concept that information provided by the study patient or about the study patient will not be disclosed to others without the patient's permission or knowledge.

premarket approval (PMA): Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III medical devices are those that support or sustain human life, that are of substantial importance in preventing impairment of human health, or that present a potential, unreasonable risk of illness or injury.

premarket notification (PMN): See definition of 510(k) above.

principal investigator (PI): The individual conducting the clinical investigation as indicated on the FDA Form 1572. This individual agrees to take ultimate responsibility for the conduct of the clinical trial.

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protocol: A document that describes the objective(s), design, methodology, statistical considerations, organization of a trial, and the background and rationale for the trial.

randomization: The process of assigning clinical trial subjects to treatment or control groups using an element of chance to determine the assignments to reduce bias.

regulatory compliance file: Each clinical study should have a regulatory compliance file associated with it. At a minimum, it should contain:

(a) stamped, approved, informed consent form;
(b) letter from IRB, dated and signed, indicating approval of clinical study;
(c) IRB membership list;
(d) signed protocol approval signature page;
(e) completed FDA Form 1572;
(f) CVs for all individuals listed on the FDA Form 1572;
(g) financial disclosure forms for all individuals listed the FDA Form 1572;
(h) verification of the study site's FWA;
(i) evidence that a study site selection visit was performed for any study site not used within the past six to twelve months (may depend on the standard-operating-procedures (SOPs) of the sponsor); and
(j) evidence that a study site initiation visit took place.

research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to general knowledge. Activities that meet this definition arguably constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes.

research patient identity: Identifying features, such as name or medical record number, that must be masked or otherwise hidden on copies of any source document given to representatives of any non-institutional entity. It is highly recommended that source documents that identify research patients by name, Social Security number, medical record number, etc., be stored separately from the associated case report form.

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serious adverse event (SAE): An untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent significant disability/incapacity, or is a congenital anomaly/birth defect.

significant risk device: A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject.

site: The institution or facility where research is conducted.

source document: The record in which data concerning a research patient is first captured. Examples: original documents, data, records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the trial).

sponsor: The entity (individual, company, institution, or organization) that holds the IND or which otherwise takes responsibility for the initiation, management, and/or financing of a clinical trial.

standard operating procedures (SOPs): A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human patients participating in research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles or a statement formulated by the institution itself.

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study drug disposition record: Documents that record adequate disposition of the study drug, including dates, quantity, and use by study patients. If the investigation is terminated, suspended, or discontinued or completed, then the PI is usually required to return the unused supplies of the study drug to the sponsor or otherwise provide for disposition of the unused supplies of the study drug.

study records: Two basic types of records kept regarding clinical investigation: (1) case history documentation and (2) the study protocol and related documents. Case history documents record all observations and data pertinent to the research study about each research subject treated with the test article or enrolled as a control. Study protocol documents consist of correspondence sent to or received from the study sponsor and its monitor(s), including any protocol modifications and records of IRB approval and of other communications/actions pertaining to the research study.

trial site: The location(s) where trial-related activities are actually conducted.

vulnerable subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, or nursing students; subordinate hospital and laboratory personnel; employees of the pharmaceutical industry; members of the armed forces; and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving informed consent.

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Exhibit D: Useful Citations and Web Sites

FDA's home page: www.fda.gov

Federal Food, Drug and Cosmetic Act: 21 United States Code (U.S.C.) Sections 301-399
The FDA's portion of the Code of Federal Regulations (CFR) interprets the Federal Food, Drug, and Cosmetic Act and related statutes. Title 21 of the CFR contains most of the regulations pertaining to food and drugs. Key parts include:

- Part 50 covers the protection of human subjects.
- Part 54 covers financial disclosures for clinical investigators. This regulation is intended to ensure that financial interests and arrangements of clinical investigators that could affect reliability of data submitted to FDA in support of product marketing are identified and disclosed by the sponsor.
- Part 56 covers institutional review boards (IRB).
- Part 58 covers good laboratory practice (GLP) for nonclinical (animal) studies.
- Part 312 covers investigational new drug application (IND) regulations, including regulations for clinical investigators.

Title 45 (Public Welfare, Department of Health and Human Services) CFR Part 46 - Protection of Human Subjects

Advanced Medical Technology Association (AdvaMed): www.advamed.org

Association of Medical Diagnostics Manufacturers (AMDM): www.amdm.org

European Medicines Agency (EMEA): www.emea.eu.int/Inspections/GCPgeneral.html

International Conference on Harmonisation: www.ich.org

Medical Device Manufacturers Association (MDMA): www.medicaldevices.org

Model Agreements and Guidelines International (MAGI): www.magiworld.org

Pharmaceutical Research and Manufacturers of America (PhRMA): www.phrma.org

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Hidden Technology Transfer

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Technology transfer occurs via myriad vehicles, not all of which are immediately apparent. Put differently, technology transfer is not solely effected via a traditional license agreement developed by an office of technology transfer (OTT). It is the goal of this chapter to present contemporary examples of technology transfer that occur at most academic research institutes but often outside of the OTT's purview. By understanding the different mechanisms and how and when they are used, the mechanisms can become tools used by the OTT to increase technology commercialization.

Put differently, it is insufficient to assume the OTT possesses the unfettered ability to commercialize any technology disclosed to it. The OTT must understand the various legal provisions within research contracts, material transfer agreements, and clinical trial agreements that can masquerade under nonassuming titles. Not doing so can and does lead to overlapping obligations to third parties, which then can open the institute up to untoward legal liabilities. It is likely that in your institute, more than one office or department is responsible for the vehicles by which technology can and is transferred. Working with the responsible entities can be a good place to start weaving a coordinated institutewide support network for technology transfer. Before you reach out to your colleagues in the office of sponsored programs, let's review some basics in hidden technology transfer using provisions extracted from actual agreements.

First, let us establish and agree that the transfer of technology, in its most generic definition, requires having legal rights in or to an intangible asset (e.g., intellectual property). Further, this chapter assumes the institute is the owner of those legal rights in and to the subject intellectual property. It is also assumed that an infrastructure exists at the institute that develops and manages each of the applicable instruments referred to in this chapter. A note of caution when reading the exemplary provisions provided below—in practice, intellectual property provisions should be taken in the context of an entire

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contract. Specifically, the scope of definitions for salient terms (such as invention, data, results, and personnel) must be understood to evaluate fully the impact of any hidden technology transfer.

License Agreements

The OTT is often tasked with the exclusive responsibility to negotiate agreements in which the institute grants a license to one or more existing assets. Therefore, the OTT has direct control over the terms and conditions of such grant of rights. This level of transparency to the OTT (e.g., all of the obligations in the license agreement are known to the OTT) is the baseline from which the transparency to the OTT of the obligations made in the other instruments should be compared and sought.

Material Transfer Agreement (MTA)

The MTA has become the bane of the nearly every stakeholder's existence, with good reason—they are predictably unpredictable in scope, breadth, and depth. Currently, the degree to which rights to resultant assets transferred under an MTA can range from none, such as the uniform biological material transfer agreement (UBMTA)[1] to exclusive licenses to full assignment of rights to prospective intellectual property. It is essential that the OTT know about and understand the implications of these agreements before setting forth to implement a commercialization strategy for a resultant asset.

Provisions found in MTAs that impact an OTT's ability to commercialize a resultant asset come in different shapes and sizes. Examples are given that exemplify concepts the adroit OTT should establish either exist or do not prior to taking on commercialization of intellectual property (IP).

Example 1: Prospective Assignment/License and Continuing Commitment of Resources

> *All Inventions that are developed during the course of the Research and that either solely relate to improvements, modifications, or new uses of the Material, or that are directly related to or directly derived from the Material, (for example, antibodies, tissue or cells, cell lines, genes, proteins, diagnostics, assays, new therapeutic indications, information concerning the crystal struc-*

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ture of the Material, and new methods of manufacture and administration of therapeutics developed from Investigator's or Recipient's use of the Material) will be solely owned by Provider ("Provider Inventions").

To the extent that Recipient and/or Investigator are statutorily prohibited from assigning the Provider Inventions to Provider, Recipient and/or Investigator hereby grant to Provider an exclusive, worldwide, royalty-free license, with the right to grant sublicenses, to make, use, sell, have made, have sold, offer for sale, and import all Provider Inventions and otherwise exploit all IP rights therein, subject only to the rights of the U.S. Government in federally-funded Inventions.

Upon Provider's request and at Provider's expense, Recipient and/or Investigator shall take such actions as Provider deems necessary or appropriate to obtain patent or other proprietary protection in Provider's name with respect to any of the Provider Inventions.

In this example from an MTA, the institution is left with not only no (commercialization) rights to resultant assets, but also an obligation to provide cooperative services to the provider. The former (e.g., exclusive licensing prospectively) can and does occur. The reasons often cited for accepting this position is the institute has placed a higher benefit on the performance of research than the protection of an asset, which, incidentally, cannot be created absent the original material.

The latter (e.g., provision of services) can be straightforward or can be tricky. While giving the provider assurance it will receive cooperation in protecting provider inventions, this particular provision is without clear metes and bounds on what actions the provider can require the institute to take.

For example, this obligation is devoid of a reasonableness standard. Does this provision also require doing what the provider deems appropriate in enforcing the IP? Is it limited to executing formal documents required by national laws in obtaining patent protection?

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What is your institution's policy on cooperating with a third party under such circumstances, e.g., research undertaken that was aided by an MTA? Most institutions have difficulty staffing sufficient effort to protect its own IP and would not be keen on being legally required to subsidize protection of another party's IP. Ideally, the OTT and the office responsible for MTAs know and embrace the same policies.

Example 2: Freedom-to-Operate License

> *For any invention or discovery (including without limitation a Modification) created or first reduced to practice as a result of Recipient's use of the Material that would itself be infringed by the practicing of Provider's patent rights in or to the Material, Recipient grants Provider a non-exclusive, royalty-free, sub-licensable license* ***for all purposes****. Provider agrees to notify Recipient after grant of any such sub-license to a third party.*

An automatic grant of a license of this nature may be employed when the provider of the material has associated patent rights and is capping any liability that it may be exposed to as a result of the recipient using the original material. The goal of this license is to permit the provider freedom to operate using its own material. Because it is rarely the goal of an academic research institute to usurp development of another's assets, this license is often granted to avoid inadvertent development of IP that does just that. This type of license grant is not aimed at permitting the provider to develop the recipient's resultant inventions per se.

Therefore, the institution remains in a position to commercialize the resultant asset, subject to the right granted to the provider under this provision. Such a license grant could be requested by any entity sharing proprietary materials, including public or nonprofit organizations such as research institutes. In the case in which the research institute is the provider, the license customarily reads (in lieu of the underlined text) "for research and education purposes."

Another mechanism by which an MTA can change the disposition of resultant assets is if the material is used in a project or an experiment not specifically permitted under the MTA.

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Example 3: Consequences of Unauthorized Use

> *If Recipient breaches this obligation, then Recipient agrees that any intellectual property rights or other legal rights in any work product developed or discovered in the course of such prohibited research shall be automatically assigned to Provider notwithstanding any other provision of this Agreement.*

The contract provision of example 3 addresses consequences of use of the material outside the agreed-upon scope of research. This provision is often embodied in MTAs and is nearly always rendered moot by the investigator's compliance with the limitations on the use of the material. Nonetheless, the transfer of rights to resultant assets from the institution to the provider make it relevant. If only to rule out its applicability, the OTT should determine if such a legal obligation applies to a disclosed invention at the outset of disclosure. To do so, simply ask the investigator working under the MTA about the full use of the material.

Sponsored Research Agreements

Research is one certain path to innovation, and research requires resources. The vehicles employed by research institutes to transfer the needed resources to drive innovation address commercialization of any resultant IP. The resources are often financial but can also include equipment, data sets, a visiting scientist, etc. In order to chart an informed commercialization strategy for any invention, an effective OTT official should be well-versed in its institute's policies on acceptable contract provisions regarding the disposition of IP in all manner of research agreements.

Because a lack of standardization exists across the full spectrum of research agreements, the impact of the provisions on technology transfer vary. Two key varying factors are the type of sponsor (e.g., nonprofit, government agency, for-profit) and/or the facts surrounding the research itself (i.e., investigator-initiated, translational, fee for service, etc.). This section is organized to highlight provisions common under a specific set of circumstances that affect the commercialization of an institution's IP.

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Federal Funding Agency

To the extent use of the word *hidden* in the title of this chapter implies *secret* or *covert*, this section should dispel that connotation. There is little secret about the technology commercialization intentions of the U.S. government. United States law and regulations applicable to IP funded in whole or in part by the U.S. government includes without limitation 35 U.S.C. §200 et seq., 15 U.S.C. §3710a, and 37 C.F.R. Part 401. This statute is referred to affectionately by the technology transfer community as the Bayh-Dole Act. By virtue of the existence of the OTT, your institute has erected the infrastructure to implement and comply with the obligations under the Bayh-Dole Act. Nonetheless, a complete and comprehensive command of the Bayh-Dole Act is essential in the training of any and all OTT officials.

With respect to inventions resulting from a project supported by federal funding, the Bayh-Dole Act governs the disposition of the rights to that invention. However, from time to time, a federal agency may amend certain provisions (or implementing guidelines) to support specific programmatic goals. One such program can be found at the National Cancer Institute (NCI). This program requires recipient institutes to accept the following obligation before the creation of any subject inventions.

Example 4: Nontraditional License Associated with a Federal Grant

> *Institution agrees to grant to Provider: (i) a paid-up, nonexclusive, non-transferable, royalty-free, world-wide license to all Recipient Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, or co-exclusive if applicable, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Recipient Inventions on terms to be negotiated in good faith by Provider and Recipient.*
>
> *Provider shall notify Recipient, in writing, of its interest in obtaining an exclusive license to any Recipient Invention within six (6) months of Provider's receipt of notice of such Recipient Invention(s). In the event Provider fails to so notify Recipient, or elects not obtain an exclusive license, then Provider's option shall expire with respect to such Recipient Invention, and Recipient will be free to dispose of its interest in such Recipient Invention in accordance*

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> *with Recipient's policies. If Recipient and Provider fail to reach agreement within ninety (90) days, (or such additional period as Provider and Recipient may agree) on terms for an exclusive license for a particular Recipient Invention, then for a period of six (6) months thereafter Recipient shall not offer to license the Recipient Invention to any third party on materially better terms than those last offered to Provider without first offering such terms to Provider, in which case Provider shall have a period of thirty (30) days in which to accept or reject the offer.*

Note, the provider is not the U.S. government or NCI, but rather a third party with whom the NCI has a formal agreement. Because, in this case, the success of the NCI program relies on access to proprietary materials obtained from for-profit entities, NCI procured those materials, and in doing so, reasoned the value of further immediate research with these materials justified the deviations in the IP from the standard arrangements with grant recipients. This value proposition is not unlike the decision-making process institutes use on a case-by-case basis to transfer its own proprietary materials (see the "Material Transfer Agreement" section). In fact, this provision offers the OTT an example of an alternative arrangement that may be useful for its own purposes.

The provision can be dissected into the following parts: (i) perpetual license for research purposes, (ii) first option to exclusively license for all purposes or first option to co-exclusively license for all purposes, (iii) two-way reporting, and (iv) a six-month right of first refusal. One or some combination of these parts may be useful in breaking in impasse in a negotiation with a licensee that also wishes to support research of the licensed invention.

Private, Nonprofit, and Charitable Organizations (Foundations)

Foundations are nonprofit organizations that exist to support efforts to educate, advocate and impact the course of a specific interest, such as a disease, a policy, or a convention. To achieve its mission, a foundation may sponsor research that offers a potential solution or generates evidence to answer an unanswered question or generally advances the state of affairs for its specific interest. While the foundations that sponsor basic research are often not in the business of technology commercialization per se, intellectual property created with foundation funding often must be used in a manner to support the foundation's mission.

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To this end, foundations approach the business development of IP in an altruistic manner guided chiefly by ensuring all who so desire have ready access to the resultant assets, which include intellectual property, data, and results. Types of commercialization requirements that may be incorporated into such research agreements include, assuming the institute has an IP policy:

- *Reporting requirements:* (i) of any applicable disclosure of an invention, (ii) of published manuscripts and abstracts, (iii) of commercialization activity including execution (and copies thereof) of applicable licenses, (iv) of patent protection activities, and (v) of any decision to discontinue commercialization activities.
- *Revenue sharing:* At a level that may be (i) a precisely established revenue-sharing structure (i.e., 10 percent of revenue), (ii) established at the time of invention based on the relative contributions of other parties involved in the making of the invention, (iii) established at the time of first sale based on the relative amount of total research and development dollars invested, and/or (iii) some precise percent (i.e., 200 percent) of the amount of the applicable grant.
- *Assignment:* Foundations may require assignment of the resultant asset if (i) any invention that results from the sponsored research, (ii) the recipient institute discontinues support of subject intellectual property, or (iii) the recipient institute materially breaches certain obligations with respect to commercialization of a resultant asset.
- *Commitment to commercialization:* The recipient institute represents that any business arrangements established directed to resultant assets will support and enable the mission of the sponsoring foundation.
- *Compulsory licensing:* A mandate for the recipient institute to license to a particular party or under a particular set of circumstances may be issued in the research agreement. Any evaluation by the OTT of an invention subject to compulsory licensing should consider the potential impact of such provisions on securing a licensee.
- *Grant of license:* An automatic grant of license to the sponsoring foundation to enjoy for use to support its mission. In this case as in the above, any commercialization strategy developed by the OTT for a resultant asset should consider the potential impact of reserving rights for the sponsoring foundation.

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For-Profit Organizations (Corporate)

The interest of a for-profit entity funding research at an academic institute of higher learning is wholly in juxtaposition to the interest of an academic investigator performing research. As a consequence, these research agreements present an arsenal of technology transfer opportunities but solely to that of the sponsoring for-profit entity. The effective OTT official can learn from these tactics but at a minimum needs to fully appreciate their relevance to any invention he or she may be attempting to commercialize.

Here, it is useful to segregate by the type of research proposed. For example, one type may be investigator-initiated in which an investigator submits a proposal to the for-profit with the intent of obtaining funding to carry out the proposed work (Example 5). Another type may be of the translational research ilk. In this case, the for-profit may have contacted the investigator and wishes for he or she to validate its own test product (Example 6). Yet, in another case, an investigator and a representative of a for-profit have synergistic interest and wish to collaborate to explore in related but unexplored waters (Example 7).

One can imagine that in each of these fact patterns, the nature of any agreement memorializing the different relationships would also, in turn, tackle IP differently.

Investigator-Initiated Research Funded by a Corporation

The commercialization of intellectual property arising under Example 5 should support the performance and continuance of the research project, which was the original idea of the investigator. However, absent resources to perform the work, the idea remains intangible in its purest form. Therefore, research agreements often offer the for-profit sponsor an option to license any resultant IP. If the option is directed to obtaining an exclusive license, then an automatic grant of a nonexclusive license to the for-profit for research and development purposes, which survives expiry of the option, may also be granted (similar to the approach used in Example 4). One example of contract language embodying a business arrangement under Example 5 is provided.

Example 5. Corporate Funded Investigator-Initiated Research

1. *INSTITUTE shall have sole and exclusive ownership rights to all Inventions and all Results arising out of the Research, subject only to Sponsor's option rights under this Agreement.*

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2. *INSTITUTE shall notify Sponsor, promptly and in writing, of any Invention which is disclosed to INSTITUTE. Sponsor shall treat as confidential and not disclose to any third party the contents of any notice provided to it by INSTITUTE, and shall not use any such information for any purpose other than to exercise its rights under this Agreement.*

2.1 *In consideration for the funding provided by Sponsor under this Agreement, INSTITUTE grants to Sponsor, and Sponsor accepts from INSTITUTE, with respect to each Invention, an option to negotiate a non-exclusive or exclusive license under Patent Rights claiming that Invention to develop, make, have made, use, market, offer for sale, sell, and import products in the field of _____ (an "Option");* provided, however, *that Sponsor's rights to the Option shall be subject to Federal Patent Policy [OPTIONAL: and the rights of a third party which collaborates on or sponsors the research at INSTITUTE which results in the Invention];* and provided further *that INSTITUTE may refuse to agree to grant an exclusive license if the relevant Invention relates to a research tool (as described in* NIH Principles and Guidelines with Respect to Sharing Biomedical Trial Resources). *Sponsor may only exercise the Option if: (a) there are no uncured defaults or breaches of this Agreement or any other agreement between Sponsor and INSTITUTE at the time of exercise of the Option; (b) Sponsor timely exercises the Option in writing; [OPTIONAL: and (c) Sponsor pays Patent Expenses in accordance with this Agreement].*

3. *If Sponsor elects to exercise an Option, it must do so by written notice to INSTITUTE during the period commencing upon the date on which Sponsor receives INSTITUTE's notice of that Invention and ending sixty (60) days thereafter (the "Option Term"). If Sponsor duly exercises the Option, INSTITUTE and Sponsor shall negotiate in good faith the terms of a master license agreement during the period commencing upon the date on which INSTITUTE receives the notice and ending ninety (90) days thereafter (or such longer period as the parties may mutually agree) (the "Negotiation Period").*

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Translational Research Funded by a Corporation

In Example 6, the for-profit entity is providing one or more existing assets to the investigator as well as financial resources. It is unlikely a rational-minded businessperson would do so, if in doing so, the business would be exposed to uncapped legal or business liability. Because research institutes are often bastions of unique and specialized expertise, a for-profit may find it cost effective to pay the institute to perform certain development work. Often, the opportunity to be first to publish on a new product, among other things, incentivizes the investigator to participate in this nature of collaboration. Moreover, the for-profit obtains the benefit of the acclaimed reputation of the investigator and/or institute for either product validation, product improvement, or both. The validation or product development opportunity offered under this scenario is reflected in research agreements drawn to such scenarios.

To do that effectively, the research agreement typically sets clear boundaries between existing assets and those created under the research agreement. The latter is usually transferred exclusively (either by assignment or by grant of an exclusive license) to the for-profit sponsor, which may include inventions as well as know-how, results, materials, etc. Alternatively, rights in and to an asset created under such research agreement may be designated as jointly owned between the parties. Another alternative business structure can include a two-pronged approach: (i) for-profit ownership of the resultant assets that arise under a specific set of circumstances (e.g., those that would be deemed to have been enabled by the sponsor's business) and (ii) institute ownership of assets that fall outside those defined. An example of the latter follows.

Example 6: Translational Research

> *The Parties agree that any Invention made or developed by INSTITUTE or the Principal Investigator, investigator or any employee, agent or independent contractor of INSTITUTE during the term of this Agreement which arises directly from the Sponsor's Confidential Information disclosed to INSTITUTE pursuant to this Agreement, or which use or modify (i) materials provided to INSTITUTE or the Principal Investigator by Sponsor or (ii) data emanating from the direct performance of the work in accordance with Appendix A shall be*

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> *owned solely by Sponsor ("Sponsor´s Inventions"). INSTITUTE and the Principal Investigator hereby assign to Sponsor all right, title and interest in and to all Sponsor's Inventions and shall cooperate in the filing and prosecution of patent applications and take all necessary or appropriate actions to assist the Sponsor in obtaining patent or other proprietary protection for Sponsor's Inventions. In particular INSTITUTE and the Principal Investigator shall not publish Sponsor´s Invention or parts of it till the Sponsor will have applied for an industrial property right. Sponsor shall reimburse INSTITUTE for any reasonable expenses incurred at Sponsor´s request to secure title or legal protection for any Sponsor's Invention.*

In most cases of an institute making an assignment of rights to intellectual property, a grant-back license to the institute for research and education is made. Such a grant is often required under applicable institute policies, as it enables the institute to meet its goals and mission. Although these grant-back licenses can be very straightforward, an example of a detailed grant-back provision follows.

Example 8: Grant-Back License to Institute

> *Sponsor grants to INSTITUTE a non-exclusive, royalty-free, irrevocable license to all data, results and IP for research, scholarly use, teaching, education, patient care incidental to the foregoing ("Non-Commercial Uses") and the right to sublicense to a government agency; nonprofit university or other educational institution; organization of the type described in §501(c)(3) of the Internal Revenue Code; scientific or educational organization qualified under a state nonprofit organization statute; or a foreign equivalent of the foregoing (each a "Non-Commercial Organization") solely for Non-Commercial Uses.*

Collaborative Research with a Corporation

In the scenario of Example 7, the OTT has a responsibility to understand if not participate in the discussions establishing a collaborative agreement that is a win-win for all involved. By this, it is meant, each party is poised to meet its overarching mission and specific goals

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of the collaboration. To do this effectively, each party must articulate its goals at the outset of any negotiation. The OTT, particularly if it is not directly responsible for negotiating such collaborative research agreements, should use this early intervention as an opportunity to inform the goals of collaboration on behalf of its institute. The commercialization infrastructure should reflect the collaborative nature of the relationship. For example, either joint ownership or cross-licensing of resultant intellectual property, data, and/or results can be one approach to achieve equity with respect to IP.

Because the reality is that interests change over time, the collaborative research agreement should contemplate what happens to commercialization efforts, whether under way or not, at discontinuance by either party. In Example 6, the institute would not be in a strong position to pursue commercialization efforts on its own (even via licensing of its own IP) if the for-profit discontinued support. However, in Example 7, either party could plausibly be in a position to continue the project with a different research partner. This is yet another opportunity for the OTT to inform the institute's business decisions.

Services Agreements

The last vehicle addressed is the services agreement. The research suitable for a services agreement is different from the scenario of Example 7 in that often the institute's participation is limited to carrying out a standard methodology, with little to no analysis applied, and using the specialized know-how of the investigator. The performance of such service is unlikely to yield a publication or be used to support a basic research grant for a specific research program because the for-profit may provide little context to understand the impact of any data. For example, the for-profit may provide only unidentified samples thereby limiting any analysis to the discreet data generated and to the formation of causative or correlative results. These types of services are often provided by institutes having a dedicated lab (often called a core) that carries out these standard services and can even be associated with standard rates or a fee schedule. In this case, any resultant intellectual property is likely assigned to the sponsor of the services. A straightforward example of the IP provision from a service agreement follows.

Example 9. Fee-for-Service/Development for a Corporation

> *Any information, invention or discovery, innovation, suggestion, idea, communication and report (whether patentable or not) (collectively "Invention"),*

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> *conceived, first reduced to practice, made or developed by INSTITUTE or the Principal Investigator in the course of performing the scope of work described in Appendix __, other than Sponsor's Inventions (as defined below), shall be owned by Sponsor.*

The OTT may wish to establish an inventory of the investigators and/or the core services at its institute that perform work under service agreements with any frequency. Aside from helping evaluate disclosed technologies, this information could give the OTT a comprehensive landscape of its institute's offerings to support more collaboration and in turn aid marketing efforts externally.

Conclusion

It is hoped that the information in this chapter will provide a basis to put the OTT commercialization activities in a broader context of the research institutes' policies on technology transfer. Understanding what vehicles transfer technology and how, can help the effective OTT official prevent inadvertent transfer and expand his or her negotiation tools. Conversely, if policies have not been articulated sufficiently to address technology transfer in the context of grants, contracts, or sponsored programs, then a dialogue needs to occur among the responsible parties, including the OTT and leadership within the institute. Having a uniform position on the value of intellectual property assets by all offices involved, not just the OTT, is important for the success of an institute's entire IP enterprise.

Acknowledgments

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Notes

1. The uniform biological material transfer agreement can be found at www.nhlbi.nih.gov/resources/tt/docs/ubmta.pdf.

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Invention Triage

Harl R. Tolbert

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Introduction

Technology transfer programs need to establish effective and efficient procedures to manage the review of new technologies. For all practical purposes, the technology transfer program is generally the party charged with selecting the winners and losers among an organization's technologies. In other words, selecting the technologies that will be marketed, patented, or have other resources devoted to them and determining those that will or will not be promoted. Often, the success of an office in picking between these two groups determines actual and perceived success.

Making the evaluation process somewhat perilous is the fact that every person evaluating technologies has the fear of passing on the one that got away and the subsequent retelling of the tale for years to come by administrators, disgruntled faculty, and researchers. While these stories are legend at some campuses and likely to occur in the future at others, the actual occurrence is rare. Nevertheless, every office should strive to perform a thorough evaluation of every invention disclosure and develop a complete understanding of the potential of each submission. Further, the establishment of, and compliance with, a well-crafted and thorough review process can ensure that such occurrences are unlikely to happen.

An institution's criteria for evaluating invention disclosures and technologies will vary—there is no one-size-fits-all model. Every institution's evaluation will be shaped by a variety of organization-specific issues such as patent budget, size of research program, types of technologies evaluated, goals, etc. One place to start is to think about the main goals of the office.

The two general guiding themes are:

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- maximizing commercialization, thus, leading to revenue generation
- service to your research community

These are not mutually exclusive—almost every enterprise will strive to satisfy both these demands. However, every institution is likely to place more emphasis on one area (or at the very least, place more emphasis on one in specific situations). This section should provide some examples of tools that can be useful in the management or development of a system to manage the invention disclosure review process. Not all of these examples will apply to any one institution, and it will probably be necessary for every office/individual to decide which of these methods would be useful (and, in fact, develop its own methods for its unique needs).

(For more on the invention disclosure process, See Volume 3 of the AUTM Technology Transfer Manual.)

Institutional Considerations

When evaluating technology and invention disclosures, it is helpful to have a thorough understanding of the institution's technology transfer program, its goals, and its capabilities.

Budgetary Constraints

Obviously, with an unlimited budget, the filing decision process is made very easy. However, most organizations don't have that flexibility. A decision to file a patent application today can affect your ability to file or support another application at a later time. Keep in mind that the filing of a patent application is just the start of a process that can become very time-consuming and expensive. The initial decision to file a patent application (usually in the form of a provisional patent application) can be fairly inexpensive.

However, the cost of maintaining and prosecuting the application, especially on an international basis, can become quite large. Any applications filed this year will likely incur costs such as full utility filings, nationalized patent applications, and patent prosecution in future years. These expenses will have to be paid by a current year's patent budget, which also has to pay for new patent filings that year. Before making filing decisions, some thought should be given to the resources of your institution's patent budget and the level of support you can direct to new and ongoing patent efforts.

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Research Strengths

Also keep in mind that the two main types of university-derived technologies have very different patent-filing profiles. Patented life science technologies, in particular, pharmaceutical technologies, are generally composed of one or very few patented technologies. This is usually sufficient to enable commercialization of products in this area. Mechanical products tend to be composed of many more patentable or patented technologies. Further, the pace of change and product development (and commercialization) in these areas is much faster than that in the area of pharmaceutical and biologics technologies. The time from conception/invention to product introduction tends to be much shorter with mechanical (and to some extent medical device technologies). Additionally, finding licensees and technology developers also tends to be a faster process in the mechanical arts. This results in a much more streamlined patent management process. It is not uncommon for technology transfer offices that manage predominately mechanical technologies to have patent decision guidelines that call for closing a case if it is not licensed by the time expensive national stage decisions are due.

Patented and Nonpatented Technologies

Certainly not all technologies are created equal. It is helpful when evaluating technologies to keep this in mind to manage costs associated with protecting and marketing technologies. Generally, technology can be divided into two categories: patented and nonpatented. Nonpatented technology usually includes research tools, animal models, cell lines, antibodies, data sets, etc. Oftentimes, these technologies cannot be patented.

Or, if they can be patented, their value is not enhanced by patent protection. In these cases, the decision to market them is much more straightforward because the formalities and expenses of patent protection are not an issue. Likewise, the likely reward probably will not be as high as that of a patented technology. Patented technologies, on the other hand, tend to offer much more risk and reward. The decision to seek patent protection is the start of an expensive undertaking both in terms of patent expenses and staff resources. Some thought must be given to this area to ensure the best use of these resources now and in the future.

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Patentable technologies usually can be further divided into two general groups —life science technologies and physical sciences. For the sake of this discussion, physical sciences will include the following areas: engineering, computer sciences, chemistry, etc. Generally speaking, life science technologies require more time to license and develop into products than physical science technologies. An evaluator should give some thought to the issues of expense and time to market when evaluating life science technologies.

The subdividing of technologies—first as patentable and nonpatentable and then further dividing into life science and physical sciences—is not meant to set the stage for the grouping of technologies as sets of desirable and nondesirable technologies. Rather, it is meant to help focus the evaluation and subsequent devotion of resources. In most technology transfer offices, a focus on patenting-based decisions takes center stage. This is due to the fact that the majority of non-staffing-related expenses associated with technology transfer are patent expenses.

As alluded to earlier, a technology transfer office's ability to show success in terms of turning research discoveries into products or services (as well as revenue) is dependent on making good decisions regarding which technologies to patent. These decisions also shape the direction of a technology transfer program for years to come due to the possible generation of licensing revenue and the allocation of resources by an institution to its technology transfer program.

Invention Disclosure Forms

In most instances, the new technology will arrive at the technology transfer office in the form of an invention disclosure. Most invention disclosure forms ask the same questions. At the heart of the invention disclosure is a statement from the submitters explaining why their proposed invention has merit. In other words, why the institution should invest resources, money, and countless hours of employees' (e.g., faculty members, other researchers, technology transfer staff) time, to seek some form of protection for the idea or to market it?

Usually, invention disclosure forms ask in one way or another at a minimum:

- What is the invention? A description of the technology is needed. The description should provide enough detail so that the evaluator can develop, at least, a general understanding of the technology.

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- Why is it better than what currently exists?
- What is the current state of the technology?
- What problems does this technology overcome/solve?
- Have there been (or are there planned) any public disclosures?
- When is the earliest that there will be (or has been) a public disclosure?
- Were any materials received under material transfer agreements (MTAs) from other institutions or companies?
- What was the nature of funding for the research that led to the discovery/invention/development of the research material?
- Who were the key contributors?

Technology Review

One question reviewers of invention disclosures should be asking is: Is there a reasonable chance of success in patenting the technology and a reasonable chance of finding a licensee of this technology?

Notice the use of the word *reasonable* in the previous sentence. Keep in mind that this is a very relative term. How an office/institution views reasonable regarding the two earlier mentioned criteria will vary from one institution to another. Always remember that in many, if not most, cases it will be very unlikely to get definitive answers to these two questions. The purpose of the information gathering simply serves as the basis for making qualitative, and in some cases quantitative, decisions about proceeding with patenting and marketing decisions. The views of a technology transfer program are shaped by a variety of influences, including:

- institutional history
- past technology transfer success
- patent budget
- institutional demands (researchers, central administration)

Making Patent Decisions

Prior Art Searching

While there are no absolutes, the evaluator should be seeking to gain an understanding of the chances of success of a patent application based on the invention disclosure.

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The three general criteria used by most technology transfer offices, as well as the United States Patent and Trademark Office, in assessing patentability are:

- novelty
- non-obviousness
- utility

The two areas of evaluation that influence this decision the most are issues of non-obviousness and novelty and are oftentimes the most difficult hurdles to overcome. The requirement for utility is usually not a barrier to obtaining patent protection. Other, more patent-focused reviews of this area have been written and are readily available and can give a much more nuanced view of these two issues.

Most evaluators with a basic understanding of life sciences or physical sciences, combined with some experience evaluating technology, should have some *reasonable* ability to investigate these two areas. Remember though, that the word reasonable is a relative term. Sources for information to assess these two areas are now plentiful. Most academic institutions have libraries or institutional or technology transfer office-based access to Web sites. These resources allow the evaluator to assess the relevant scientific literature and explore the issue of novelty, as well as other examples in the literature that might impact non-obviousness. Increasingly, the reach of the Internet and its various search engines are proving to be extremely helpful in identifying references that can help uncover information useful to prior art and non-obviousness searches.

Another helpful resource in the prior art evaluation, include patent databases, either United States or international. These databases offer searchable fields and, in most cases, access to published patent documents (issued patents and patent applications). In some instances, patents and patent applications can offer more information than scientific literature, which usually must meet standards of peer review before being published.

Often, questions of patentability in light of prior art are not easily answered by reviewers without the assistance of patent counsel. In most cases, patent counsel can usually only give general input and estimates of patent office success. Perhaps even more helpful

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though, a patent attorney can describe the likely hurdles a specific technology might face during examination and the costs associated with attempting to overcome these hurdles. However, in some less complicated cases, patent counsel, when budgets and time allow, can quickly provide guidance that can be extremely useful in patent decision making.

Commercial Potential

While many methods of deciding what is "a good technology" exist, it's important to keep in mind that ultimately the technology has no value unless a licensee takes over its further development and commercialization. To that end, a few central questions should be answered:

* *Is there a product/service enabled by this technology to the point that a customer would pay a licensee for the product or the service?* If this question cannot be answered, there may be serious concerns whether the technology has any or much commercial value at all. Once this question is answered, keeping in mind that there may not be an absolute, clear-cut answer because potential products/services provided by the technology may not be readily apparent at the moment. In some cases, it may take a while to get good answers to this question.

* *What is faster/better/cheaper about this technology?* Many invention disclosures ask the submitter to explain why their proposed invention is better than what is currently available. Even if an invention disclosure form does not ask this question (or more likely than not—if a submitter does not provide an answer to this question), seek answers to this question. To do this, the evaluator must understand the market to some extent.

* *Is this feasible?* Some invention disclosures propose products or services that may not be feasible given the market for which they are destined. In the life sciences for instance, it is common for in vitro methodologies to have little potential to be effective in vivo. Also some in vitro methodologies are very complex and offer little practical implementation in in vivo situations. Likewise, some engineering or chemical technologies may be so resource intensive or complicated that their practical implementation may be doubtful. To answer these questions, the evaluator must start to use basic tools of market research.

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The market research performed to evaluate early-stage technologies to render decisions of whether or not to file a patent application is related to, but slightly different, than the market research a company would use to determine what products to put on the market. When evaluating academic research, it is not feasible to try and make detailed analyses and predictions regarding proposed product sales. Such an analysis is often undertaken in the commercial sector and would likely happen at some point for the technology, if licensed.

However, the evaluation undertaken at the invention disclosure stage is usually so far removed from the actual product and its final attributes, such an analysis is not feasible or reliable. For the purpose of deciding whether to file a patent application or not, the goal of market research should be to determine if a suitable market exists and if there is a need for the technology.

One mistake often made in market research is to look at the size of the marketing universe for a potential product or service. Using this approach alone is a mistake. One should not assume that a product for a market that happens to be very large is more valuable that a product that is destined for a small market. It is more appropriate to think of each specific technology in terms of what would be the actual product. Then one can evaluate how that product would compete in the overall market for this type of good or service. The following questions aid in that evaluation:

- Would it provide solutions that currently do not exist?
- Would it allow options to customers that currently do not exist?
- Would someone be willing to pay your licensee for this good or service?
- These questions are sometimes overlooked at the expense of good science, institutional pressure, or researcher pressure.

Speak with the Inventors

Usually, the complete picture of the proposed technology cannot be determined by reading the invention disclosure alone. It is usually, in fact almost always, helpful to meet with the submitters of the disclosure after an initial read of the disclosure and review for patentability and market potential. This discussion will provide additional insight into the

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technology because the written disclosure oftentimes lacks all of the details. Also, the disclosure may be written in great technical detail, but may not provide practical applications.

A meeting with the inventor is usually very helpful in making sure the evaluator has a thorough understanding of the technology, its stage of development, and its commercial possibilities. This meeting will also provide the evaluator with the opportunity to ask the submitters thoughtful, informative questions about what has been uncovered in the prior art search and initial market review. The submitter interview is also very helpful in providing initial marketing targets and a list of companies that might serve as potential licensees given the submitters' contacts and knowledge. Following the meeting with the submitter(s), revisit both the prior art search and market review using insight provided by the researcher. Submitters typically are eager to discuss the technology, speak with them as often as needed to make a well-informed decision. However, please be respectful of their time and well-prepared for the meeting.

Here are possible questions for the submitters:

- Does the submitter of the technology (or the technology transfer office) have any existing idea of who could move this technology forward?
- Does the submitting researcher have any plans/capability to move the technology forward?
- How is your submission different from any prior art you have discovered?
- Is the technology a standalone? What additional technology would be needed to develop a product? If so, who would provide the additional technology or development?
- What additional research will be done and how will it affect the technology at hand?
- Can you re-confirm the likely public disclosure date?
- What makes this technology faster, better, cheaper?

Evaluation Resources

Most technology transfer offices use a variety of subscription-based services to accomplish the bulk of their market research and prior art review needs. The variety of these services range from canned market research reports to compilers of information ranging

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from product sales, news articles, securities filings, company reports, etc. Most technology transfer offices are called upon several times a year by a variety of purveyors of these services. In addition to many of these subscription-based services, there are many sources of free market research and prior art information, which include:

* *The Internet:* The ever-growing scope of the Internet allows anyone with a computer to be able to quickly search for potential customers/users of a technology to serve as confirmation of market potential. With the scope and content of this resource ever growing, the possibilities of the information available will continue to grow. As always, when searching for information online, practice a reasonable amount of care when using this information as a part of your decision-making process. Try, whenever possible, to verify this information.

* *Your alumni:* Chances are that the some former members of your organization will invariably be involved in the areas of research and commercialization of technologies that your office will be reviewing. In most cases, these alumni will be open to the idea of discussing, in a nonconfidential manner, the technologies and their proposed markets with you. This is particularly true of physicians in the area of medicine and medical devices. These alumni, with practical and current marketplace experience, can be very helpful in explaining the state of a technology marketplace, unmet customer needs, financial considerations particular to a given market, etc. Many technology transfer offices have developed databases or other internal methods of tracking and quickly reaching out to members of these communities.

* *Your technology transfer colleagues:* Your colleagues in other technology transfer offices will have some expertise in evaluating, marketing, and licensing technologies similar to those you are evaluating. In most instances, they will be more than happy to provide their insight.

* *Patent databases:* The information compiled by patent databases usually contains some information regarding companies active in a certain area of technology and product development. Also by examining organizations active in similar areas of technology development, you can start to compile a partial list of possible licensing targets.

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* *National Institutes of Health Web sites:* For life science-related technologies, the National Institutes of Health provides a wealth of information that can assist in prior art searching and market research. They can be particularly helpful when reviewing prior art. These include GenBank, Protein, BLAST, and RePORTER (formerly known as CRISP).

* *Government Web sites that monitor product development and approvals:* This is particularly true on the Food and Drug Administration's (FDA) Web site in the area of pharmaceuticals, biologics, and diagnostics. For instance, the FDA's Orange Book provides information on patent expiration and exclusivity periods for pharmaceuticals. The FDA Web site also contains the Green Book, which contains exclusivity and patent expiration data for veterinary pharmaceuticals.

* *Government agencies and Web sites that track health statistics:* The United States government and several other nations compile health-related information and make it freely available on Web sites. These include the Centers for Disease Control's Bureau for Health Statistics. This site provides detailed health statistics in a comprehensive and organized fashion that makes searching for potential market sizes relatively easy. Several United Nations organizations also compile and display health-related statistics. In most cases, the there is no one-stop shop for such information—evaluators must rely on search engines and diligence to find necessary information

* *Industry contacts:* Technology transfer professionals are likely to have developed industry contacts in specific areas that can serve as a source of valuable information when making decisions about unrelated technologies. These contacts can be helpful in the evaluation of a current project. While most contacts will generally be very helpful be careful not to overuse this resource and be cognizant of their time. Be prepared and organized before reaching out to them.

* *Technology review committees:* Office colleagues are another helpful resource in evaluating invention disclosures. This will help the evaluator apply institutional/office norms and concepts to the evaluation process. In some instances, the process of group involvement in the decision-making process is taken to another level by the use of committees,

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composed of researchers and faculty members who serve as a panel to provide input. The use of such a committee can be beneficial in providing participating researchers with sense that their input is valuable. It allows them to have some input into organizational decisions regarding patent decisions. As an evaluator, it is also helpful to have a panel of technically proficient reviewers to aid in the evaluation. While very helpful to both the evaluator and the panel members, a technology transfer office must be careful to emphasize, to whatever extent is possible, that the input of such a panel is advisory in nature. In both instances (input from office colleague or a technology review panel), the group will be relying on the main evaluator to conduct the prior art searches and marketing review. Be prepared, anticipate questions, and have the answers ready.

Making Decisions to File

Following the analysis, if questions of patentability and commercial potential are satisfactorily answered, the next step is to move forward with a patent application. This process usually involves engaging outside patent counsel who will solicit input from the technology transfer office and the submitters to draft an application. Bear in mind though, that every institution will have different criteria for patent filings and management of technology. Before making decisions, or even starting the evaluation process, it is helpful make sure the evaluator is aware of institutional norms for filing, strategic technology transfer plans, resources, and anticipated resources.

Following the evaluation, if it is decided that a patent application should not be filed, several options remain. As mentioned earlier, some technologies do not warrant, or benefit from, patent protection; they may be marketed and commercialized without patent protection. Also, some technologies may benefit from additional research or data generation. If time permits (and the researcher's disclosure plans allow), it may be useful to keep the case open and monitor the developments in the research and then make patent or marketing decisions.

Many institutions have policies that allow for technologies not commercialized or patented to be assigned to the submitters. However, the process of allowing ownership to revert back to the submitters only pertains to the institution's rights. If other ownership or as-

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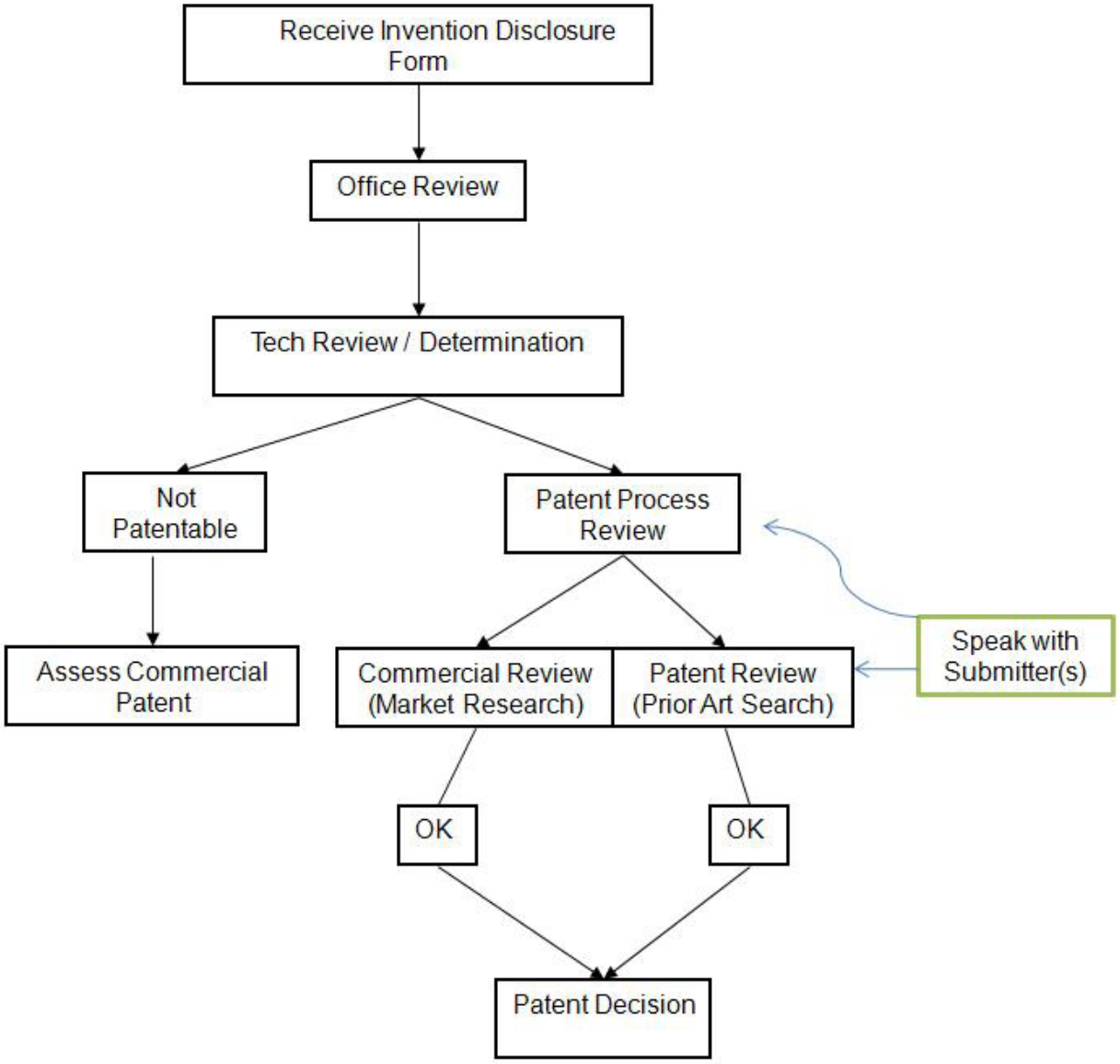
signment interests are present, which is usually in the case of federal funding, permission from the research sponsor will be needed as well.

The following flowchart visually outlines the invention evaluation process.



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Intellectual Property Clustering

Andrew R.O. Watson, PhD, and Angus Livingstone

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Introduction

Every university has them: numerous pieces of intellectual property (IP) that remain unlicensed and may never be fully exploited. As a large percentage of university patented and unpatented IP goes unlicensed, IP clustering is a viable option in addressing this problem. Tapping into even a small portion of the value of this otherwise unlicensed IP can bring new licensing revenues into university technology transfer offices and fulfill the missions of many such offices by transferring technology from the laboratory to the market for public benefit. Clustering IP can create a new, more marketable and valuable product with which to approach corporations and investors. There are several variations on IP clustering, each with their own processes and challenges.

IP Clustering: Variations

While there is no agreed taxonomy for IP clustering methodologies, we have chosen to group them into four categories: patent pools, IP portals, IP bundles, and IP aggregation. Each will be outlined in further detail below—examining its characteristics, current examples, and considerations for its use. It is worthy to note that this is a very dynamic field with evolving practices and players coming and going on a regular basis. This is an indication that the field of IP clustering is still in its infancy with many changes likely to continue as new practices are tried and reformed.

Underlying the need for IP clustering is the desire of both IP owners and users to efficiently operate in an increasingly complex environment. The explosive growth in filing of patents over the past thirty years by an increasing number of organizations has lead to IP fragmentation and the creation of "patent thickets," which occur when multiple organiza-

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tions each own at least one patent that is collectively necessary for the exploitation of a particular technology. A dense web of overlapping intellectual property rights, which it must get through in order to commercialize a new technology, confronts a company that wishes to develop a technology.[1] Potential users of IP are confronted with the unwieldy task of identifying the owners of technology-enabling IP and negotiating access through agreements with multiple parties.

The providers of IP, often academic institutions, are confronted with identifying potential licensees and enticing them to negotiate a license when the providing institution can only provide one piece of a very complex IP puzzle. IP clustering is used to ameliorate the challenges of both the IP providers and the IP users by making it easier to identify the IP of interest and reducing the transaction costs by making IP available from multiple providers through a single license agreement with standardized terms.

Patent Pools

A "patent pool" is an agreement between two or more patent owners to license one or more of their patents to one another or third parties. Alternatively, a patent pool may also be defined as "the aggregation of intellectual property rights that are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool."[2]

Patent pools are not a new idea and were widely used in the late nineteenth century for industries such as sewing machine manufacturing. In the early twentieth century an aircraft patent pool was privately formed, encompassing almost all aircraft manufacturers in the United States. In 1924, an organization first-named the Associated Radio Manufacturers and later the Radio Corporation of America, merged the radio interests of American Marconi, General Electric, American Telephone and Telegraph (AT&T), and Westinghouse leading to the establishment of standardization of radio parts, airway frequency locations, and television transmission standards.

In recent years, patent pools have solved both research and development (R&D) (upstream) and access (downstream) problems. The pool may involve simple cross-licensing among two or more competitors in order to share a handful of patents necessary for the manufacture and sale of a particular product. Or it may involve a large industrywide pool

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open to anyone, encompassing hundreds of manufacturers and thousands of patents, as well as other IP, such as rights to use data, know-how, or trademarks. Commons and IP clearinghouses are alternative names that are used to describe pools. Pools usually offer standard licensing terms to licensees and allocate a portion of the licensing fees (royalties) to patent owners according to a pre-set formula or procedure.

Patent pools take many different forms and are organized in response to a particular set of policy objectives and circumstances. There are pools that manage the patents on standards for new information technologies, that enhance R&D for new biomedical or biotechnology agricultural products, or that seek to promote social objectives. Some pools are organized by patent owners, others by manufacturers, and yet others by nonprofit institutions, including governments. Examples of patent pools organized for similar purposes include:

- promotion of standards
- innovation
- social benefits

While each differ in terms of its primary objectives, organization, and administration, all share the common benefits of addressing issues related to blocking patents and patent thickets, reduced transaction costs through a single published licensing process and reduced litigation exposure, and institutional exchange of related technical information.

The law regarding patent pools has changed dramatically over the last century. Antitrust laws and patents have often been in conflict, especially where patent pooling or patent cross-licensing is concerned. A patent is a government-granted limited property right to exclude others from making, using, or selling the patented invention. Antitrust laws, such as the Sherman Act, however, were designed to prevent the creation of monopolies and restraints on interstate commerce. Although these laws seem to be incompatible, both antitrust law and patent law are aimed at encouraging innovation, industry, and competition.

In 1995 the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued the *Antitrust Guidelines for the Licensing of Intellectual Property* (guidelines)[3] and specifically addressed the topic of patent pooling. In particular, the guidelines state that IP pooling is procompetitive when it:

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- integrates complementary technologies,
- reduces transaction costs,
- clears blocking positions,
- avoids costly infringement litigation, and
- promotes the dissemination of technology.

The guidelines also discuss that excluding firms from an IP pool may be anticompetitive if:

- the excluded firms cannot effectively compete in the relevant market for the good of incorporating the licensed technologies,
- the pool participants collectively possess market power in the relevant market, and
- the limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies.

In 2007 the DOJ and FTC issued a joint report entitled *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition.*"[4] This report highlighted several key issues of potential concern when it comes to certain IP pools. Primarily the agencies highlighted that IP pools should be composed of complementary IP rather than substitute IP in order to reduce the risk of price-fixing, and participating institutions should retain the rights to license their IP outside of the clusters to encourage continued innovation.

Standards-Based Patent Pool

MPEG-2 (http://www.mpegla.com/main/programs/M2/Pages/Intro.aspx) was formed in 1997 by the trustees of Columbia University, Fujitsu Ltd., General Instrument Corp., Lucent Technologies Inc., Matsushita Electric Industrial Co. Ltd., Mitsubishi Electric Corp., Philips Electronics N.V. (Philips), Scientific Atlanta Inc., and Sony Corp. (Sony) to jointly share royalties from patents that are essential to compliance with the MPEG-2 compression technology standard.

Innovation Patent Pool

The Open Invention Network (OIN) (http://www.openinventionnetwork.com) was formed as a collaborative environment for using the Linux system. Patents owned by the OIN are available royalty-free to any company, institution, or individual that agrees not to assert its patents against the Linux System. The OIN aims to ensure openness of the Linux source

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code, so that programmers, equipment vendors, and institutions can use Linux with more freedom to operate around IP issues.

GreenXchange (http://greenxchange.force.com/vGXhome) is a project of Science Commons with the intent of creating an open innovation platform promoting the creation and adoption of technologies that have the potential to solve important global or industrywide challenges. The goal is to encourage patent holders to make their patent portfolio available for licensing through public license offers that are offered to everyone on reasonable terms, while retaining the defensive benefits of patents.

GreenXchange proposes the following principles for patent licenses:

- The terms and conditions of the license should be made public and openly available for all to read.
- The offer is valid and complete, so that anyone who can agree to it is empowered to accept without further negotiation.

Patent owners are encouraged to make their patents available for licensing without fee or with only a nominal fee and with few or no field-of-use limitations. GreenXchange is proposing a patent nonassertion statement that creates a voluntary research exemption, permitting nonprofit research use by anyone, to help mitigate some of the effects of the narrowing of the experimental-use exception by courts.

Social Benefit Patent Pools

The Golden Rice Initiative (http://www.goldenrice.org/) is based on a line of rice that has been genetically engineered to produce and accumulate vitamin A (i.e., beta-carotene) in rice grains. This humanitarian initiative has the potential to save hundreds of thousands of children and women per year from vitamin A malnutrition, particularly in developing countries where it can lead to conditions ranging from blindness to death. This scientific breakthrough would have remained an academic exercise if a public-private-partnership and patent pool had not been created for product development and deregulation. The inventors and owners of ancillary technologies needed to develop the rice have provided the patent pool with a free license for smallholders in developing countries. Thus, farmers

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in developing countries meeting the threshold requirements will be able to consume their produce, sell it, and replant the seed.

SARS IP Working Group

In 2005, there was a proposal to create an upstream pool to address R&D for a severe acute respiratory syndrome (SARS) vaccine. Following the outbreak of SARS, many research institutes and private firms rushed to sequence the SARS genome and apply for patents. The WHO SARS Consultation Group and key SARS IP owners created the SARS IP Working Group, which found that R&D would be delayed and constricted by the multiplicity of patents and that this would adversely affect the development of a vaccine. The group suggested that a patent pool be developed to promote the development of a treatment or vaccine. The creation of the pool was pursued by the IP owners but was ultimately abandoned after the SARS threat subsided. For more, see http://www.who.int/entity/bulletin/volumes/83/9/707.pdf.

GSK Patent Pool for Neglected Tropical Diseases (NTDs) in Least Developed Countries

The GSK Patent Pool for Neglected Tropical Diseases (NTDs) in Least Developed Countries (http://www.gsk.com/collaborations/patentpool.htm) was established in 2009 to encourage development of new and improved cures and treatments for such diseases. This patent pool targets sixteen diseases. The pool includes GlaxoSmithKline's current patent filings on small molecule pharmaceuticals to treat NTDs (approximately eighty patent families, which include more than 500 granted patents and more than 300 pending patent applications). The pool is administered by BIO Ventures for Global Health (http://www.bvgh.org). In July 2009, Alnylam agreed to contribute more than 1,500 issued or pending patents on its RNA interference technology patent estate to the GSK patent pool, and in 2010, MIT agreed to contribute patents to the pool.

Eco-Patent Commons

The Eco-Patent Commons (http://www.wbcsd.org) initiative is an IP clearinghouse intended to facilitate sharing and accessing of IP rights, mostly patents, relevant for environmental technologies. In January 2008, four companies, namely IBM Corp., Nokia, Pitney Bowes, and Sony, in conjunction with the World Business Council for Sustainable Devel-

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opment, launched the Eco-Patent Commons. The commons is open to any company that contributes at least one patent that pertains to technologies having environmental benefits. Examples of activities that the commons considers as environmental benefits include energy conservation or efficiency, materials reduction, or increased recycling ability. For a representative survey of patent pools, see "Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures," *KEI Research Note 2007:6.*[5]

Notes for the Technology Transfer Practitioner

In recent years patent pools, whether standards-, innovation- or social benefit-based, have increased in popularity, and there is currently a wide range of pools/commons for the technology transfer professional to consider. They usually share the characteristics of being open, transparent, nonexclusive, regulated, fixed IP valuation, and they are managed by a third party. The array of options prompts the observation, "so many pools and so little time." Often, the pools are restricted to issued patents and, for many academic institutions, given the cost of patent prosecution, the majority of issued patents have already been licensed and may not be eligible for inclusion in the pool.

For standards-based pools, the test for eligibility for a given patent is strict and, for those patents that qualify, the patent pool may be the best source of finance return. For innovation-based pools, the benefit is primarily through the codification of a research-use exemption, and participation in the pool may well lead to commercial licensing resulting from increased research use of the patent. For social benefit pools, for-profit rights are normally retained and good public relations associated with making the institution's patent available for third world, environmental, or other social benefit applications, whether or not these are ever realized, is beneficial in and of itself.

IP Bundles

Intellectual property bundles are formed through the combination of complementary technologies to increase the value of the individual parts. For example, a bundle might include a pen from one party, ink for use in the pen from another party, and paper from a third party. Together the pen, ink, and paper can hold greater value than each of the parts on its own. Within the technology transfer profession, a number of universities are creating or

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have attempted to create bundles involving their IP, which as separate pieces may have low commercial appeal on their own. There are several examples of groups creating IP bundles; some of which have had success, those that have not had success, and others who are still in the early stages of developing their IP bundling model. The following are examples of some efforts at creating IP bundles.

The InterAct Partnership (http://www.interactpartnership.co.uk) is a partnership between six leading government research organizations in the United Kingdom and is funded by the UK Department of Innovation. The group was formed, in part, to combine the IP of these institutions to create new commercialization opportunities. The institutions consist of the Centre for Environment, Fisheries and Aquaculture Science; the Defence Science and Technology Laboratory; the Food and Environment Research Agency; the Health Protection Agency; the Health and Safety Laboratory; and the Veterinary Laboratories Agency.

Each of these institutions has its own fields of expertise, but they also have several overlapping strengths. InterAct combines partner technologies from diverse areas to develop projects to address a variety of market needs and actively commercializes such projects to bring them to market. InterAct portrays itself as an example of how successful IP bundling across diverse organizations can add value both for the institutions and the commercial licensees. In its first three years, InterAct helped the member institutions identify more than seventy new project opportunities through seventeen facilitated workshops across overlapping areas. InterAct expects to bring complementary groups of IP assets to market through licensing, joint venturing, new company creation, and other routes. As of 2009, InterAct had catalyzed the formation of fifteen successful exploitation vehicles, which includes eleven licenses, three enhanced service offerings, and one spinout company.

The Inter-University Technology Bundling Project (IUTBP) (http://larta.org and http://www.larta.org/ClientsAndPrograms/Universities.aspx) is a joint program between Loma Linda University and the Larta Institute that has an overall goal to increase successfully transferred innovation coming from Larta's Network T2 (NT2) member institutions (some of the participating institutions include several of the University of California campuses,

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California State University campuses, as well as the California Institute of Technology and Cedars-Sinai Medical Center) by overcoming competitive issues, creating virtual bundles of compatible IP from multiple NT2 sources, and facilitating the transfer of those bundles to the marketplace.

The IUTBP was built off of a pilot program from Larta, the Virtual Bundling Agent, which ran from 2005-2007. The IUTBP received a three-year grant in 2008 from the National Science Foundation (NSF) to create the infrastructure and system for identifying IP bundles and matching these bundles to companies for commercialization. At the time of this funding from the NSF, the IUTBP had forty-one IP bundles that had been identified from the work of the Virtual Bundling Agent and were ready for marketing to potential commercial licensees. The Virtual Bundling Agent developed confidentiality and noncompetition agreements between all of the NT2 institutions to overcome competitive issues, as well as convened expert panels to build industry-specific, complementary bundles from the IP of the NT2 institutions. Information about the bundles was then widely disseminated in broad and targeted ways for licensing purposes.

However, the process evolved from strictly licensing established IP bundles to soliciting specific needs from industry partners and then sharing these with the university partners. Industry partners are now asked to provide a statement of technology problems that need innovative solutions. The statement provided by the industry partners will help narrow and guide the university partners into identifying potential solutions from within their institutions. IUTBP collects these potential solutions, which may contain a bundle of IP available for licensing from any of the NT2 member institutions for review by the industry partner. Thus far no results have been reported on the success of this IP bundling project.

The Technology Research Collaborative (TRC) was created in 2003 under a memorandum of understanding between a variety of organizations in New Mexico. These included the University of New Mexico, New Mexico State University, New Mexico Institute of Mining and Technology, the MIND Institute, Sandia National Laboratory, Los Alamos National Laboratory, and the National Center for Genome Resources. The plan was to bundle patents and have licensing handled by one institution that would be agreed upon by the

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other institutions. In 2005 the TRC members entered into an interinstitutional agreement to allow for the bundling of patents from the participating institutions.[6] However, nothing further became of the group's bundling efforts as the TRC shifted direction away from the bundling of precommercial IP.[7]

The Innovation Bundling Initiative, or IBI, was established in 2007 between Sandia National Laboratory, Los Alamos National Laboratory, Lawrence Livermore National Laboratory, and the Nevada Test Site.[8,9] The initiative was jointly developed by the Technology Ventures Corp. under a contract with the National Nuclear Security Administration to assist with the commercialization of technology. The institutions executed an IP bundling agreement that established the legal process for IP bundles to be out-licensed to commercial entities.

Under the initiative, patents originating from these facilities were to be put together into groups by subject matter and technology similarity. Under the IP bundling agreement, prospective licensees only needed to negotiate licenses for IP bundles with one licensing facility regardless of which of the institutions the IP came from. The IBI encouraged leveraging of Department of Energy R&D funds dedicated to complementary projects within the labs and the leveraging of the IP developed by the projects. The group was also focused on nonexclusive bundle licensing to improve the likelihood that the technologies would be successfully developed.

The IBI had more than 2,000 available patents entered into a common database that had been broken out into broad clusters such as nanotechnology, photovoltaics, and water remediation. The next step was to bundle the specific IP into single portfolios with overlapping technologies. The group's hope was that bundling their IP could make their technology more appealing and powerful as an IP portfolio. However, no results on the success of this initiative are known.

Notes for the Technology Transfer Practitioner

True IP bundling exercises are aimed at identifying and combining complementary technologies (i.e. pen, ink, and paper) in a way that creates increased utility and value to the end user. This form of IP clustering stands to create the highest value return of various forms of clustering, but these bundles are the most challenging to identify even concep-

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tually, leastwise to mine the IP assets of the various participants to identify bundling opportunities. In the therapeutic domain, this could entail identifying IP that covers composition of matter, method of production, and use claims. With software, it could be a combination of a modeling program, interface programs, and proprietary access to data. In other applications, identifying synergies between technologies is not as straight forward. Bundles may also involve different forms of intellectual assets including patents, software, research tools, data, or digital content. Compounding the complexity, IP bundles often require one-off custom interinstitutional agreements and do not benefit from the standardized approach taken with patent pools.

IP Portals

Technology or IP portals have been around for quite some time. These online Web sites collect and list IP that is available for licensing from single (such as a single university) or multiple (such as several universities) sources. In recent years some of these portals have been acquired and/or merged with other portals. Still others are recently coming into existence. Each has a slightly different focus, participating membership fees, ability to access and search technologies, and ability to receive automatic updates. Think of some of the larger IP portals as a shopping Web site such as Amazon.com that clusters products/technologies from multiple providers in one location. IP portals fall into two general types that university technology transfer offices might utilize to further commercialize their available IP, private and university portals.

Private IP Portals

Flintbox (http://www.flintbox.com) was created at The University of British Columbia and is now operated on a global basis by Wellspring Worldwide. Flintbox's goal is to serve as a global IP exchange providing easy and open access to innovation. It is the only innovation database in Canada offering online licensing, early-stage research results, and patents for license in one accessible platform. Institutional membership is free as is searching the available technologies or projects. Licensing can be conducted online with downloads and ecommerce enabled. Technology listings include a summary, patent information, description, areas of interest, what the posting party is seeking or offering, advantages, potential applications, state of development as well as any downloadable materials.

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The iBridge Network (http://www.ibridgenetwork.org), a program of the not-for-profit Kauffman Innovation Network Inc., provides a centralized online source for research and innovations. The providers listing their technologies and other opportunities are predominantly universities. With membership, universities can search and post technologies as well as enhance their experience by receiving personalized emails on topics and innovations of interest. Technology information includes a title, posting institution, description, innovation details, and IP protection. There is also the option to enter into licenses directly from the Web site.

The UTEK Knowledge Express Free eMarket (http://www.knowledgeexpress.com) is a service designed to benefit the business development and technology transfer community. After registration on the Free eMarket, profiles and technologies can be submitted, which are then posted to all of Knowledge Express' services. Knowledge Express profiles and technologies can also be searched following the free registration. The Free eMarket requires no contracts, fees, or obligations. The technologies listed provide titles, inventors, abstract, applications, patent information, keywords, license information, and correspondence address including e-mail. Also, the dates the technologies were recorded and last updated are listed.

Others include:

- Folio Direct (http://www.foliodirect.net/)
- University-Technology.com (http://www.university-technology.com/index.php)
- yet2.com (http://www.yet2.com)

University IP Portals

Universities' own Web sites are a valuable resource when it comes to IP clustering within an IP portal. Some database systems used by university technology transfer offices to track their IP have features built in to help display available technologies online. Other universities have built their own custom systems to take the information from their databases and produce their own IP portals. However, these custom designed IP portals are not restricted to individual universities but can also be expanded to include groups of universities.

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IP portal examples on a university's own Web site are demonstrated by the authors' current institutions. The University of British Columbia's University-Industry Liaison Office (UBC's UILO) has a Web link on its Web site entitled "Licensing Opportunities" (http://www.uilo.ubc.ca/licensing/opportunities.html). Technologies available for licensing have been clustered into diverse technology categories ranging from agriculture, aquaculture, and forestry to drug delivery to telecommunications and display to vaccines. Each available technology link opens a technology licensing opportunity page describing the available technology. Information included for each technology includes a title, value proposition, advantages, principal inventor(s), technology details, publications/references, patent status, development stage, reference number, contact information for the technology, and the date the information was last updated.

Oregon Health & Science University (OHSU)'s office of Technology Transfer and Business Development has a link on its Web site entitled "Available Technologies" (http://www.ohsu.edu/tech-transfer/portal/index.php). Similar to the available technologies from UBC's UILO, the available technologies from OHSU are broken down further into technology categories ranging from bioinformatics to databases to diagnostics to education and training to therapeutics. Each technology link opens a separate Web page listing the title, reference number, category information, inventors, value proposition, summary, market summary, patent status, inventor profile, publications, licensing opportunity, and contact information for the available technology. The technology information on the Web site is updated live when changes are made to OHSU's internal database. Furthermore, specific technologies are available for licensing online through either an academic license or a commercial license. License fees through the IP portal are handled by invoicing or through PayPal.

IP portals have been developed on regional scales as well. Two examples are the Massachusetts Technology Portal and Innovate Collaborate Oregon. The Massachusetts Technology Portal (http://www.masstechportal.org) is a joint project of the Massachusetts Association of Technology Transfer Offices and the Massachusetts Technology Transfer Center. This IP portal is designed as a unified search engine serving as a one-stop shop for technologies available for licensing from research institutions within the state of Massachusetts. Search criteria include the IP type, any word in the IP title, technology type, inventor, any word in the IP summary, and the organization.

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Innovate Collaborate Oregon features innovations and opportunities from four of Oregon's research universities in a searchable IP portal (http://www.icoregon.net). Technologies available can be searched in several ways. First, a keyword search is available. Second, an advanced search is available that can search for a technology by keywords in the titles, in the descriptions, or by inventor name. A third method to search is by technology category. The search results can be sorted by title or date published to the IP portal.

Beyond regional efforts to cluster technologies from multiple institutions in an IP portal, another effort is to cluster IP from institutions participating in research consortiums. One example of this effort is the Clinical and Translational Science Awards (CTSA)-IP Web site (http://ctsaip.org). The CTSA program is a consortium of numerous medical research institutions across the United States and is funded by the National Center for Research Resources, part of the National Institutes of Health. There are currently fifteen institutions that have posted their available technologies on the CTSA-IP portal. The portal includes a text-searchable interface and regular, automatic updating with a standardized template to facilitate broad participation by CTSA consortium members.

Others include:
Pharma-links (http://www.pharmalinks.org/index.php)
NASA (http://technology.nasa.gov/)

Patent Auctions

In recent years several new companies have sprung up to conduct auctions involving IP, primarily involving patents. Online patent auctions have been around for several years. Such Web sites as ipAuctions.com (http://www.ipauctions.com) and patentauction.com (http://www.patentauction.com) can help companies and research institutions off-load their unused IP by clustering the IP into categories of related IP that can be searched by potential buyers. IpAuctions.com requires a listing fee and auction sale percentage to be paid by the seller. There are no fees for the buyer. Patentauction.com is completely free for the seller and the buyer. Beyond the online patent auction Web sites, several companies conduct live IP auctions as well. The first was Ocean Tomo, which held its first live IP auction in 2006 (http://www.oceantomo.com). The patents are clustered into lots based on the field of the IP. Ocean Tomo charges a fee for each piece of IP listed as well as a percentage of both the buyer's commission and seller's premium of the final bid price.

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Notes for the Technology Transfer Practitioner

Intellectual property portals exist at the level of the institution, the region, (inter)nationally, and by sector. In all cases, IP clustering occurs through a combination of classification systems and search engine that will allow a potential customer to readily identify IP of interest. Accordingly, IP portals serve as a passive marketing mechanism. Their benefits include the ability to profile an array of opportunities including expertise, patents (applied and issued), data, tools, biological materials, and content. Some portals will facilitate low-cost transactions through the use of click-wrap agreements, e-commerce, and downloads. The use of IP portals is not mutually exclusive, and a single institution could list its IP simultaneously on many different portals.

The experience on effectiveness of IP portals has been mixed with larger portals including many different institutions resulting in more transactions. This can often be traced to better placement through search engines like Google as well as a more effective marketing campaign. One important consideration in the use of any portal is to understand the internal resource requirements to keep information current. This is best addressed through automating the information flow from the office's internal information management system to the portal(s) in question.

Patents held by universities have been involved in IP auctions in the past, both online and live auctions. However, the greatest deterrent for U.S. universities to participate in such auctions has been the involvement of any U.S. government funding in the development of such IP. Under 37 CFR 401, the Bayh Dole Act, university and nonprofit organizations that have developed IP under funding contracts with the U.S. government may not assign the rights to such IP without the approval of the appropriate U.S. federal agency, except where such assignment is made to an organization that has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions under 37 CFR 401 as the U.S university or nonprofit. On occasion IP is developed at universities that do not involve funding from a U.S. government agency, but these are not the norm, so universities need to proceed with some caution in exploring whether or not to use the services of IP auctions.

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IP Aggregation

Another form of IP clustering is the aggregation of related or similar IP. Intellectual property aggregation is similar to IP bundling, except that IP aggregation is the clustering of similar IP, not complementary IP as in IP bundling. For example, think of IP aggregation as a book of matches. A single piece of IP is a single match where as multiple pieces of similar IP is a book of matches. The book of matches has increased value versus a single match alone.

One group who has been embarking on IP aggregation is the West Coast Licensing Partnership (WCLP) (http://www.westcoastlicensing.com). Originally conceived in 2006 by Caroline Bruce from The University of British Columbia's University-Industry Liaison Office, the group has focused on improving the commercialization and access to proprietary technologies and research tools. Members of the WCLP, which are located up and down the West Coast of the U.S. and Canada, have collaboratively developed a joint portfolio of compatible technologies that can be combined or aggregated into a package for licensing purposes under a single nonexclusive license. This simplified licensing strategy significantly reduces commercialization barriers associated with high administrative overhead.

The WCLP is an unincorporated, largely self-financed association of research institutions operating under a governing memorandum of understanding that outlines the bundling/aggregation management procedures, the revenue sharing breakdown, and the rights to IP relating to technologies within the bundles. Interinstitutional agreements (IAs) are also entered into to govern the commercialization of each group of aggregated IP. In the IAs, it is important to negotiate the distribution of royalty revenues that would result from any licensing agreement in advance. IP has currently been aggregated into groups of mouse models and biomarkers. IP is aggregated in the following manner:

- *Information collection*: Technologies to be made available for nonexclusive licensing by the WCLP are identified by member institutions. Due to the fact that not all member institutions use the same internal database systems, the relevant information for these technologies is entered into an Excel worksheet circulated by and returned to the institution managing the partnership (host institution).
- *IP aggregation*: The WCLP host institution aggregates the technologies into broad compatible categories in consultation with the other participating member institutions.

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- One institution assumes responsibility for overseeing each particular aggregated bundle (managing institution).

Once assembled, the managing institution is responsible for creating marketing materials and negotiating nonexclusive license agreements. The WCLP has also worked out arrangements with third parties to fulfill the transfer of any tangible assets covered by a license, such as the Jackson Laboratory in the case of mouse models. The success of the WCLP is still to be determined.

Notes for the Technology Transfer Practitioner

The goal of IP aggregation is that by aggregating technologies from multiple parties and out-licensing under a single license agreement, the process will save time and money for both the participating parties and the licensees in the long run. IP aggregation is similar to IP bundling in some respects but it is also distinctly different in that it focuses on grouping similar/like technologies rather than complementary technologies as in IP bundling. One thing to consider with IP aggregation is the value to be placed on the aggregated group of technologies. Each individual piece of IP can be licensed as a stand-alone technology, but the idea of aggregating each piece with like technologies will hopefully add value to the overall group versus the individual tools and technologies.

One way to address this is to have each party assign a price to its technology and then set the total price for the aggregated bundle as the cumulative price. There may be other methods, but this has worked for members of the WCLP. Attention also needs to be paid in aggregating technologies that are truly similar; otherwise the aggregated group may become less attractive to potential licensees.

Considerations

No IP clustering method is perfect or free from issues that may arise. One of the greatest strains on a university technology transfer office is time and funding resources. How much time will be required by the technology transfer staff to undertake any one of these IP clustering methods? Clearly, some methods take much less time and effort than others. Also, certain IP clustering methods require funds that may not be available. In many cases

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universities simply do not have the funds to undertake certain methods of IP clustering. Those that have had some success have received funding from internal and/or external sources, whether being from private foundations or the government. Therefore, each institution must determine which IP clustering methods are the right fit.

Conclusion

There are multiple methods for university technology transfer professionals to cluster their IP, either within their own university's portfolio or along with the portfolios of other institutions. As a large portion of university IP is never commercialized, IP clustering may be a way to increase the potential of some orphaned IP finding a commercial home.

Notes

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Research Discoveries after Kubin

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Introduction

In re Kubin, decided by the U.S. Court of Appeals for the Federal Circuit on April 3, 2009, substitutes the old rule on awarding patents for DNA research with a new one.[1] Specifically, the existence of a general method of isolating DNA molecules is now relevant to the question of whether the DNA molecules themselves would have been obvious under 35 U.S.C. § 103. With the commercialization of biomedical discoveries made at academic or basic research centers being highly dependent upon patents to protect the substantial investment of risk capital for product development, will this new rule adversely affect those technologies based upon DNA—technologies at the forefront of today's molecular medicine?

Patent Primer for DNA Inventions

One of the judges of the three-judge panel that decided *Kubin* sensibly requested the advocates during oral argument to state their positions in a way that he could understand because he humbly admitted that he lacked a scientific background. Introductions on patent law, technology transfer, and biological science are provided to assist those, who, like the judge, lack a certain background. These tutorials are helpful as a basis for understanding the full impact of *Kubin*.

Let us begin with a patent primer and first examine some basics that apply to all inventions coming from many biomedical research programs. To start: A patent protects an

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invention or discovery by giving its owner the right to exclude others from its use. Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States. The Constitution of the United States sets forth the reasons for patenting in Article I, Section 8, by giving Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Under this power Congress enacted the first patent law in 1790, with the most recent patent law being reenacted in 1952. The patent laws are now codified in Title 35 of the United States Code. The operative words from the Constitution, of course, are *limited* and *right* or temporary monopoly. The Constitution authorizes these awards of a temporary monopoly to inventors for their discoveries to promote the progress of the useful arts, of which the development of new drugs and medicines is certainly one.

DiMasi et al. estimated the average cost of new drug development, including unsuccessful products and financial opportunity costs.[2] This publication determined that the average research and development (R&D) cost per new drug, from concept to U.S. Food and Drug Administration (FDA) approval, is 802 million in year 2000 dollars.

Take, for example, the case of thyroid-stimulating hormone (TSH).[3] Many valuable proteins occur in nature only in minute quantities or are difficult to purify from natural sources. The availability of substantially pure TSH now makes the diagnosis and treatment of human thyroid cancer a reality. Previously, the only available method to diagnose and treat human thyroid cancer involved administering TSH to stimulate the uptake of radioactive iodine into the cancer. Such stimulation was used as a diagnostic test to localize the tumor by scanning and was subsequently used to treat the cancer by giving large doses of radioactive iodine to kill the cancer. All of the diagnostic tests and therapies depended upon high levels of human TSH.

However, there was not enough natural product available from human pituitaries collected at autopsies. Furthermore, even if available, the human pituitaries had been found to be contaminated with viruses. As a result, the regulatory authorities had forbidden the use of the natural product for any human diagnostic or therapeutic studies.

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The diagnosis and treatment of thyroid cancer now involves cloning the gene for TSH and using it to make *recombinant* TSH. Recombinant TSH means making TSH by cloning the gene. TSH is now available in large quantities and is uncontaminated with viruses or other byproducts of collecting human pituitaries from autopsies. The recombinant TSH is used to achieve maximal uptake of radioactive iodine into the tumor for both diagnosis and treatment.

Although the exact cost of bringing this specific treatment from concept all the way to FDA approval has not been disclosed, a figure anywhere near the DiMasi et al. estimated average would represent a significant investment and substantial risk of capital. By virtue of the temporary monopoly, patents let companies at least recoup the high cost of R&D, thus giving companies an incentive to invest in new drugs and laboratory tests.

What in the way of DNA-related inventions can be patented? You cannot patent an idea, but rather a practical application of that idea. In the language of the statute, anyone who "invents or discovers" a "process, machine, manufacture, or composition of matter" or "improvement thereof" may obtain a patent. These statutory classes of subject matter taken together include, in the words of the legislative history of the 1952 Patent Act, "anything under the sun that is made by man," plus processes for making the products. Accordingly, subject matter of DNA inventions would typically be eligible for patent protection if it is made by man, i.e., if it is manmade, as opposed to being simply a product of nature.

Products of nature cannot be patented because they are not "made by man." Nevertheless, we can patent natural substances, provided that they are "isolated and purified," because they do not occur in that form in nature. U.S. Patent No. 4,703,008, a representative patent, is directed to a purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin (EPO). EPO is a drug that increases red blood cells. It is prescribed to patients with cancer undergoing chemotherapy, because the chemotherapy tends to cause the red blood cells of the patients to decrease thus making the patients who are already suffering from cancer anemic and weak. The EPO restores the red blood cells to normal.

The United States Patent and Trademark Office (USPTO) takes the position that an isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is

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eligible for a patent because that DNA molecule does not occur in that purified or isolated form in nature.[4] EPO is one such gene. Accordingly, you cannot patent a gene per se that is present in a human body, only an "isolated and purified" gene in a test tube.

The steps for obtaining a patent for a DNA invention require describing the invention in a patent application, including teaching how to make and use the invention (formal requirements). But to meet the substantive conditions for patentability, an invention must also be novel and nonobvious. Novelty means the invention must be *new* (i.e., original), as well as not being precluded from patenting by what is defined in the patent law as a "statutory bar." For example, an invention cannot be patented if the invention is publicly disclosed (such as by publication of a manuscript) or commercialized (such as by offer for sale). The U.S. provides a grace period of one year before such statutory bars come into play.

Even if the subject matter sought to be patented is novel and involves one or more differences from the prior art, a patent may still be refused if the differences would be obvious. In other words, the subject matter sought to be patented must be sufficiently different from what has come before to a person having ordinary skill in the art to be nonobvious. For example, in the original obviousness case decided by the Supreme Court of the United States in 1850, the substitution of porcelain for wood to make a doorknob was deemed to be unpatentable.[5] The prior art was a wood doorknob. Even though the porcelain doorknob invention was novel in view of this prior art doorknob, it was nevertheless unpatentable because it would have been obvious to substitute porcelain for wood in a doorknob.

Patenting and Licensing DNA Inventions from Basic Research Programs

In general terms, DNA inventions (perhaps more appropriately termed as genomic inventions) arising from basic research programs can be thought to include a wide variety of technologies and materials: cDNAs, expressed sequence tags, haplotypes, antisense molecules, small interfering RNAs, full-length genes, etc.[6] The commercial use of these sequences can involve nucleic acid-based diagnostics, potential gene therapy applications, the development of new DNA and RNA, as well as the expression products themselves—the basis for the founding of the biotechnology industry.

Patenting and technology commercialization programs (such as licensing) at basic research organizations provide a means for getting new DNA inventions to the market for

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public use and benefit. With this public and commercial use of DNA inventions often comes new recognition of the value of basic research programs to the university or other organization that originated it. These inventions also serve as a helpful means to attract new R&D resources and partnerships to the laboratory. Through licensing or other technology transfer means, there is thus a return on investment whether that is measured in terms of financial, educational, or societal parameters or some combination thereof. Finally, there is an economic development aspect to the commercialization of DNA inventions via new job and company formation for the sale and delivery of innovative products.

A substantial portion of the DNA inventions that occurring at basic research programs arises from research that is federally funded. The Bayh-Dole Act of 1980[7] allows such grantees and contractors to retain ownership in subject inventions made using federal funds, seek patent protection on these inventions, and license these inventions with the goal of promoting their utilization, commercialization, and public availability. In 1986, federal laboratories were given a statutory mandate under the Federal Technology Transfer Act[8] and Executive Order 12591 to ensure that new technologies developed in federal laboratories were transferred to the private sector and commercialized.

Commercialization of DNA inventions from nonprofit basic research institutions typically follows a multistep process as academic and federal laboratories typically do not provide, nor have the means to provide, commercialization of the technology themselves. A contractual agreement (typically a license) is created to give permission to use DNA patents, materials, or assets to bring a product concept to market. Financial consideration or other benefits are received by the research institution in exchange through what is often an agreement with a small company that will bring in a large corporate partner later in development.

Patent and Licensing Practices for DNA Inventions

Thus for research institutions, commercial applications or reasonable expectations of commercial applications are the key driver in determining how to effectively handle patenting and licensing of DNA inventions. However, explicit commercial applications are not always clear at the early development stages for such inventions. At the early stages

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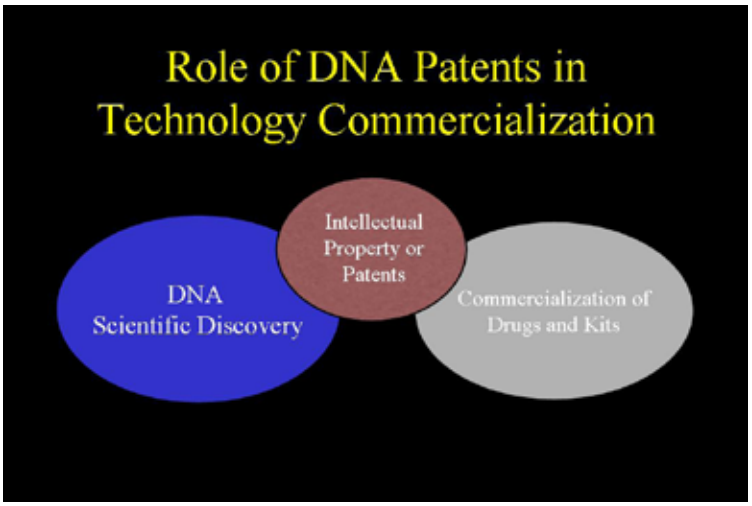
of this process, patent protection for DNA inventions is generally sought when significant further R&D by the private sector is required to bring the invention to market, such as in the examples of TSH and EPO previously described and shown in a general nature in Figure 1.

Figure 1: Role of DNA Patents in Technology Commercialization



In contrast, when significant research and development are not required for DNA inventions, patent protection is likely not needed—such as is often the case for research materials and research tool applications. For example, for a DNA invention where publication alone is sufficient for dissemination and commercialization, patent protection may be an unnecessary expense and not valued by licensees. When patent protection is obtained, it is possible for basic research institutions to discern those applications that absolutely require exclusive licensing to attract investment and risk capital from those that may not.

The Invention: DNA Encoding the Protein NAIL

Given the importance of patents and licensing to achieve commercialization of DNA inventions, what is the impact of *Kubin* on basic research institutions? The invention claimed in the 1999 patent application, naming *Kubin* and Goodwin as inventors, was related to cloned and sequenced DNA encoding the protein NAIL (*n*atural killer-cell *a*ctivation *i*nducing *l*igand). NAIL is useful for regulation of the immune response. Figure 2 illustrates the protein sequence (discussed below) of NAIL.[9] The sequence for NAIL goes from 1 to 365 and reads as depicted in Figure 2.

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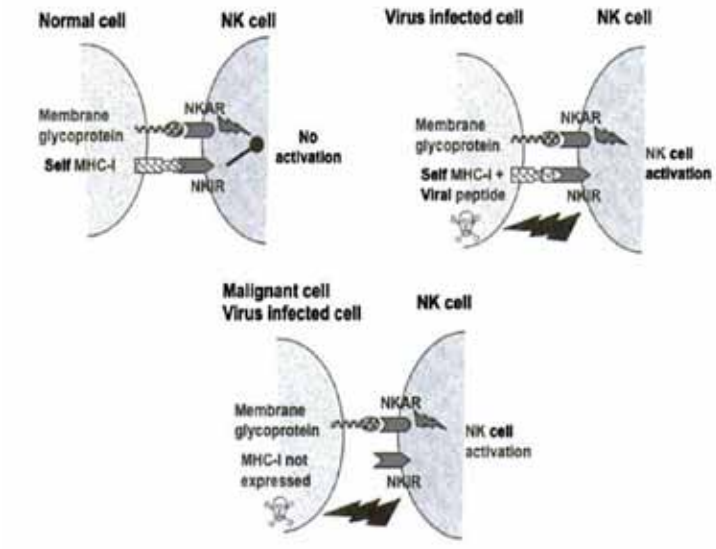
Figure 2: The Kubin *Invention: DNA Encoding the Protein NAIL*

```
  1  MLGQVVTLIL LLLLKVYQGK GCQGSADHVV SISGVPLQLQ PNSIQTKVDS
 51  IAWKKLLPSQ NGFHHILKWE NGSLPSNTSN DRFSFIVKNL SLLIKAAQQQ
101  DSGLYCLEVT SISGKVQTAT FQVFVFDKVE KPRLQGQGKI LDRGRCQVAL
151  SCLVSRDGNV SYAWYRGSKL IQTAGNLTYL DEEVDINGTH TYTCNVSNPV
201  SWESHTLNLT QDCQNAHQEF RFWPFLVIIV ILSALFLGTL ACFCVWRRKR
251  KEKQSETSPK EFLTIYEDVK DLKTRRNHEQ EQTFPGGGST IYSMIQSQSS
301  APTSQEPAYT LYSLIQPSRK SGSRKRNHSP SFNSTIYEVI GKSQPKAQNP
351  ARLSRKELEN FDVYS   (SEQ ID NO:2)
```

Turning to biology, Figure 3 illustrates the mechanism of target cell recognition by natural killer (NK) cells.[10] The activation or lack of activation of cell-killing pathways depends upon the balance between activating receptors (NKAR, which interacts with cellular glycoproteins) and inhibitory receptors (NKIR, which interacts with self-major histocompatibility complex MHC-1 molecules). If the inhibitory receptor is not triggered (due to either lack of interaction of the inhibitory receptor with MHC-1 self molecules or lack of expression of MHC-1 molecules on the cell membrane), stimulatory activity prevails and the target cell is killed.

Figure 3: Mechanism of Target Cell Recognition by Natural Killer Cells



Adapted/reproduced from Virginia M. Litwin (2007). Originally published in Medical Immunology. *Refer to Note 10.*

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The first panel of Figure 3 illustrates no activation. Here, in the normal cell, the inhibitory receptor is triggered (due to both interaction of the NKIR inhibitory receptor with self MHC-1 molecules and expression of MHC-1 molecules on the cell membrane), thus the cell-killing pathway is not activated.

The second panel of Figure 3 illustrates NK cell activation by a virus-infected cell. Here, in the virus-infected cell, the inhibitory receptor is not triggered (due to lack of interaction of the NKIR inhibitory receptor with self MHC-1 molecules), thus stimulatory activity prevails and the target cell is killed, depicted by the skull and crossbones symbol.

The third panel of Figure 3 illustrates NK cell activation by a malignant cell. Here, in the malignant cell, the inhibitory receptor is not triggered (due to lack of expression of MHC-1 molecules on the cell membrane), thus stimulatory activity prevails and the target cell is killed, depicted, again, by the skull and crossbones symbol.

Putting it all together, the *Kubin* invention is related to a NKAR activating receptor, called NAIL, which interacts with a membrane glycoprotein, called CD48. NAIL maintains a balance with a NKIR inhibitory receptor, which interacts with a MHC-1 like-ligand. NAIL kills target cells that are virus-infected or malignant due to lack of interaction of NKIR and ligand (skull and crossbones).

Concluding with the science of DNA, Figure 4 illustrates the central dogma of molecular biology.[11] According to the dogma, and as depicted in the living cell illustrated in Figure 4, DNA is made into RNA, and RNA is made into protein. DNA is short for deoxyribonucleic acid, RNA is short for ribonucleic acid, and protein, of course, is the basic building block of all living cells. The terms *gene* and *DNA* are used interchangeably, because a gene is a piece of DNA. Accordingly, one gene makes one protein. Referring to the amino acid chain in Figure 4, a protein, by definition, is a chain of amino acids.

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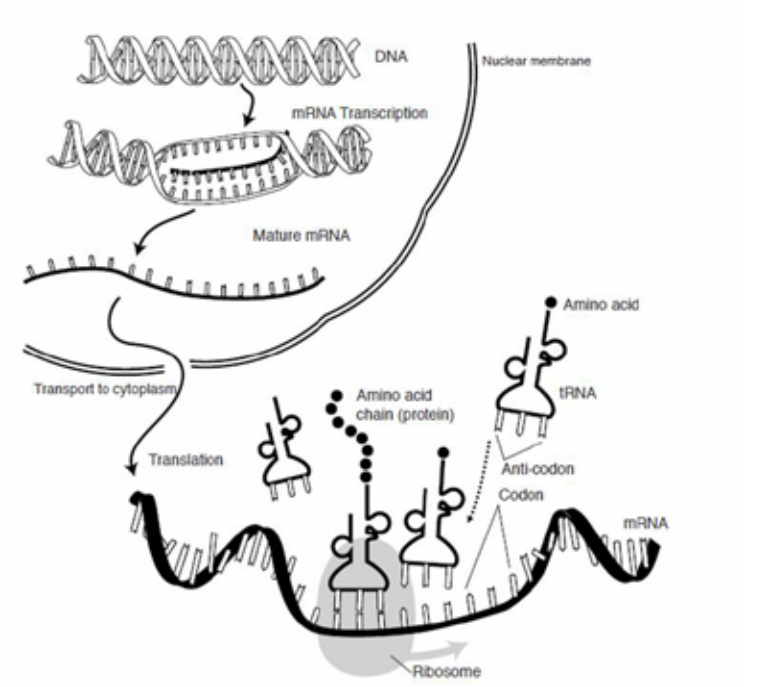
Figure 4: The Central Dogma of Molecular Biology = DNA → RNA → Protein.



There are a total of 20 separate naturally occurring amino acids. Any standard textbook lists the amino acids and provides their three-letter and one-letter abbreviations. Each type of protein has a unique sequence of amino acids, and there are thousands of different proteins, each with its own particular amino acid sequence. You can deduce the protein sequence from the DNA sequence. You cannot, however, deduce the natural DNA sequence from the protein sequence (due to redundancy of the genetic code, i.e., more than one triplet of DNA bases can encode the same amino acid).

Returning now to Figure 2, it illustrates the amino acid sequence of NAIL. The sequence is 365 amino acids long. The first amino acid in this sequence reads M, which stands for methionine, with the three-letter abbreviation being Met and the one letter abbreviation being M. Next in the sequence comes L, which stands for leucine, with the three-letter abbreviation being Leu, and the one-letter abbreviation being L. Then comes G in the sequence, which stands for glycine, with the three-letter abbreviation being Gly, and the one-letter abbreviation being G. Using these first three amino acids as illustrations, you can now understand the order, or sequence, of amino acids in NAIL.

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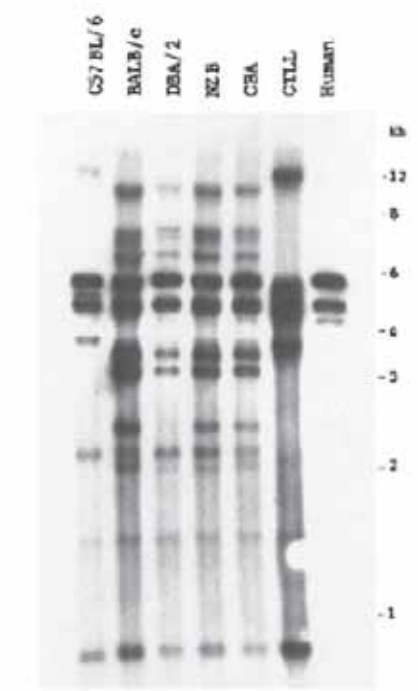
The Prior Art: Maniatis Laboratory Manual and a Protein Band on a Gel

The first of three pieces of prior art in the *Kubin* case was *Molecular Cloning: A Laboratory Manual* by Sambrook, Fritsch, and Maniatis (2d ed. 1989).[12] This is the Maniatis laboratory manual, so-called for the last named author. It is considered by many to be a cookbook for cloning genes.

The second piece of prior art was Mathew et al., *J. Immunol.* 151 (1993): 5328-5337 (Mathew article), as illustrated by the representative drawing reproduced in Figure 5.[13] The prior discovery in the Mathew article was related to a NKAR activating receptor in the mouse, called 2B4. The mouse 2B4 gene was cloned and sequenced. The genomic DNA blot analysis shown in Figure 5 identified a human homologue, or counterpart, of the mouse 2B4 gene (lane "human").[14] The human homologue turned out to be NAIL, but the gene was split (two bands) and was neither cloned nor sequenced.

Figure 5: The Kubin *Prior Art: Mathew Article (1993)*

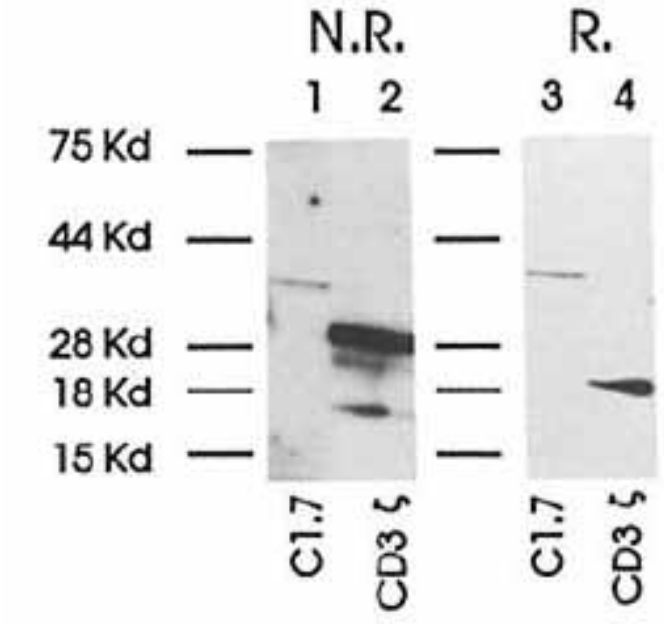


© 1993 The American Association of Immunologists Inc. Originally published in The Journal of Immunology. *Refer to Note 13.*

The third piece of prior art was U.S. Patent No. 5,688,690, to Valiante and Trinchieri (Valiante patent), as illustrated by the representative drawing reproduced in Figure 6, although the drawing actually appeared in the authors' publication (published within the one-year grace period) and was merely described in the Valiante patent.[15] This other prior discovery in the Valiante patent was related to a NKAR activating receptor in the human, called P38.

The immunoblot analysis shown in Figure 6 of human NK cells probed with a monoclonal antibody (mAb C1.7), which was generated against human NK cells and mediated cell killing, identified a NKAR having a molecular weight of 38 kD (lanes 1 and 3).[16] It is true that the NKAR protein was separated from nature as a band on a gel. The NKAR protein weighing 38 kD, called P38, turned out to be NAIL. But the NAIL gene was never cloned or sequenced. To repeat, and in contrast, the *Kubin* invention is related to the cloning and sequencing of the gene for NAIL.

Figure 6: The Kubin *Prior Art: Valiante and Trinchieri Paper (1993)*



© Valiante and Trinchieri, 1993. Originally published in The Journal of Experimental Medicine. *Refer to Note 15.*

Binding Legal Precedent for DNA Inventions: *In re Deuel*

To determine whether the invention is patentable over the prior art, a court needs to conduct a factual and legal analysis. Additionally, under the theory of consistency in the law, known as *stare decisis,* the court must also follow binding legal precedent. In other words, a case must be decided the same way when the legally relevant facts are the same or substantially similar. Here, the binding legal precedent was *In re Deuel*, decided previously by the Federal Circuit in 1995.[17]

In *In re Deuel,* the invention was related to cloned and sequenced DNA encoding the protein HBGF (heparin binding growth factor). HBGF is useful for stimulating cell division and, thus, wound healing. Figure 7 illustrates the amino acid sequence of HBGF.[18] The sequence for HBGF goes from 1 to 168 and reads as depicted in Figure 7.

Figure 7: The Deuel *Invention: DNA Encoding the Protein HBGF*

```
Met Gln Ala Gln Gln Tyr Gln Gln Gln Arg Arg Lys Phe Ala Ala   15
Ala Phe Leu Ala Phe Ile Phe Ile Leu Ala Ala Val Asp Thr Ala   30
Glu Ala Gly Lys Lys Glu Lys Pro Glu Lys Lys Val Lys Lys Ser   45
Asp Cys Gly Glu Trp Gln Trp Ser Val Cys Val Pro Thr Ser Gly   60
Asp Cys Gly Leu Gly Thr Arg Glu Gly Thr Arg Thr Gly Ala Glu   75
Cys Lys Gln Thr Met Lys Thr Gln Arg Cys Lys Ile Pro Cys Asn   90
Trp Lys Lys Gln Phe Gly Ala Glu Cys Lys Tyr Gln Phe Gln Ala  105
Trp Gly Glu Cys Asp Leu Asn Thr Ala Leu Lys Thr Arg Thr Gly  120
Ser Leu Lys Arg Ala Leu His Asn Ala Glu Cys Gln Lys Thr Val  135
Thr Ile Ser Lys Pro Cys Gly Lys Leu Thr Lys Pro Lys Pro Gln  150
Ala Glu Ser Lys Lys Lys Lys Lys Glu Gly Lys Lys Gln Glu Lys  165
Met Leu Asp                                                 168
```

The first of two pieces of prior art in the *Deuel* case was *Molecular Cloning: A Laboratory Manual* by Maniatis, Fritsch, and Sambrook (1982).[19] This was the Maniatis laboratory manual previously noted, but in its first edition.

The second piece of prior art was European Patent Application No. 0 326 075, naming Bohlen and Gautschi-Sova as inventors (the Bohlen application), as illustrated by the representative drawing reproduced in Figure 8. This prior discovery in the Bohlen application was related to a HBGF in the cow, because the SDS-PAGE analysis shown in Figure 8 identified a bovine, or cow, HBGF having a molecular weight of 18 kD (lane 2).

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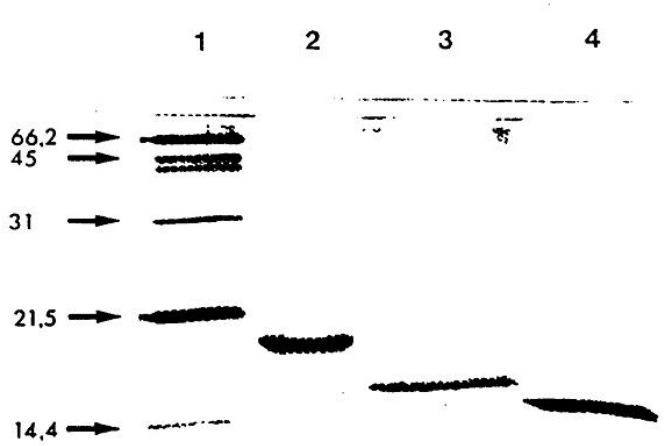
A human homologue of the bovine HBGF protein was also identified. A total of 19 amino acids were determined (amino acid 33 to 51 in Figure 7) for HBGF, which were found to be identical for human and bovine HBGFs. It is true that both the bovine and human HBGF protein had been separated from nature as a band on a gel. But neither the bovine nor human HBGF gene had been cloned or sequenced. To reiterate, and in contrast, the *Deuel* invention was related to the cloning and sequencing of the gene for HBGF.

Figure 8: The Deuel *Prior Art: Bohlen Application*



In re Deuel stands for the *old rule* that had guided the patenting of DNA for many years, specifically, that the existence of a general method of isolating DNA molecules is essentially irrelevant to the question of whether the specific molecules themselves would have been obvious and, thus, unpatentable. The Federal Circuit in *Deuel* reasoned that the applicant did not claim a method, but instead compositions. Accordingly, the issue was the obviousness of the claimed compositions, not the obviousness of the method by which those compositions were made. Therefore, a cookbook for cloning genes and a protein band found on a gel did not make the DNA sequence encoding the protein unpatentable (i.e., obvious).

In re Kubin: The Decision

Despite the legally relevant facts being essentially the same, the Federal Circuit did not decide *In re Kubin* the same way as *In re Deuel. Kubin* took the position that, in *KSR International Co. v. Teleflex Inc.,*[20] the United States Supreme Court had discredited

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the old rule of *Deuel*. While the Supreme Court did indeed seem to discredit one ruling of *Deuel* that "obvious to try" does not itself alone constitute obviousness, the Supreme Court did not discredit the other old rule of *Deuel* that the patentability of the sequence of the DNA molecule itself is unrelated to the method by which the gene is cloned. Nevertheless, the Federal Circuit panel in *Kubin* effectively overruled *Deuel*.

The Federal Circuit panel in *Kubin* concluded that the existence of a general method of isolating a DNA molecule is relevant to the question of whether the DNA molecule itself would have been obvious. So the obviousness of the method by which the gene is cloned could make the gene itself obvious. Continuing, the panel reasoned that it would have been "obvious to try" using the Maniatis laboratory manual. Additionally, there would have been a "reasonable expectation of success" in cloning the gene. This is because of an increased level of skill in the art (i.e., nucleic acid research) since *Deuel* was decided in 1995.

Therefore, a cookbook for cloning genes and a protein band found on a gel in the opinion of the Federal Circuit panel did indeed make the DNA sequence encoding the NAIL protein unpatentable (i.e., obvious). Because neither the United States Supreme Court nor the Federal Circuit itself (in an en banc decision of the entire court) reversesed this ruling by the *Kubin* panel, "the existence of a general method of isolating a DNA molecule is relevant to the question of whether the DNA molecule itself would have been obvious" will now be the new rule. In view of this panel decision, the question for many is whether the skill in the art in the laboratory has indeed progressed so far and what might be the implications for development and commercialization of inventions coming from basic research.

Commentary and Discussion for the Future

Try to imagine the amino acid sequence of NAIL, knowing that it is 365 amino acids long and that there are 20 amino acid choices at each position. The number of possibilities can be calculated mathematically. You have a 365 amino acid protein, and 20 choices for each amino acid, so there will be 20 to the power of 364 possibilities. Do not count the first amino acid because it is always Met. That is 20 times itself 364 times. This is a really big number, perhaps so big as to exceed the total number of particles in the universe!

In comparison to mouse NAIL, human NAIL turned out to show 54 percent amino acid identity, but which amino acids were identical was impossible to know until after the

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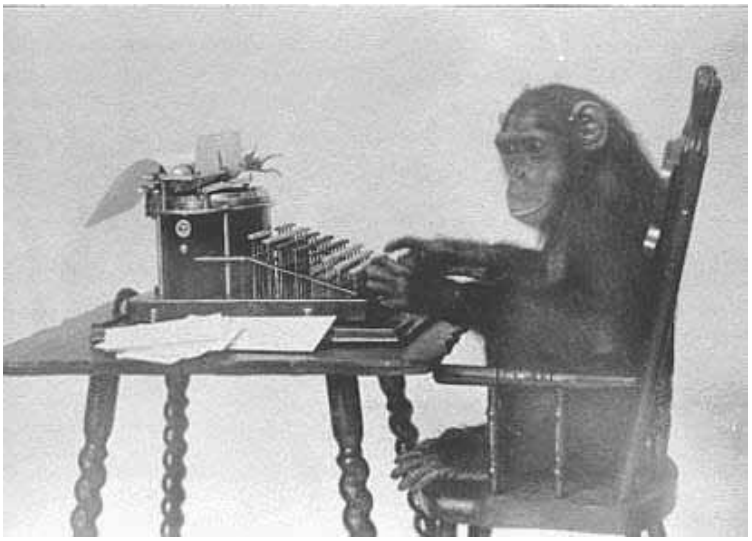
gene for NAIL was cloned. If you have an infinite number of monkeys sitting at an infinite number of typewriters for an infinite number of years typing at random then one would eventually type the entire works of Shakespeare (Figure 9). By analogy, given an infinite number of trials, you would eventually come up with the amino acid sequence of NAIL. Yet, creating an invention in the face of a nearly infinite number of possibilities is the first class of situations that the *Kubin* court agreed would *not* give rise to obviousness.

Figure 9: DNA Obviousness after Kubin*?*



Public domain photograph from Wikipedia

Emerson wrote: Build a better mousetrap, and the world will beat a path to your door. You cannot, however, patent an idea, e.g., the idea of building a better mousetrap. But you can patent a practical application of that idea, for instance, the actual prototype snap-trap mousetrap itself. Sure, "obviously" many scientists would have wanted to sequence the gene (a good idea), and the protocols for doing so apparently existed (Maniatis laboratory manual), but *Kubin* was first to actually sequence the gene. [21] And a form of invention, the result of exploring a general technology giving only generic guidelines and generalized instructions, is the second class of situations that the *Kubin* court agreed would *not* support obviousness.

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How do you reconcile the *Kubin* invention as falling into both of these two classes of situations that would *not* give rise to obviousness and as being ruled obvious? You scotch any precedent for the new rule. Is this new rule desirable when many economists believe that patents stimulate investment by fixing the "copying" problem so that a company can recover the cost of development, which for a new drug based upon a gene or other discovery to go from concept to FDA approval is cited to be on average $802 million?

Most all genes are cloned by the Maniatis laboratory manual. Most all chemical compounds are prepared by conventional chemistry processes.[22] Most everything in mechanical engineering (ME) and electrical engineering (EE) is a combination of well-known components. Under the reasoning of *Kubin*, gene sequence inventions, chemical compound inventions, and ME/EE inventions could arguably be unpatentable. Again, is this reasoning based on *Kubin* (taken to an extreme) desirable, even if it would contravene the patenting of most inventions?

With reference to the recent H1N1 flu virus, there is a need for a vaccine. Yet published reports indicate that "[v]accines against novel influenza A (H1N1) virus infection are being produced using methods similar to those used for seasonal influenza vaccines."[23] Extending the reasoning of *Kubin* to vaccines being produced using methods similar to those used in the art for making earlier vaccines, this vaccine could arguably be unpatentable in the United States. Once again, is this tentative result desirable given the need to attract investment in the development of technologies such as these arising from basic research?

The issue for research institutions is not only currently filed DNA sequence inventions being arguably unpatentable, but also certain DNA sequence patents being arguably invalid now.

Table 1: Comparison of Relevant Kubin and Deuel Dates

Name of Court Decision	Date of Court Decision	Date of Maniatis Prior Art	Filing Date of Patent Application
In re Kubin	3 Apr 2009	1989	Eff F/D = 23 Mar 1999
In re Deuel	28 Mar 1995	1982	21 Jun 1990

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Referring to Table 1, DNA sequence patents filed after the filing date of the patent application of *Deuel*, June 21, 1990, are susceptible to invalidation. This is because, under the reasoning of *Kubin*, DNA is arguably obvious since *Deuel*.

Tips for Technology Transfer Officers at Basic Research Institutions

Assuming that *In re Kubin* remains good law, a university technology transfer office (TTO) that has a new DNA sequence invention could describe how to make and use the invention without citing the Maniatis laboratory manual for the procedure on cloning the gene. The TTO would still submit the sequence data, and then go ahead and cite the Maniatis laboratory manual for the protocol on how to make the DNA *given* this sequence. But then you must be prepared to argue that cloning the gene could not have followed the Maniatis laboratory manual and optionally provide objective indicia of nonobviousness.

Objective indicia of nonobviousness mean considerations demonstrating that the subject matter sought to be patented is sufficiently different from what has come before so that it may be said to be inventive to that "hypothetical" person having ordinary skill in the art. Some such indicators include recognition by others, commercial success, and long-felt need. Another good argument for patentability is that the prior art teaches away from the claimed invention.

For NAIL, you could have argued that the Mathew article was published 1993, and the original Valiante and Trinchieri paper was published 1993, too. By contrast, the effective filing date of the *Kubin* patent application was 1999. That is six years after each of these references became public. If it was so obvious, why did it take six years to clone the NAIL gene? Additionally, you could have run the experiments to show that cloning the NAIL gene could not have followed the prior art, that using NK cells as a starting material failed, that using specially prepared NK cells activated by CD48 (or other nonobvious technique) was required to clone the NAIL gene. Finally, you could have argued unexpectedly superior properties of the NAIL gene.

The TTO might want to take a different approach by arguing that the *Kubin* lawyers lost based on a technicality. The argument goes that the prior art Valiante patent was unusually close to the *Kubin* invention, because the Valiante patent described the encoded protein band on a gel, prophetically applied the Maniatis laboratory manual to the problem

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of cloning the gene in Example 12, and made publicly available the very tool (mAb C1.7) for carrying out the method of cloning the gene. If the judges ruled narrowly in the *Kubin* case, then details that do not hew closely to the *Kubin* facts should save the research institution's DNA inventions from obviousness and unpatentability.

Although *Kubin* may have an adverse effect on the patenting of long-patentable genes, method-of-use patents should still be viable. Basic research institutions could offset *Kubin* by better identification of the function and use of the encoded proteins and focusing the patenting process on those properties and activities. Readers of *Kubin* may counter that the Federal Circuit seemed to find a biological feature that distinguished over the prior art (binding CD48) inherent to NAIL, thus not only was the product still obvious but also methods involving "inherent" biological features might also be unpatentable.

The rebuttal is that a method-of-use claim (e.g., administering NAIL to bind CD48), as opposed to a patent on a product, would be patentable, because a new and nonobvious use of even a known compound may be patentable over the prior art. Yes, method-of-use patents may be narrower than patents on the corresponding products. But the judiciary has apparently constrained the reach of Constitutionally authorized rewards for DNA sequence inventions.

Implications for Biotechnology Development

Under the central dogma of molecular biology, DNA sequence information has been everything. Under *Kubin*, DNA sequence inventions may arguably be unpatentable now. Perhaps the demise of the patenting of DNA inventions can be considered not a sea change but rather a reflection that molecular biology has evolved and advanced during past decades so that biotechnology itself has become more predictable. Various arguments (pro or con) from a scientific perspective can be made if indeed such "predictability" is now present or not, but it will be important to see if the U.S. Patent and Trademark Office and the courts extend such predictability to other requirements for patenting DNA inventions such as the "written description" and "enablement" of these inventions in a patent application.

Even with changing standards for patent protection, obtaining patents for DNA inventions remains a necessity for basic research institutions to attract private-sector firms to invest

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in these inventions to make new preventive, diagnostic, and therapeutic products. Thus by careful and prudent management of DNA inventions in their portfolio along the lines described above, these institutions should still be able to reach their goal of having new health-care treatments and services reach the public.

For more information on patents, see Volume 3 of the 3rd Edition of the Association of University Technology Managers Technology Transfer Practice Manual. *See also the chapter entitled "Understanding Patent Preparation and Prosecution," by Matthew S. Rudd, JD, and William E. McCracken, JD, in Volume 4.*

Notes

1. *In re Kubin,* 561 F.3d 1351 (Fed. Cir. 2009).
2. Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The price of innovation: New estimates of drug development costs," *Journal of Health Economics* 22 (2003): 151-185.
3. U.S. Patent No. 6,284,491.
4. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).
5. *Hotchkiss v. Greenwood,* 52 U.S. 248 (1851).
6. Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18413 (Apr. 11, 2005).
7. Pub. L. No. 96-517, now codified in 35 U.S.C. §§ 200-212. Regulations for implementing the Bayh-Dole Act are found at 37 C.F.R. §§ 401.1-401.17.
8. Pub. L. No. 99-502.
9. U.S. Patent Application No. 09/667,859.
10. Virginia M. Litwin, "Lymphocyte Ontogeny and Membrane Markers," in *Medical Immunology,* ed. Gabriel Virella (New York, N.Y.: Informa Healthcare USA, Inc., 6th ed. 2007), 113-134.
11. National Human Genome Research Institute, "Talking Glossary of Genetics," April 29, 2009, http://www.genome.gov/glossary/.
12. Joseph Sambrook, Edward F. Fritsch, and Thomas Maniatis, *Molecular Cloning: A Laboratory Manual* (Cold Spring Harbor, N.Y.: Cold Spring Harbor Laboratory, 2d ed. 1989).

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13. Porunelloor A. Mathew, Beth A. Garni-Wagner, Kevin Land, Akira Takashima, Earl Stoneman, Michael Bennett, and Vinay Kumar, "Cloning and characterization of the 2B4 gene encoding a molecule associated with non-MHC-restricted killing mediated by activated natural killer cells and T cells," *J Immunol.* 151 (1993): 5328-5337.
14. This is not the intact gene, because NAIL was apparently a so-called split gene and thus appeared as more than one band (two bands) on the gel.
15. Nicholas M. Valiante and Giorgio Trinchieri, "Identification of a novel signal transduction surface molecule on human cytotoxic lymphocytes," *J Exp Med.* 178 (1993): 1397-1406.
16. Because NAIL was separated as a protein band on a gel, the protein was in the prior art.
17. *In re Deuel,* 51 F.3d 1552 (Fed. Cir. 1995).
18. U.S. Patent Application No. 07/542,232.
19. Thomas Maniatis, Edward F. Fritsch, and Joseph Sambrook, *Molecular Cloning: A Laboratory Manual* (Cold Spring Harbor, N.Y.: Cold Spring Harbor Laboratory, 1982).
20. *KSR International Co. v. Teleflex Inc.,* 550 U.S. 398 (2007).
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Policies and Procedures for the Distribution of Licensing Income

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Each technology transfer office has its own policies and procedures for distributing licensing or royalty income to inventors and their departments. Taking care of this administrative task in a fair, consistent, and timely manner may not generate accolades from recipients of the income. However, failure to distribute licensing income properly will likely generate unfavorable responses from the stakeholders of the income. This chapter provides a framework to help technology transfer professionals smoothly carry out this important task.

Legislative Rational for Distributing Licensing Income

Congress passed two acts in 1980 that created much of the potential for the transfer of federally funded inventions out of universities, nonprofit research institutions, and federally owned laboratories. The Stevenson-Wydler Act (P.L. 96-480) set the foundation for commercialization of innovations within federal agencies and their laboratories. The Bayh-Dole Act (P.L 96-517) followed, which allows universities and research institutions to take ownership of federally funded inventions for the purpose of transferring them to industry.

These acts permit the receipt of licensing income from industry in exchange for the rights to use the intellectual property. However, the acts vary in their provisions concerning how that licensing income should be used or distributed. The Stevenson-Wydler Act specifies that the federal agency must share at least 15 percent of the licensing income received with the inventors for their own personal use. Additionally, each inventor's share of licensing income is capped at $150,000 per year. The Bayh-Dole Act also requires that universities must share licensing income with inventors, but does not specify any minimum or maximum percentage or specific amount to be shared.

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Practical Rationale for Distributing Licensing Income

Most company employees do not have the opportunity to receive a significant share of income resulting from their inventions. In high technology and biotechnology companies, employee innovation is often critical to the success of the companies, and employees are expected to innovate as part of their work. Although innovative employees may receive bonuses or awards, no additional compensation may be expected even if their inventions are blockbusters for their companies.

This particular employment understanding does not work well in academia. Universities are nonprofit organizations and are not in the business of developing new products. Moreover, most university employees are not evaluated for promotion or tenure based on their number of inventions. Instead, the focus is on publications, research support, and teaching. Therefore, the potential for receiving a share of licensing income is an additional inducement beyond traditional academic activities to encourage university employees and their departments to participate in the technology transfer process.

Intellectual Property Policies

Most organizations have written policies detailing many of the obligations expected of employees. These policies may be bundled into a single employee handbook or may be kept as separate documents. It is important that employees be provided with a copy of the policies and asked to review them as part of their employment. Intellectual property policies govern, among other things, the ownership of intellectual property that is generated by university employees as well as how licensing income will be shared with the employees and departments. An institution may have a single intellectual property policy or may have multiple policies that deal with various aspects of technology transfer.

For example, Virginia Commonwealth University (VCU) uses a single policy that governs most of the technology transfer office's activities.[1] On the other hand, University of California has separate policies that deal with commercialization of patents and copyrights and acceptance of equity from licensees.[2] In any case, the university's intellectual property policy should clearly describe how licensing income is to be distributed. The remainder of this chapter will discuss many of the details that should be included in the policy.

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For more on intellectual property policies, including samples, see volumes 2 and 3 of the AUTM Technology Transfer Practice Manual, 3rd Edition.

Licensing Income Defined

Before a technology transfer office can distribute licensing income/royalties that it receives from a licensee, it must define what will be considered licensing income. For the purposes of this chapter and for many institutions, the terms *licensing income* and *royalties* are used interchangeably. At VCU, gross licensing income is defined as the following:

> Anything of value received by the University, including cash payments as well as the market value of any property or services received, in consideration for a transfer of rights and/or title to Intellectual Property in which the University claims an interest. Funds received by the University to support research that results in the development of Intellectual Property is not royalty income.

Note that licensing income is consideration that is received in exchange for granting rights to the licensed technology. License agreements are sometimes executed along with research agreements that fund further development of the technologies within the university. These agreements should clearly distinguish between cash received for research and development of technologies and cash received in exchange for access to intellectual property. Because universities have a fiduciary responsibility to distribute the appropriate portion of license income to inventors, university officials should avoid executing research contracts that appear to trade the potential to receive licensing income for sponsored research funding. In *Singer v. Regents*, the University of California ran into this issue with the courts finding that universities don't have the right to trade the inventors' share of license income for research funds.[3]

As VCU's definition of licensing income above suggests, licensing income may be in the form of noncash payments. Ownership shares in the licensee are common for many licenses to newly formed companies. If the company is successful (e.g., acquired by another company, goes public through an initial public offering, etc.) this equity consideration could be quite valuable. The topic of equity distribution is specifically discussed below. Other forms of licensing income consideration, including tangible and intangible property, are

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less common in university license agreements. Before agreeing to accept such forms of consideration, it is best practice to have a plan of how to convert such property into cash for distribution.

Distribution of Gross vs. Net Licensing Income

An institution may incur expenses directly associated with a licensed technology before or after it is licensed. It is common practice to deduct these expenses from licensing income before distribution. Some of the most common expenses are associated with patent prosecution, copyright, and trademark registration protection. There are several other direct expenses that may also be deducted from licensing income, including, but not limited to, marketing fees charged by outside consultants; advertising fees for posting technology summaries; attorney fees for the drafting, negotiation, and maintenance of license agreements; and royalty audit charges. Indirect costs, such as technology transfer personnel salaries or the purchase or lease of office equipment, generally are not deducted from license income.

Each technology transfer office, based on how it is structured and incurs these direct costs, should determine what costs may be deducted from the licensing income prior to distribution. Some institutions employ in-house patent counsel and agents that take care of the majority of patent drafting and filing, while other offices only use outside patent counsel for such activities. An office that uses both internal and external patent counsel for initial patent filings may decide not to deduct any initial patent filing costs from licensing income, or deduct a standard charge, in order to treat all inventions in the same manner. No matter how costs are treated, it is important that the calculation of net licensing income is consistent and appears objective to the inventors. Most importantly, the definition and calculation of net licensing income should be clearly described in an intellectual property policy or similar document.

An intellectual property policy may also detail what percentage of the gross licensing income will be used to reimburse the direct costs. For example, some institutions may chose to apply 100 percent of the gross licensing income toward these expenses until they are fully reimbursed. The drawback of this strategy is that it may prolong the time that inven-

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tors have to wait to receive income distribution for a licensed technology.

This is especially true if there are patent costs that are not reimbursed by the licensee and the initial licensing fees are small. As discussed above, a practical purpose for distributing licensing income is to encourage inventor participation in the technology transfer process. VCU employs this philosophy by applying up to 66 percent of the licensing income to reimburse costs and distributing the remaining 33 percent (or more) so that the inventors get some money shortly after the technology transfer office receives it.

Parties to the Distribution

The intellectual property policy should specify all the parties that may receive a percentage of the licensing income. Many universities distribute some of the income to the inventor's affiliated departments and/or schools. Other organizations, including research institutes, may not distribute to departments because of their organizational structure or simply because they chose not to.

The Institution/Technology Transfer Office

Most institutions retain some portion of licensing income to use for a variety of purposes. If the total licensing income for a technology transfer office is low or moderate, these retained funds may be used to supplement the funding of operations or technology transfer-specific initiatives. The Stevenson-Wydler Act encourages federal agencies and laboratories to use some of its retained licensing income to promote entrepreneurship among their employees. Many offices have created successful technology maturation or gap-funding programs that help inventors further develop early-stage technologies to make them more attractive to potential licensees. These funding programs may yield significant returns on investment by increasing the value of early-stage university technology prior to licensure.

Alternatively, technology transfer offices that receive higher levels of licensing income may transfer those funds into their institutions for other purposes, including most of it into the institutions' general funds. This money may be used for institutional projects, including new faculty startup packages, research funds, endowed chair positions, and even to build new research and teaching buildings.
The Stevenson-Wylder Act encourages federal laboratories to use some of the retained

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licensing income to reward employees for scientific and technical developments even though such developments may be classified or sensitive and, thus, not transferrable through the classic technology transfer mechanisms. In these cases, the intellectual property policy may not necessarily need to address how much money needs to be transferred into the institution from the technology transfer office. Such a decision may come directly from the institution's president, director, or its board of visitors.

Technology transfer offices that are separate legal entities from their institutions do not necessarily complicate the distribution. These offices may be nonprofit foundations or may be for-profit entities that manage most of the technology transfer process for the institution. These types of offices may require a separate contractual understanding, which will lay out the percentage to be retained by the office before being distributed to all parties in the institution.

Inventors, Authors, and Contributors

The technology transfer office should ensure that distribution of licensing income to inventors is consistent and fair. Failure to appropriately carry out this task may lead to inventor alienation from the official technology transfer process and loss of future intellectual property. An inventor who feels that he or she did not receive a fair share of income not only may withhold disclosure of future inventions, but may also actively discourage other faculty from working with technology transfer. The intellectual property policy should clearly spell out what percentage of licensing income the inventors should expect and when they should expect to receive it.

Universities widely vary in how much licensing income they share with inventors. In addition, some universities have sliding scales that decrease the percentage of license income shared with inventors as the income generated from a particular invention goes up. Lach and Schankerman[4] surveyed the distribution policies from 102 U.S. universities and compared that data with *AUTM Licensing Activity Survey*™ data collected in the 1990s. For that period and for universities without the sliding scale, they found that the average inventor's share was 41 percent with a range of 25 to 65 percent. They found a much wider range for universities that used a sliding scale to specify distribution with an expected average inventor's share of 51 percent.

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Lach and Schankerman also found that there is a positive correlation between the amount of total licensing income a university receives and the percentage of licensing income paid to inventors. This suggests that a generous licensing income-sharing policy encourages successful innovation and commercialization through technology transfer.

In addition, the authors suggest that the distribution policy may act as a sorting mechanism in the faculty-hiring process whereby faculty candidates who are more likely to develop valuable new technologies may seek to be hired by universities with the most generous sharing policies. It would be interesting to know if these correlations still hold true using more recent AUTM and author survey data. It would also be interesting to know if there is a correlation between total licensing income and the share of licensing income that goes to the inventor's lab.

Many institutions have policies that allow the inventors to collectively determine how the inventor's share for their technology will be divided among themselves rather than splitting the licensing income equally. This may allow for inventors/contributors with only minor contributions to technologies to be included in the invention disclosure without too many arguments amongst all the contributors. However, all inventors and contributors should consent in writing to any sharing arrangement other than an equal split. One of the drawbacks of this type of policy is that the inventors may not be able to decide on a split. In these cases, it may be helpful for the institution's intellectual property policy to state that, if the inventors cannot agree upon how to share the inventors' portion of the licensing income, then the income will be shared equally.

In addition to having a policy that specifies the percentage to be shared with inventors and authors of copyrights, institutions must decide if they will share licensing income with contributors who are not inventors or authors of technologies. A contributor, for example, might be an employee who did a lot of the non-inventive bench work behind a particular technology or oversaw the work of programmers writing code for a new software program. For universities, the Bayh-Dole Act only states that inventors should receive some licensing income. For federal laboratories, the Stevenson-Wydler Act does recognize that laboratories may consider compensating collaborators in addition to inventors.

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Departments and Schools

Distribution of a percentage of licensing income to the inventor's affiliated department and/or school helps to provide some recognition of the resources that may have been used in developing the licensed technology. In addition, departmental chairs and school deans may view technology transfer more favorably if they have an opportunity to receive some relatively unencumbered funds if their faculty, staff, or students develop commercially viable technologies. It may be beneficial to specifically target department chairs and school deans for technology transfer education and outreach activities so that they, in turn, may encourage their employees to submit invention disclosures.

Many successful technologies result from collaborations across departments or schools. Institutions that allow inventors to decide relative distribution among themselves should define in their policy how the departmental or school shares of licensing income are to be divided up for such collaborative inventions. For example, the departmental distribution may be proportional to the inventorship contribution or the policy may simply state the departmental shares will be divided equally.

Special Considerations

There are a number of situations, some of which are outside the control of the technology transfer office, that may affect the distribution of licensing income. Although it is not possible to discuss every situation, some of the more common examples are given below.

Changes to Intellectual Property Policies and Distribution Formulas

As a rule, policies of an organization require periodic review and, as necessary, modifications to clarify intent or adjust to changing times. Intellectual property policies are no exception. In fact, because intellectual property policies may be relatively new to the scene for many universities (many technology transfer offices were established in the 1980s and 1990s after the passage of the Bayh-Dole Act), there have been some recent growing pains associated with improving these policies.

A common modification is to adjust licensing income distribution formulas. Employees who may develop or already have developed valuable technologies have a vested interest in their institution's distribution formula. As such, it is a good idea to only change the distribution policy through the institution's policy approval process.

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In addition, policies should have a clause that states that they are subject to review and amendment according to the institution's approved procedures. If this sort of clause is not present in an institution's intellectual property policy and the institution amends the policy by lowering the percentage of license income to be shared with inventors, then inventors may be able to dispute this if they were hired before the change in policy.

This sort of situation occurred in a lawsuit[5] between Douglas Shaw, an inventor, and the University of California (UC). Between the time Shaw was hired and his development of new, commercially valuable strawberry strains, UC reduced the licensing income distributed to inventors in its intellectual property policy. Shaw was able to successfully persuade the court that he was hired under a binding contact that did not have a provision that stated it was subject to change by the university. The court determined that Shaw should receive the higher rate under the policy in place at the time of his hiring rather than the policy in place at time the invention was disclosed to UC.

Adherence to the intellectual property policy does not, however, prevent all the parties associated with a particular technology from agreeing to an alternate distribution formula for that particular invention. For example, the inventors may collectively decide that they want their portion of the licensing income to go back into the research program rather than to them personally. Inventors should be advised that there might still be tax implications associated with this forgone personal income. TechTransfer at University of Michigan has posted some tax guidelines for their inventors who are considering waiving their share of licensing income.[6]

Inventorship Disputes

A dispute between inventors has the potential to derail all the efforts of the technology transfer office in commercializing the invention. Inventorship disputes over license income distribution may develop over who is listed as an inventor and/or contributor on the invention disclosure and any resulting intellectual property or may come in the form of who contributed the most and should get the greater portion of licensing income.

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Determining who actually should be listed on an invention disclosure or patent application can be challenging if the researchers cannot agree. If a patent is involved, a patent attorney may be brought in to interview the researchers to determine who should be listed as an inventor on a patent. Although this costs money, it can add an element of objectivity to the discussion and will help to educate the researchers about inventorship. After determining who is an inventor, any contributors could be added to the disclosure by the inventors.

For those cases in which these issues still cannot be resolved, the researchers may use the dispute mechanisms in the intellectual property policy to try to resolve the misunderstanding. Having a clearly defined and impartial dispute mechanism built into the intellectual property policy may help avoid escalation of the dispute beyond the boundaries of the institution and into the courts. Many institutions, including VCU, have a standing dispute resolution committee made up of faculty and staff outside of the technology transfer office. These committees usually report their recommendations directly to the vice president for research, president, or similar senior official.

Distribution of Equity as Licensing Income

Many technology transfer offices accept equity ownership in some of the companies to which they license. Startup companies generally are much more willing to give equity rather than cash. In some cases, the initial equity received ends up being more valuable than other forms of consideration given in license agreements.

For example, Stanford's Office of Technology Licensing executed an exclusive license agreement in 1999 with a newly formed startup company named Google. In lieu of an upfront licensing fee, it accepted stock in the company. In 2004, Google went public, and the following year, Stanford sold Google stock for $336 million.[7] Although most technology transfer offices do not report such dramatic success in liquidating their equity holdings, many offices have been able sell some of their equity holdings once they become public or have realized gains when the licensee was purchased by a third party.
Acceptance of equity in startup licensees poses a challenge in licensing income distribution for two reasons. First, the equity may never become liquid. It may take a number of years, if ever, before the company goes public or gets acquired and allows the institution to cash out its equity. This means that the office either has to hold on to the inventors'

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share of the equity until the liquidity event or must ask the licensee to issue stock certificates directly to the inventors at the time the license is executed. This distributed equity may be in addition to the equity that entrepreneurial inventors may receive as founders of a startup.

The second challenge with taking equity is that, at least initially, the office may have difficulty valuing the shares received from a license. If a company has not yet gone through a financing event, such as venture capital investment, that would require a professional valuation of the company, then a technology transfer office will find it difficult to assign a dollar value to the equity it holds in the company. Without a firm dollar value to the inventor's share of equity, the institution cannot distribute cash to the inventors as an equivalent to the equity held. This second challenge makes it very unlikely that the equity would be initially distributed as cash.

These challenges leave technology transfer offices with two choices: distribute the inventors' share of stock once it is received by the office or hold on to the inventors' share until the office is able to convert the shares into cash. Some offices may choose to immediately distribute the equity rather than assume the fiduciary responsibility of managing this investment on behalf of the inventors.

On the other hand, inventors may not want to deal with this responsibility themselves. In addition, if there is ongoing collaboration between the institution and the licensee that involves an inventor working on the university side of the collaboration, then the equity personally held by the inventor may raise conflict-of-interest concerns within the institution. This is not as much of a problem if the inventor already holds founder's equity. Many institutions have policies to hold onto the equity without distribution until the equity is liquid. Many of these offices that hold onto the equity, either within their foundations or their treasury offices, have a policy to sell the equity as soon as possible rather than to try to wait until the equity becomes more valuable.

Effect of Sponsor Contracts on Distribution

The funding used in the development of an invention may have an impact on the distribution of licensing income for that invention. For example, some unusual forms of federal

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grants require that funds received from the licensing of technologies developed under the grant shall be used for further research and not distributed according to the intellectual property policy. Some nonprofit funding foundations expect to receive some share of the licensing income for the inventions created using their money. Usually their share is taken off the top before any funds are distributed according to policy. Institutions should clearly communicate intellectual property ownership or licensing terms or any stipulations concerning the distribution of licensing income to the researchers at the time a funding award is made. In addition, the intellectual property policy should address these situations by allowing flexibility in license income distribution.

Distribution for Jointly Owned Intellectual Property

Many institutions deal with jointly owned intellectual property on a regular basis. Interinstitutional or royalty-sharing agreements may affect licensing income distribution within each institution depending on how these agreements are structured. Typically, the lead institution for licensing will first distribute any licensing income between the institutions and then each institution will distribute the income according to its own policies. Less typical are agreements that call for the lead institution to distribute licensing income directly to the other institution's inventors in addition to their own. This may be acceptable for some institutions, but should be anticipated by the institutions' policies.

It is not uncommon for a technology transfer office to receive an invention that lists a nonaffiliated outside inventor. If it is acceptable to the outside inventor and the institution, the institution may accept assignment from the outside inventor and then treat that inventor as its own for the purposes of licensing income distribution.

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Notes

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Overcoming Objections to License Terms

R. Page Heller, PE

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Introduction

This chapter is designed to give you tools to use during the negotiation of a license agreement between a not-for-profit university or institute and a for-profit industry partner. It addresses some of the more common objections raised during the negotiations so that you may be aware of what to expect. Further, it provides the not-for-profit some suggestions for handling these objections and preventing them from causing the negotiations to fail.

It is not intended that this section be all-inclusive. Even after twenty years in the business, a technology transfer professional can find new and original issues cropping up in license agreement negotiations. Thus, this chapter cannot cover all issues. However, it will address some of the more common objections.

Commercial corporations are accustomed to everything being negotiable. They have guidelines and rules that are stable for the most part, but what the contract contains hinges on is profitability. If the negotiated deal makes sense from a financial perspective, rules and guidelines can often be bent.

Universities and other research-intensive entities, however, often play by different rules. There are firm rules that supersede profitability. Sometimes it is better to walk away from a deal than to waive or bend a rule. This stems from the fact that nonprofits often represent constituents consisting of the public, elected officials, and government, rather than stockholders.

Regardless, every negotiation, whether for-profit or nonprofit, is based on one key aspect for bringing it to a timely close. That one aspect is whether or not you can meet the ex-

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pectations of the person with whom you are negotiating. To meet the expectations, you must first understand the expectations.

Years of experience demonstrate that this is an advantage for the nonprofit. Why? Because the ultimate measures of success are often different for the corporation and the nonprofit. Where the corporation is focused on the bottom line (profit), the nonprofit is focused on getting the technology out for public benefit.

You may have more detailed expectations to meet. The corporation may need to use money available in this year's budget. Alternatively, it may wish to postpone costs until next year's budget. You may be able to time your due dates to accommodate its needs.

It may need to conserve cash. It may have cash on hand but need to keep the product cost low. You may be able to adjust a balance between royalties and fees to reach an agreement. But, in any event, you must understand the corporation's expectations.

Since the measures of success for nonprofit and for-profit are different, there is almost always a way in which both parties can benefit and call the agreement a success. This fact makes negotiations between institutions and corporations a joy to undertake. Your success rate in concluding deals is likely to be very high.

There are, of course, still challenges in getting to yes and concluding a contract with a corporate entity. That is why I have written this chapter, to help you with the hard spots along the path of negotiation.

Following, roughly in order of the number of occurrences I have personally experienced, are topics that I have found to raise objections during negotiation. With each topic is a discussion of some tools you may wish to use to counter objections.

Sublicenses

You must determine if it makes good business sense to allow your licensee to grant to others the same rights that it enjoys in the license agreement. This right to sublicense allows the

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licensee to act as a middleman or an agent, representing your intellectual property rights to others. This is often allowed in exclusive license agreements where you would like your licensee to act in full control of the intellectual property. It is seldom seen in nonexclusive license agreements, since the intellectual property rights owner usually wants nonexclusive licenses to come only from them for tighter control. Of course, as in most of intellectual property matters, there are plenty of examples of exceptional cases where these general rules of thumb do not apply.

If you have a nonexclusive licensee who wants the right to sublicense, remind the licensee that it would be confusing to the marketplace to have both you and it offering licenses and could lead to difficult situations if the terms were different. Let the licensee know it is your institution's decision to remain in control of licensing the intellectual property rights.

If that is not convincing, you will be faced with weighing the risk to your institution of having a nonexclusive licensee representing the rights to the intellectual property at the same time you are doing the same. If, for instance, you are addressing different markets, then it could make sense to proceed under such circumstances.

Control

Here is another factor to consider in sublicensing. Many templates for exclusive license agreements grant rights to the licensee that allow it to sublicense rights in the same scope of the grant it has been given. These templates sometimes have a clause that requires the licensee to get consent from the grantor before entering into a sublicense. You may want to have this strict control, since the licensee will be acting as a middleman or agent for you in representing the intellectual property to others. You may find, however, that processing such requests for consent may be time-consuming and unproductive. In such cases, you may wish to consider replacing the consent clause with one that simply states limitations you can live with in sublicensing practice.

For instance, you could simply require that the licensee refrain from entering into sublicense agreements that are objectionable to state and federal law and the policies of your institution. That may be the criteria you would use to review a sublicense on a consent

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basis anyway, but now you have not delayed the process. A more general approach like this can save time in cases where you don't really want to have to examine each proposed sublicense agreement.

Regardless of which clause you use, it is a good idea to contractually require that the licensee provide you with copies of all sublicense agreements. That will allow you to monitor the progress and ensure you are not being misrepresented. You might also insist that the licensee include in its sublicense agreement a clause indemnifying the institution, echoing that of the primary license agreement. A direct indemnity is your best protection.

If that is a barrier to sublicensing the intellectual property rights, an alternative would be to incorporate in your agreement language stating that the licensee will indemnify you against actions stemming from sublicense agreements. Before drafting language that would include a clause asking the licensee to ensure that the sublicensee indemnify the institution, check with your state laws to ensure they allow third-party indemnity. More on the issue of indemnity follows in a later section.

Determination of Sharing

When a sublicense agreement is in place, it will hopefully begin to generate revenue. How that revenue is to be shared between you and your licensee is spelled out in the license agreement. But, what should the split be? How should it be expressed?

The division of revenue depends on the business model being employed. Most of the time, the model used is in the form of a royalty on sales paid from the sublicensee to the licensee. Ideally, you would like to receive the same royalty whether the licensee sells directly or uses a sublicensee to make the sale. In this manner, you are whole (in a business sense) regardless of what business model the licensee uses. This is good for the licensee also, in that it is free to structure its business in a way that is best-suited for the market and change it along the way if the first method doesn't work. Thus, a good starting point is to ask for the same royalty that you would get if he or she made the sales directly.

But, what if the company structures a deal with its sublicensees for annual fees and doesn't plan on tracking individual sales? Or, what if the deal combines fees and royalties

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in a proportion not anticipated and a fixed royalty coming back to you would not work for the company?

In such cases, it may make sense for the owner of the intellectual property and the company to split the total revenue stream equally. This is often a starting point in such negotiations, where the revenue stream is complex.

Template license agreement language reflecting this kind of split is often misunderstood. It sometimes reads, "Licensee will pay to university fifty percent (50%) of revenues from sublicensees…." From my experience, this is often interpreted as a 50 percent royalty on sales of product or services made by the sublicensee, when it is intended to be more closely related to a royalty collected. I say more closely, because sometimes the deal between licensee and sublicensee is not strictly a percentage of sales, but may be an annual fee or a fee tiered on sales volume or some other arrangement.

So, in a case where a 5 percent royalty is fair value, the corporation may be thinking you want a 50 percent royalty if a sublicensee sells the product while you are thinking that you will get half of something close to 5 percent. Have an example on hand of how the transactions would take place if a sale is made. A good example will go a long way to resolving this issue of potential misunderstanding.

I have also found it helpful to rewrite template language to use the word *half* instead of fifty percent (50%). For some reason, that doesn't trigger the association with a royalty on sales quite as often. You could, of course, also leave it blank so an explanation can accompany the negotiated figure. This approach has the downside of failing to set the expectation that you should receive half, of course.

There are other arrangements that may make good business sense as well. If the licensee adds the licensed technology to a larger portfolio and licenses rights to the entire portfolio to a sublicensee, you may wish to settle for a smaller percentage of the sublicensee payments, since they might consist of one payment for the entire portfolio of rights.

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It might arise in a completely different business model that sublicense revenues are the only income to the licensee, in which case some percentage may go to support its overhead costs prior to the split.

You can think of many ways to structure the sharing of income from sublicensees. You might begin with template language requiring the same royalty regardless of who sells the product or service. If there is objection, then consider a half-and-half split, but be liberal in coming up with alternative sharing mechanisms that make the business model work.

Most of all, make sure you have structured a deal that allows your licensee enough flexibility to modify or adjust its business model in a way that provides the best chance for commercial success. If your licensee cannot succeed, then you will not benefit. Worse, you could find yourself back at square one, looking afresh for a new licensee. So, understand your licensee's requirements and create a winning scenario for the licensee and yourself.

Software

If you are licensing software, you will have several interesting business models to consider. The simplest is one in which you license software directly to the end users. In this business model, it is likely that end users will expect that they can call you for support when their screen goes blank or they can't get a new feature to work. However, you may not wish to support the sales, marketing, and support efforts to do this, so you may wish to find a licensee who will supply such services and, in turn, license to end users.

Then there is the issue of creating new versions of the software. You may wish to control all new versions of the software or you may want to find a licensee to take over the development of derivative works. In some cases, you may wish to create derivative works in parallel with a company, creating a branch in the development tree ultimately resulting in two products.

Let's take a closer look at a few common business models and the issues associated with the license agreement for each.

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Case I: Licensing Directly to End Users

The simplest software license is one to the end user. In this business model you will market the software, create new versions, and (optionally) offer support services to the end user. In this model you would typically prefer to restrict the end user from making modifications, making copies (except for backup purposes), and distributing the software.

The basic considerations might look like this:

Copies	One for backup only
Distribution	No
Modification	No
Reverse engineer	No

In this model you may wish to get creative in how the software may be provided to a number of users from a central server. You will need to consider how to restrict its use for a set fee or perhaps structure a fee per user. Often, these agreements have a fee for the initial software installation, then a fee per user. It is also typical to find annual maintenance fees which may, in part or in whole, go back to the lab supporting the software to help cover its costs.

Case II: Licensing to a Distributor

If you want to control the software development, but don't want to provide support services, consider licensing the software to a distributor, that is, a company that will market and license the software to end users. In this scenario, you will want to restrict the ability of the distributor in modifying the software and creating derivative works. If you can provide only executable code, rather than source code, it would be preferable.

The basic considerations might look like this:

Copies	Yes
Distribution	Yes
Modification	No
Reverse engineer	No

Please give strong consideration to a formal program of software releases in this business model. It is imperative that you maintain control over what version you provided to the

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distributor and at what time. This will go a long way to resolving potential problems in the future, when a feature may need to be tweaked for an important customer who has an early version of the product.

Consider limiting the distribution by geographic area or field of use. If you run into objections from a prospective licensee during negotiations, it may be because your restrictions interfere with its business plans. By placing strict restrictions in your original draft and then backing off of them, you will learn a great deal about the details of the prospective licensee's plans.

Case III: Licensing to a Software Developer

In this business model, you prefer to turn the software over to someone who can create a commercial version, market it, and distribute it. You are turning over control of the future of the software for commercial purposes. You will be supplying the source code in this case.

The basic considerations might look like this:

Copies	Yes
Distribution	Yes
Modification	Yes
Reverse engineer	Not applicable

Here's a contentious question. If you licensee creates a derivative work, who owns it? If the licensee owns it, then you may launch down a slippery path where eventually the licensee will claim that the fifth or sixth version looks nothing like the original and therefore does not infringe the copyright. Sometimes that can even happen before the product hits the market.

Although you will very likely get kick-back on this provision, you may wish to join the many nonprofit institutions that require derivative works made by the licensee to fall under the ownership of the institution; put more simply, the institution will own derivative works made by the licensee. At first, this policy doesn't seem right. Why would the institution own a derivative work created by the company?

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The problem occurs when the institution does not own the work. When that happens, it opens a door for the company to consider that it is developing works that are moving away from the original copyright. Sooner or later (and more likely sooner) it will consider that the work it is preparing to sell doesn't look like the original work (as mentioned above) and, therefore, no royalties are due.

The defense for such a request is in the purpose, which is to circumvent any contention that a future work does not infringe the original copyright and, therefore, no royalties are due. In fact, you have to wonder why the licensee that insists on owning the derivatives really wants to do that.

This suggestion is not a legal opinion, rather a business one. It can be used to avoid confusion in later years, since it might be thought possible to show that the licensee-created derivative work isn't similar to the original work and, thus, what is being sold doesn't fall within the scope of the license agreement. In all likelihood, however, a good intellectual property attorney may be able to demonstrate the progression from the original work to the one the licensee claims is not infringing and maintain the contractual obligation. But, from a business perspective, who wants to go through such a contentious procedure with a licensee? It is much better to insist on ownership and avoid the later conflict.

Now, if the company still resists, try offering a position where royalties are reduced as the company creates more and more derivations. Presumably, the value of the product is being increased as the company incorporates new features. Thus, you will be getting a smaller percentage of larger sales. I prefer to reduce royalties as a factor of time rather than trying to keep track of the number of version releases. It is an approximation, but much easier to calculate, not to mention avoiding potential arguments on down the line.

Indemnity

Nonprofits often have different standards of indemnifying contractual partners than industry. In industry practice, it is often acceptable to contractually promise to indemnify the other party in preparation for some hypothetical situation when lawsuits may begin to fly. Nonprofit entities, however, seldom do that to the same extent that an industry entity

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would. In fact, some state institutions are prohibited. More on this later.
Consider that an industry partner typically licenses patent rights from the nonprofit, then uses those patent rights to design and develop a product and market the product to the public. The nonprofit maintains little control over the process and has little influence over the ultimate product reaching the public. If the product infringes someone else's patent (or even another patent owned by the institution) or ends up harming someone, the responsibility of the nonprofit is likely to be insignificant.

Further, nonprofits rarely have the staff and time necessary to perform a freedom-to-practice analysis that is often used by industry to determine the risk in finding that the contemplated product may infringe someone else's patent (or, again, even another patent owned by the institution). These studies tend to be expensive and require near final engineering designs of the product. Since the nonprofit usually works with early-stage technologies, a freedom-to-practice analysis would likely be money wasted, as it would not reveal much about the licensee's ultimate exposure.

Thus, the nonprofit usually draws a hard line on the issue of indemnity, taking the stance that it will not indemnify the licensee. Further, it generally adheres to the philosophy that the for-profit licensee must assume all risk associated with its efforts to commercially develop and exploit licensed technology. Thus, the nonprofit will ask the licensee to indemnify the nonprofit.

Academic institutions typically employ rather broad indemnity clauses, whereby they stipulate that a for-profit licensee must indemnify the academic institution for any and all third-party actions, claims, or lawsuits arising out of the design, process, manufacture, or use of the licensed technology. Private institutions have a little more flexibility on this issue, but typically follow the same model, since it makes good business sense.

It makes good business sense when viewed from the standpoint that the institution enables the commercialization, but is not in control of it. It would be unreasonable to expect that a party assume risk for something in which it has no control. The institution retains only a minimal interest.

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As mentioned previously, some state institutions are prohibited from accepting the liability associated with indemnifying another party. There are usually state laws that govern the extent to which a state agency or institution may indemnify another party in a contractual agreement. You should become familiar with them. Typically, a government entity is restricted from assuming indemnity since it is considered acquiring a potential debt, which may only be done by an act of the legislation.

That said, it is likely that you will encounter resistance on the indemnity clause on occasion. I would estimate that the issue came up for discussion in approximately 25 percent of my cases over fifteen years. Most of the time, a recitation of the above reasoning solves the issue. In the remainder, you are best advised to get your legal counsel to engage the prospective licensee and work on the exact language of the clause. There is a great amount of case law behind the words chosen for the indemnity clause, and you do not want to attempt to change the clause without a legal background in the area.

Royalties

Here is a familiar topic: royalties. A royalty is a payment made by a licensee for ongoing use of intellectual property, usually in return for rights to make, use, and sell (along with perhaps other rights) product or services. The royalty I will discuss in this section is that compensation that is most commonly expressed as a percentage of sales for some defined area (geographic or field of use).

The Basis

The basis of a royalty is most often the whole of some measurable quantity from which a percentage is taken as compensation. It may be the total gross sales of a product that incorporates devices or methods described in the patent that is licensed, for instance. So, as the licensee makes sales, it may report the sales once each quarter and pay a certain percentage to the patent owner. That seems simple enough. But, there many cases where it is not so simple.

Consider, for instance, a case where the product described by a patent is a small part used in a much bigger product. The patent may describe, for instance, a rubber seal that is as-

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sembled into an aircraft engine that is sold as a unit. A license agreement would typically ask for percentage of the sales price of the seal, but perhaps it is never sold independently and, thus, no sales price exists.

Compensation could be made a much smaller percentage of the sales price of the entire engine. For instance, instead of asking 5 percent of the sales of the seal, you could adjust a percentage by the ratio of the manufactured cost of the seal to the manufactured cost of the engine. This approach is often suggested by the licensee, and it is often unfavorable to the licensor. The value of the seal may be in reduced maintenance scheduling, which may save the buyer many thousands of dollars a year. However, the manufactured cost may be only $1.50.

A better approach may be to do some analysis on the true value that the seal brings to the sale and reduce that to a fixed fee charged for each unit sold. Most of the time, a fixed-fee structure will be a more accurate representation of the value of the intellectual property than the manufactured-cost ratio. This approach offers the potential customer's savings as the basis, rather than manufactured cost.

Consider the importance of your intellectual property to the sale of the product or service. If your patent describes a primary active ingredient used in a pharmaceutical, then it is critical to the sale. In such cases, a royalty on gross sales makes sense. If your patent describes a coating for the pharmaceutical in tablet form, then it may not be quite so critical. If there are alternative coatings for the tablet form and the drug can be made in liquid and capsules that don't use the coating, then your basis will be restricted to only tablet form pills, limiting the sales figure used for a basis.

Bottom line: Spend time in choosing a basis for the royalty that reflects the value of the intellectual property to the company. Ask yourself how the licensed technology will increase the company's market share or how it will increase sales of an existing product line. Use that as a beginning for choosing a reasonable basis for your royalty.

Make certain the basis you choose can be easily determined in an audit. For instance, do not choose "profit" as your basis. There are many different ways to calculate profit for an

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individual product or service. You will not control what gets amortized and applied as a deduction to gross sales. You shouldn't have to be concerned about the efficiency of the company in making the product, anyway. Thus, you should not use profit as a basis.

The gross sales are the easiest measure. It can easily be determined from Security Exchange Commission filings if the company is public. Formulas based on gross sales are next best. A fixed fee per unit is another approach, calculated once at the beginning of the contract and adjusted periodically for inflation. A fixed annual fee is yet another approach, perhaps leveraged to total annual sales.

Whatever you choose as a basis, make sure it helps the licensee to succeed commercially. Just as before, you must again be in tune with the expectations and plans of the licensee.

Tiered Structure

Reconsidering the aircraft engine example, if you were to use a unit fee for consideration in a license agreement, but the same rubber seal was to be used in several different size engines that each sold for a different price, then a fixed fee might be too high for a small engine or too low for a large engine. In such a case, you may wish to create a table of different fees for different units sold. The fee would be tiered to engine size.

There are other cases where you may wish to tier percentages as royalty rates, rather than fees. For instance, if you have a product where the initial sales will be made to so-called innovators in the market at a relatively high margin, you may wish to begin with a higher royalty, then reduce it when sales to the innovators rolls off and sales to the masses begin. Then as the product ages, prices may be reduced causing a tight, commodity-like margin in the later years of the product cycle. The royalty could be a second tier lower at that time. With this philosophy, the royalty rate may be tiered to the expected margin. This allows the business to grow and contract with its ability to generate profit.

Alternatively, the product may be entering a mature market where the price is relatively fixed. In such cases, where early sales may bear the cost of amortization of capital equipment, margins may be tight in the beginning, only to open up as the company makes a

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name for itself and sales accelerate. Ultimately, you might expect that a new product will come along and supplant the existing sales, causing an abrupt end rather than entering a more commodity-like period of sales. This happens in some areas of electronics, for instance. In such cases, a tiered royalty rate that is increasing, rather than decreasing, may be appropriate.

These tiered royalty structures are often employed by the negotiator to overcome an objection to a certain proposed royalty rate. When a tiered rate structure is proposed, the ensuing discussions can teach the licensor details of the licensee's marketing plans. Sometimes it may even be revealed that plans have not been made at all.

Royalty Stacking

A new drug introduced by a pharmaceutical company may rely upon several patents from several different licensors. If each licensor asks for a royalty supported by the market rate for drugs sales, the sum of all the royalties could make the product unviable in the marketplace. In such cases, the licensee may ask for a reduction in the royalty owed to you when it must pay royalties to others on the same product (royalty stacking). This is a standard way of handling the situation in a fair and equitable manner.

Of course, it is only fair and equitable if all parties are reducing their royalties together. Be aware that you might be asked to play a secondary role, reducing your royalty while another party does not. Don't forget to ask if all others will have the same clause. As additional protection, it is common practice to reduce the royalty to no less than, say, half of the original rate.

As with the discussion on the basis, it is important to determine the value of your intellectual property to the sale of the product or service. If the patent rights are essential, then you have a much stronger bargaining position and could, perhaps, insist that your percentage of the sale not be reduced or perhaps be reduced only slightly. However, if your intellectual property is a minor contribution, perhaps you should accommodate a reasonable reduction without much discussion.

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There are no absolute answers to the royalty-stacking dilemma. It is probably not possible to keep the licensee paying the same royalty rate under all conditions and still provide each licensor with fair compensation. Each case must be analyzed individually and a mutually agreeable solution determined.

Caps

Most nonprofit organizations have a responsibility to the government and the public as stakeholders. Care must be taken to ensure that they are treated fairly in a license agreement. There is often an expectation that intellectual property will generate a return that can be used to further research in some way, as in the U.S. Bayh-Dole Act.

When a licensor counter-offers a royalty capped at some figure, meaning it will not pay more than some absolute threshold, you must question the reasoning. In general, a royalty offered as a percentage of sales shares the risk of success between licensee and licensor. If the product is successful both share in the success. If the product fails in the marketplace, neither benefits.

A cap on royalties changes this premise, however. Now, only if the product is marginally successful does each party benefit. If the product is wildly successful, only the licensee benefits from the high-end sales.

When a prospective licensee demands a cap, it is a tough position to be in. It is not a partnering relationship. You will need to consider whether to walk away from the deal or whether there are extenuating circumstances that would cause you to accept the unfavorable condition.

A tiered royalty can be a solution. A windfall clause can be another. A windfall clause stipulates that, when some unexpectedly large threshold of sales is exceeded, then the licensor will receive some additional consideration, many times in the form of a lump sum. Neither of these alternatives is ideal, and they should be considered sparingly.
Consider trading this term for something entirely new. For instance, add a clause that asks the licensee to fund a chair for the principal investigator. The public relations benefit to

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you may be of some value. Or, ask for a commitment for additional research funding. Adding new terms is always a good way to counter an unfavorable term.

Equity

There are cases where there is just not a good financial solution to the problem of getting a just return for the value of a licensed technology and allowing the company to make enough profit (or capital) to succeed. Take, for instance, a startup company. "Cash is king" is often the cry of a startup since it is hard to raise money and early investors want to make sure every cent of their investment is working to produce a product. In such cases, it could be possible to lower fees and royalties in exchange for equity in the company.

Equity Basis

If the licensor is to take an equity stake in the licensee, on what basis should it ask for a given percentage of the ownership of the company? Determine whether you are dealing with C corporation, an S corporation, a limited liability partnership, or some other entity. Then, determine how others have come to own a portion of the company. This will help you begin to form a basis for your request.

For a C corporation, for instance, you will want to study a capitalization table to determine how many shares are outstanding and who owns what series. Find out how many shares have been authorized by the board, since some may be held in treasury and not yet issued. It is most common to base your request on a percentage of total outstanding and issued shares in such a case.

Consider that warrants or options may have been issued that can later be converted to shares, causing you to be diluted. You may wish to incorporate those warrants and options in the capitalization table if they are not already there.

I wish I could go through each different case of company formation, but that would require several chapters unto itself. It should suffice to say here that the basis for determining a reasonable percentage to request will depend on the structure of the company, the rights held by the existing shareholders or partners, and the value of the consideration you agree to forego.

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You might not make your request as a given percentage of a company, but instead ask for a number of shares of stock. In this case, you will want to establish the value of the technology you are licensing and use a price per share to convert that value to shares. Be careful. If you are dealing with a startup company, or one that has only one round of private financing, the price per share may have little relationship to the value of the company. It is best to solicit help from a colleague with experience in equity licenses.

I prefer to stick with percentages. If this becomes an issue, then consider tying the receipt of the equity to a milestone. For instance, when the company meets a certain investment closing that may already be in the works.

If you are considerably early in the life of the startup, then consider asking for an antidilution clause that keeps your ownership at a certain percentage up to the time the company receives, say, $30 million in total investment. That will keep you from being diluted in the early stages of formation, but get you out of the way when a venture capitalist comes in to make an investment.

Preferred/Common

You may wish to consider asking for a position based on preferred shares of a startup company. Preferred shares offer the owner an advantage over common shareholders, typically in the form of a position first in line for any money divvyed up upon liquidation of the company. In other words, preferred shareholders are paid back before distribution of any remaining funds is made to common shareholders.

Providing a licensor preferred shares can be an advantage for a startup company just getting under way. The price per share established for the preferred share transaction doesn't set the price per share for common stock. Thus, the company is provided with great flexibility in establishing whatever price per share it needs to raise capital without being concerned with adjustments to the licensor's position. Some nonprofits ask that their preferred shares be issued as nonvoting shares if they are concerned with the perception that they are directing or influencing the management decisions of the company.

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Options

More complex structures may be considered for cases where the license agreement is negotiated prior to the issuance of shares or when the equity partners earn their way into equity positions. In such cases, you may wish to consider taking options rather than shares. Options can be structured to allow the owner of the options to purchase shares at a favorable price at some later date. It can be used as a way to provide a promise for shares without incurring the tax consequences prior to knowing the true market value of the shares.

Although most persons reading this will be working in organizations that are not concerned with the tax consequences, options are a good way to align the interests of the nonprofit licensing the technology with the corporate officers who are in charge of taking it to the marketplace. Considering options can place you on a level playing field with the founders or early investors.

Milestones

Negotiated milestones are an important part of any license agreement. They must be taken very seriously, since they can make the difference between the public benefiting from the technology being licensed or never seeing it.

Purpose

Milestones are checkpoints used by the licensor to measure progress of the licensee. In license agreements between nonprofits and industry, they are used as a measure of progress in the development of the technology. They are usually taken very seriously and can cause significant changes in the terms if missed.

They are one of the mechanisms the nonprofit can use to ensure that the industry partner is not licensing the technology to keep it off of the market. That can be a valid business strategy if the technology might compete with an in-house development, however, it does not serve the public mission of the nonprofit.

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Industry-to-industry license agreements contain milestones on occasion, so your industry partner may be accustomed to the contract having milestones. However, there are several factors related to the milestones that may be unfamiliar.

Deliverables

Milestones are typically treated with a less emphasis in a typical license between two industry partners than they are between a nonprofit and industry. In the two-industry scenario, milestones may be a general indication to one party that something is getting accomplished, but they are rarely cause for termination of the agreement, should the licensee miss one. More often, they are used to complete a report to management.

As a result, the industry partner, as a potential licensee, may consider reasonable a milestone that reads, "Licensee will complete efforts to build a prototype no later than twenty-four months from the effective date of this agreement." But, if your responsibility is to make sure the public can benefit from your license agreement, then you are likely to find that unsatisfactory. It is too easy to defend that "efforts" were made to build a prototype even if no prototype was built. What you really want to know is that one was built, tested, and shown to meet some standard.

Make sure your milestones have deliverables that can be sent to you without your requesting it. A copy of an investigational new drug application or an investigational device exemption would be examples of a deliverable in the medical field. Engineering drawings or mask works would be examples in the electronics field. These documents give you some surety that the technology is truly being developed and not sidelined.

Choose your milestone in a way that meets an objective along the path to the marketplace. This can include the completion of drawings, plans, certifications, field installations, preclinical trials, clinical trials, marketing plans, advertising campaigns, or first sales, to name a few. The point is to select milestones in a manner that allows you comfort in reporting to your superior that the licensee is diligent in its commercialization effort.

Often, missing an important milestone will give the nonprofit a right to terminate the agreement. When you discover that a licensee has indeed missed an important milestone, you must decide how to best reach the public with your innovation. Perhaps terminating

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the agreement and licensing it to another entity would be best. It is also possible that leaving the current license in place, but perhaps adjusting its terms would be best.

Penalty

Probably the most common kick-back in the milestone negotiation will be the severity of the penalty for missing a milestone. Often the industry partner is expecting perhaps a penalty payment. What they find in the template agreement, however, is often the right of the licensor to terminate the agreement. That may raise some eyebrows.

It is important to explain the rationale for such a harsh condition. It is the duty of the nonprofit to see that the technology has the best shot at benefiting the public. If the licensee runs into significant trouble in development, doesn't have adequate resources to make it happen, or goes off in a different product direction, then the nonprofit must have the ability to get the technology back so it may be licensed to someone who might succeed. Sometimes this means terminating the rights of a large company and licensing the technology to a niche player, who can address a very narrow market that the large company finds uninteresting.

In some rare cases, it may make rational business sense to eliminate from the license agreement the possibility of termination for a missed milestone and simply move exclusive rights to nonexclusive rights or perhaps implement a field-of-use restriction. This could occur, for instance, in a case where a professor has an idea, but has not developed it. You would like to give him or her the chance to develop it by licensing it to his or her own company, where his or her knowhow will play a crucial role in the development.

In such a case it doesn't make much sense to terminate such an agreement, since most of the concept development will take place only as a result of the license agreement. It may be unlikely that you would be able to license it to anyone else, since the knowhow is critical. Thus, you may wish to allow the professor's company to continue with nonexclusive rights or a reduced geographic area, even if he or she misses a major milestone.

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Patent Prosecution

Here is where the rubber meets the road in a license agreement. If the contractual obligations surrounding the patent prosecution are not handled well, there may be nothing to work with when it comes time to enforce patent rights against an infringing competitor. Your flexibility in implementing features mentioned in this section will vary depending on your circumstances and desires.

University Prosecutes

In most licensing arrangements, the licensor (often a university) will take charge of prosecuting the patent. The licensor will own any resulting patent, so it makes intuitive sense that it controls the prosecution.

When the licensor controls the prosecution, it is typically able to choose an attorney to handle the case at will. In state institutions, this can be important, since the state attorney general may have established guidelines for preapproving attorney's representing a state agency.

You will need to consider how much control you want the licensee to have. It may ask for an obligation that you include anything it suggests to be included in the patent application. You may want to change that to an obligation to allow it the opportunity to comment and, perhaps, an obligation to consider its comments (without a promise to implement them).

The problem is that the licensee may have different objectives in the patent prosecution. I have seen some who attempt to interject a claim that would include one of its own employees as an inventor, for instance. That, of course, would drastically change the entire licensor-licensee relationship, since the licensor would then be able to proceed to commercialization without a license from the licensor.

Industry Prosecutes

The cost of speculative patent prosecution can become quite significant. Even when the licensee reimburses the cost of prosecution, the float between paying the attorneys and receiving payment from the licensee can get quite high for the licensor.

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To reduce this cost, some nonprofits look to ways of having the licensee prosecute the patent applications directly. The licensee hires its own attorneys and manages the prosecution. They are, of course, prosecuting the applications on behalf of the licensor, since the resulting patent should be in the name of the licensor and not the licensee.

There are problems with this approach, however. It is quite easy for the industry partner to simply put the prosecution into the existing tracking system for the company and forget the unusual circumstance that it is prosecuting on behalf of someone else. This can lead to incorrect filing of assignments, incorrect assignee listings, and so forth.

In many cases, reporting from licensee to licensor on upcoming patent actions can be late or forgotten. This can cause degradation in the value of the resulting patent since the claims may not have the refinements of the original inventor.

Worse yet, it can be tempting to insert a company co-inventor into the process and confound the ownership of the resulting patent. This can lead to rather contentious disputes, distracting the parties from accomplishing the goal of technology development.

Still, there are cases where it makes sense to allow the licensee to prosecute the patent applications. If the technology serves a niche market and the company is the largest patent holder in that market area, then it may make sense to use the expertise its attorney has built up in his or her knowledge of the prior art. The resulting patent may be very strong, resulting in a benefit to you. This type of case may prove worth the risks outlined above. As with most of these negotiation tips, it comes down to making a sound business decision.

If you elect to let the licensee prosecute your patent application, then be prepared to place some safeguards in the contract. Stipulate that the licensee will provide copies of all attorney and patent office correspondence to you with sufficient time for you to review and comment on the material. Require approval of certain types of actions, such as adding claims, filing continuing applications, filing declarations, abandoning applications, filing appeals, and so forth.

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Dispute Resolution

When two parties enter into a license agreement, they most often do so considering that they are creating a partnering relationship, one of cooperation, one of common goals. In most cases, this is exactly what happens. The university offers consultation and prosecutes the patent application. The licensee pays royalties and often funds further research. While you hope that this will be the case in all license agreements, sometimes the parties begin to disagree on the direction of the commercialization. Sometimes the relationship sours and tempers rise.

It is common in contracts between two companies to have a clause that allows the parties to attempt to resolve disputes between the two without going to court. It offers an alternative to suing each other. It most often involves an arbitrator, who is usually a retired judge or attorney who listens to both sides and offers advice.

Arbitration can be binding or nonbinding; that is, you must take the advice of the arbitrator if it is binding or agree that you will consider the advice and make your own decision if it is nonbinding. Sometimes even a nonbinding clause can lead to a solution that is much less expensive than going to court.

Public institutions typically do not accept any terms of arbitration. Occasionally, the state of which the institution is a part will have a law stipulating a specific kind of dispute resolution. Otherwise, it is most typical for a public institution to disallow any kind of dispute resolution clause. It can even require an act of legislation to include an arbitration clause.

Private institutions that resist dispute resolution clauses can sometimes accept nonbinding arbitration. To ensure that no one party has the advantage by selecting an arbitrator favorable to them, I suggest that a mechanism be established where each party selects an independent individual and the two of them select an arbitrator.

It is difficult to come up with suggested alternatives to arbitration for a general article, like this one. Check with your own institution to find out what constraints it may have on arbitration. Use your best judgment to determine a set of conditions you can live with, then set your template in a manner that allows some room for negotiation.

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Conclusion

If two parties agreed on every term and condition of a template license agreement, there would be no need for negotiation. It is expected, however, that the parties are likely to see things differently and disagree on a number of points. It is important to be prepared for the most common of these disagreements and know your limits.

The nonprofit organization has different objectives than the for-profit. The need to satisfy pubic interest brings aspects to the license agreement negotiation that holds great importance, like the right to terminate on missing milestones, the control of patent prosecution, and the elimination of arbitrary caps on royalty payments.

It is also crucial that the licensee have enough flexibility to succeed in reaching the market. To make sure that happens, you will need to understand and align with the company's expectations and plans. Without that, you cannot meet your own objectives.
Ultimately each license agreement will be based upon a unique set of criteria that demonstrate success. It is up the intellectual property manager to negotiate each deal with sound business judgment to reach a license agreement that best serves the nonprofit and the public while allowing the company flexibility to succeed.

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Patent and Other Intellectual Property Donations

Lora Mae Frecks, MPA

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Introduction

Most professionals working in technology transfer will encounter a patent donation at some point in their careers. Few will know where to turn for assistance and even fewer will have previous experience in this area. This chapter is meant to provide a framework for assessing and implementing patent and other intellectual property donations.

Overview

Donations can be a useful tool in technology transfer but should not be conducted informally or without careful consideration of the circumstances and potential consequences for both the potential donor and the potential recipient.

The wide variance of laws and regulations between countries, states, local governments, and individual institutions make it impossible to provide specific instructions for handling a patent donation in all circumstances. However, some generalities remain true for all donations. Below is a summary of steps to follow while proceeding successfully through a patent or other intellectual property donation.

1. Establish a knowledgeable team and designate a donation coordinator.
2. Gather facts and understand your circumstances.
3. Determine how to proceed.
    a. Decline a patent donation.
    b. Accept/offer a patent donation.
    c. Propose some other means of transferring the technology.
4. Implementing the donation.

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5. Postdonation activities.

Step One: Establish a Team of Experts and Designate a Donation Coordinator

Conducting a patent donation requires experience, expertise, and skill in a variety of fields including: negotiations; science; technology evaluation; market assessments; federal invention reporting; and tax, patent, and contract laws. It is unusual to find this range of expertise in one individual. As a result, it is best if the donor and potential recipient each establish a team of experts and designate a representative to coordinate the efforts of its respective group of experts. Designating these two individuals can greatly expedite communications between the two organizations and minimize the potential for miscommunications.

This step may seem overly bureaucratic, but seeking this expertise is crucial to achieving a successful donation that advances the technology's commercial and scientific potentials. Be assured, no committee meetings of this team are needed to complete the donation agreement. The involvement of these individuals can be as informal as your organization's culture permits. However it is crucial that someone in your organization obtain input from these experts. Not doing so may cause damage to your organization's relationships with the researchers and other organizations involved in the potential donation (including any federal agencies that funded the donated technology).

At a minimum, make sure your team includes individuals with some combination of expertise in as shown in Table 1.

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Table 1: Expertise

Expertise	Role in Donation
Organization administrator	• Identify relevant formal and informal organizational policies
The field(s) of science related to the technology	• Evaluating the technology
Patent law	• Assess patentability of technology • Assess existing patent applications and/or patents • Prepare any formal assignments
Contract law	• Interpret donor agreement language in light of relevant case law
Accounting/tax law	• Ensure your organization understands all financial repercussions of donation
Federal invention reporting (Bayh-Dole Act compliance)	• Determining whether technology was supported by federal funding • Assessing whether invention reporting on track before donation • Ensuring compliance after donation • Coordinating release activities and related paperwork with federal funding agency and donator

Step Two: Gather Facts and Understand Your Circumstances

The purpose of this step in the process is to determine whether a donation is appropriate and beneficial to your organization. Donors and recipients need to carefully consider if they have found the best match for moving the technology forward scientifically and commercially. Unfortunately this step can be labor intensive and tempting to either skip over entirely or to devote only minimal resources to investigate. Resist these temptations and fully investigate the circumstances surrounding each proposed donation. Not doing so could place your organization in an extremely difficult position.

Rules and Regulations Landscape

Many rules and regulations may impact either the terms of the donation agreement or your organization after the donation is completed. These rules and regulations may be at

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any level of government or even within your own organization. Without identifying and responding to these rules and regulations, your organization risks noncompliance and the resulting negative consequences.

Bayh-Dole Act and Federal Agency Invention Reporting Requirements

First, determine whether the technology being considered for donation was supported by federal funding. Federally funded inventions can still be donated, but the federal agency that provided the financial support must be involved in the process. Specifically, the donor will need to release the technology to the appropriate federal agency that can then pass the technology on to the recipient.

When beginning a donation of a federally supported technology, locate the appropriate individual(s) within the federal agency and provide them with preliminary notice of what the donor and recipient hope to accomplish and why the donation is desirable. You will need to comply with all paperwork and other requirements the federal agency indicates are necessary. Utilize the iEdison Web site (www.iedison.gov) as much as possible to locate agency contacts and facilitate the return to the agency.

Even after the donation is complete, federally funded technologies will have additional federal invention reporting compliance requirements that will require additional reporting to the federal agency by the donor. In addition, the Bayh-Dole Act will require the recipient to share revenue related to the federally funded technology with the inventors. This will include the inventors still located at the donor's institute and will involve keeping in touch with the donor's inventors as their careers progress.

Internal Policies and Politics

The next layer of rules and regulations to be explored are those at your own organization. Institutions can have a surprising number of older formal and informal policies that are either directly or indirectly related to donations. Begin by exploring your organization's and any parent organization's formal policies concerning donations and determine what terms would be needed in a donation agreement to accommodate these policies. Next, determine whether your organization has any practices, informal policies, or strong cultural

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biases that would make this particular donation difficult to implement. In investigating this step be sure to include in your inquiries and analysis the specific people and technology involved in this particular donation.

Rules and Regulations Impacting Finances

Lastly, explore any rules and regulations involving finances that may impact the donation or cause the donation to impact your organization financially. A change in 2004 to the U.S. regulations concerning tax deductions related to patent donations diminished the financial windfall to donors. Due to the 2004 changes, donor tax deductions related to the donation were linked to revenues associated with the donated technology received by the recipient. U.S. regulations also require recipients to report revenues related to the donated technology for the life of any patents. Small errors in considering a donation or in negotiating a donation agreement can have large financial consequences for both parties. Therefore it is imperative for both donors and recipients to check with experts in this area before proceeding with a donation.

Evaluate the Technology

Technologies being considered for receipt via a donation should be evaluated at least as rigorously as the organization evaluates new invention disclosures. Follow your organization's existing evaluation methods but also consider the following factors. First, is additional research needed to advance the technology and, if so, how will it be funded, who will direct the research and where will it be conducted?

Next, consider the existing intellectual property protection. Do the existing patents provide adequate protection for the technology? Is there enough potential in the existing patent applications to obtain adequate protection for the technology? Is the patent portfolio too large or too small? If more patent applications are needed, where would the funding and detailed scientific expertise be found?

Lastly, consider whether this is a technology your organization would benefit from adding to its intellectual property portfolio. Is there an adequate market for the technology? If not, does the technology meet some social need? Does your organization have the resources to see the technology brought to market?

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Understand the Donor

Donations can come from a number of sources and for a number of reasons. Understanding the donor's goals and motives can greatly assist your organization in evaluating a potential donation and negotiating a donation agreement that pleases both parties. Table 2 is a list of potential sources of donations and possible motivations for each. This list is not meant to be inclusive, but instead to prompt you to consider this factor in your evaluation of the potential donation and your negotiation and monitoring of a donation agreement.

Table 2: Sources of Donation

Donation Source	Possible Motivations
Alumni or other benefactors	• Giving back to organization or community • Loss of interest or resource(s) to pursue project independently
Industry	• Closure of a research area favored by a very important person (VIP) in that business who believes in the technology • Budgeting purposes • Change in business goals • Transfer of a research VIP from the business to a research organization
Other universities or research institutions	• Transfer of researcher from one institution to another • Reorganization of research institute • Bundling of technologies

Caution

When approached by anyone wishing to make a donation to your organization, be as interested and respectful as possible during the initial contact and research the potential donor as thoroughly and quickly as possible after the initial contact. During the initial contact gather as much information as is reasonable under the circumstances regarding the individual, his or her organization, the technology, and the reasons and goals for the donation.

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Step Three: Determine How to Proceed

Declining a Donation

When your organization decides to decline a donation, this information should be communicated to the potential donor as quickly as possible. Promptly declining a donation enables the donor to approach another potential recipient and ultimately move the technology forward in a timely manner.

These communications will vary greatly depending on the specific circumstances surrounding each potential donation. However, it is good practice to verbally communicate your organization's intention to decline the donation and follow up with a written communication formally declining the donation. Carefully consider which individual(s) in your organization will handle each communication. For example, the potential recipient's designated donation coordinator may verbally communicate the potential recipient's intention to decline the donation and also prepare a formal letter that is signed by the organization's chancellor or president.

While it is not necessary to spell out your reasons for declining a donation, doing so can help the potential donor understand your organization's motives for declining such a valued technology. Providing such an explanation can also help the potential donor understand what types of technologies and circumstances may be a good donation match for your organization in the future. Table 3 is a small list of possible reasons for declining a donation to facilitate the preparation of these communications.

While declining a donation, always keep in mind that the next technology offered by the same potential donor may be a better fit and something your organization will want to receive. Your organization's interactions with potential donors should prompt potential donors to want to interact with your organization again in the future. Even if future donations seem unlikely, the potential donor may someday become a benefactor, licensee, or interested in sponsored research or clinical trials at your organization. Interacting promptly and in a manner understandable to the potential donor will increase the chances that your organization will be considered for these future activities.

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Table 3: List of Reasons for Declining a Donation

While the donation technology is an excellent technology with a lot of promise, it is not a good match for [insert name of the potential recipient] because…
• While [insert name of the potential recipient] is strong in [insert A, B, and C] areas of science, I believe we currently lack the expertise in the area of science needed to move the donation technology forward. • Fully developing the technology will require more business resources and expertise than [insert name of the potential recipient] currently has available. • We believe a startup would be needed to develop the technology further and [insert name of the potential recipient] has already allocated all of its business development resources for the next few years. • After reviewing [insert name of the potential recipient] existing intellectual property portfolio, we determined that the donation technology would not be a good fit. • There is too great a financial risk for [insert name of the potential recipient] to accept the donation.

A Note for Donors

Once a potential recipient has communicated that it does not wish to agree to a donation, accept the organization's decision. Your next step may be to identify another, better match for the donation or you may develop a new plan for the technology (perhaps forming a startup yourself, further developing the technology in-house, or abandoning the technology). However you proceed, be thankful that your organization avoided becoming entangled with an organization not truly committed to participating in a donation or moving a donated technology forward scientifically and commercially.

Proceeding with a Donation and/or Proposing Some Other Means for Transferring the Technology

Once you have determined that your organization would benefit from working with a technology you will need to determine the best means for transferring the technology from one organization to another.

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Donations are only one of many means for transferring patents or other intellectual property from one organization or individual to another. Since donations are a fairly drastic and often irreversible course of action, it is important to carefully consider whether a donation is the best means for accomplishing your goals. However, if your organization's team of experts has done its job, this should be one of the easiest steps in the process. Table 4 is a list of possible modes for transferring the technology.

Table 4: Possible Modes for Transferring Technology

Transfer Means	Results
Donation	Gives ownership of a technology to another, sometimes in a conditional manner with return to the donor if milestones are not met by a recipient
Exclusive license for all fields and a worldwide territory	Grants one non-owner the exclusive right to utilize technology for a limited timeframe
Nonexclusive licenses or exclusive licenses for specific fields or territories	Grants several non-owners the right to utilize the same pieces and/or different pieces of a technology in the same and/or different locations for a limited timeframe
Confidential disclosure agreement or nondisclosure agreement	Grants one or several non-owners the right to utilize know-how for a limited timeframe and usually for a specific purpose
Material transfer agreement	Grants one or several non-owners the right to utilize research materials or know-how for a limited timeframe and usually for a specific purpose

Step Four: Implementing a Patent or Other Intellectual Property Donation

After it has been determined that a donation is necessary, documents related to the donation must be prepared, the terms of those documents must be negotiated, and the technology must be actually transferred after the donation is complete.

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Negotiating the Donation

Negotiations for a donation are very similar to those for other types of agreements. The most significant differences is that the donor and recipient will need to first negotiate and agree to what documents will be used to complete the donation.

Assignments and Other Documents Related to Donations

When you have verified that a patent or other intellectual property donation is the best means for transferring the technology, the donor and recipient organizations will need to agree on what agreements and other documents to use to complete and document the donation.

Assignments

The most basic and informal of patent and other intellectual property donations should involve a formal assignment of the technology from the donor to recipient. The assignment should clearly identify what is being assigned and should reference any formal protection sought for the technology such as patent applications, trademarks, servicemarks, copyrights, etc. If no such formal protection exists, the assignment should clearly identify the technology via references to invention disclosures or other means of description (such as materials describing know-how). The assignment should also be formal enough to be recorded by any necessary entities such as the United States Patent and Trademark Office. Legal counsel should be consulted to ensure the assignment meets the requirements of the particular circumstances.

It is important to note that a donor can assign a technology to a recipient with requirements that must be met for the assignment to be effective or remain effective. This is actually a type of license agreement, but may be utilized in a donation. If the recipient does not meet all the requirements in such an assignment, ownership of the technology will return to the donor. Even with extensive experience in donations, a technology transfer professional should seek the aid and advice of legal counsel before attempting such an assignment.

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Donation Agreements

Donations agreements can contain assignments or be used in conjunction with formal assignments to transfer a technology from the donor to a recipient. Donation agreements are common in formal circumstances, but can also be useful for more informal donations. The contents of your donation agreement will vary greatly depending on your circumstances. As with the assignment, make sure the donation agreement clearly identifies only those technologies that the donor and recipient intend to transfer. Some area of the donation agreement should clearly identify what invention disclosures, patent applications, patents, trademarks, copyrights, and/or other intellectual property are being transferred via the donation agreement. Depending on your circumstances, it may also be necessary to delineate in the donation agreement exactly which fields and/or territories are being donated.

A donation agreement template is included in Appendix A of this chapter for your reference. This template is not to be construed as legal advice and should only be used as a starting point for your own document. Language and entire sections should be altered to meet the needs of your particular donation.

Transferring Responsibility for the Donated Technology

Transferring the documentation related to the technology and responsibility for the technology can be one of the most difficult aspects of a donation. Logistically, it is best if this transfer of documents (such as patent files and/or invention disclosure files) happens immediately after the donation is finalized. This enables the recipient to promptly take over responsibility for directing patent prosecution or any other form of formal intellectual property protection.

If any outside legal counsel has been responsible for seeking formal patent, trademark, or copyright protection for the technology, the donor should consider carefully whether or not to keep the case with the existing legal counsel. Discussing the circumstances with the donor, inventors, and counsel to determine whether the any of the potential benefits or problems in Table 5 will be a factor in your decision.

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Table 5: Potential Benefits or Problems

Pros	Cons
• Opportunity to work with new counsel • Counsel is already familiar with technology, patent application, and inventors • Counsel may be familiar with the inventors	• Law firm may not be able or willing to adapt to your organization's practices or needs • Counsel may be too familiar with the inventors

Step Five: Postdonation Activities

Regardless of whether you work for the donor or recipient, your organization's involvement with the donation agreement does not end once the agreement is signed. Even if the donation agreement is fairly informal and contains few terms, it important to enter the donation agreement into your tracking and documentation systems. Monitor the terms of the donation agreement as you would a license, interinstitutional, or any other type of agreement. In simpler terms, do what you said you would in the donation agreement.

With regard to record keeping, even after you have donated a technology you should keep a copy of any invention disclosures, patent files, and other documentation related the donation. Keep the records for the longer of the life of the donation agreement or the life of any patents included in the donation plus six years. While keeping these records will require some time to compile and physical and/or electronic space to maintain, your organization may need these records in the future. Without your documentation, future technology transfer professionals in your office will be unable to adequately respond to future administrative inquiries, litigation threats, or other matters related to the donation or the donated technology.

Conclusion

To summarize the highpoints, exercise caution when entering into donation agreements. Ensure your organization is aware of the circumstances and consequences of the agreement. Be attentive to federal funding constraints. Communicate clearly with the other

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organization(s) at all stages of the donation, including after the donation is completed. Finally, expose as many technology transfer professionals in your organization as is reasonably possible to each donation.

Intellectual property donations or some other similar type of agreement will likely be necessary more frequently in the future. Forces driving this trend include a shift toward knowledge-based economies and increases in the pace of research and business. The increasingly mobile nature of researchers and their teams will also make donation agreements or some variation thereof more necessary in the future. Providing the technology transfer professionals in your organization with training and opportunities to participate in patent donations now will enable your organization and the profession to respond to this future need.

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Appendix A

Technology Donation Agreement

This agreement, effective as of ___date____ ("Effective Date"), is between ___name and address of donor____ ("Donor") and ___name and address of recipient____ ("Recipient").

RECITALS

WHEREAS Donor has developed and solely owns …*description of donated technology*… ("Donated Technology") with respect to which Donor has filed and solely owns the patents and patent applications in Attachment A ("Donated Patents").

WHEREAS Donor wishes to donate Donated Technology, Donated Patents, and technical information related to and needed to practice Donated Patents ("Donated Know-How").

WHEREAS Recipient wishes to accept the donation from Donor of the Donated Technology, Donated Patents, and Donated Know-How.

WHEREAS…*Include as many recitals as needed to include all the facts and goals that the donor and recipient wish to state within the donation agreement.*

NOW, THEREFORE, in consideration of the foregoing premises and the respective undertakings of the Donor and Recipient set forth below, the Donor and Recipient agree as follows:

Add sections and subsections or delete sections as are needed to address the terms agreed to by the donor and recipient.
Consult legal counsel and other experts.

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SECTION 1: DEFINITIONS

SECTION 2: ASSIGNMENTS

SECTION 3: CONFIDENTIALITY

SECTION 4: GOVERNING LAW

SECTION 5: INDEMNITY

SECTION 6: PRESS RELEASES

SECTION 7: MISCELLANEOUS

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Understanding Patent Preparation and Prosecution

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Introduction

A patent can be a useful tool for protecting intellectual property. A well-written patent can keep competitors from copying successful products and can also help lure potential investors. At the same time, rattling the proverbial patent saber may lead to royalty income from licensing agreements. Successfully litigating a claim for patent infringement can cripple a competitor, solidify your market position, bring in significant awards from damages, and even lead to further licensing agreements.

It is important for those seeking patent protection to understand what goes into a well-written patent application. Of particular importance is the tension between the standards for patentability and the desirability of maintaining a range of coverage that is adaptive to meet future needs. While it may be relatively easy to produce a patent application that scrupulously complies with statutory and judicial guidelines, following these guidelines while, at the same time, building in interpretative adaptability and breadth may be a far less trivial matter.

Claim Drafting

The crux of any patent lies in its claims. Patent claims define, in technical terms, the extent of the protection conferred by an issued patent or the protection sought in a patent application. Claims are often compared to the recitation of boundary lines in a deed for land because both identify the property that the owner has the right to exclude others from. In order to enforce a patent in court, the patent owner or patentee must demonstrate that what the other person is using falls within the scope of a claim of the patent.

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The claims of a patent appear at the end of the patent document, immediately following the written description of the invention. The claims are set forth as separately numbered paragraphs in a single-sentence format. The first claim of an issued patent is always numbered "1," with each claim thereafter following in an ascending numerical sequence. Most patents contain about ten to twenty claims, although there are some patents with only one claim and others with hundreds of claims.

Claim Format

There are two basic claim formats: independent claims and dependent claims. Whereas *independent* claims stand on their own, *dependent* claims depend on another claim and generally are directed to particular embodiments as fall-back positions. The rules of claim drafting also permit *multiply dependent* claims that are dependent upon two or more claims.

Independent Claims

Each independent claim consists of three parts: the preamble, a transitional word or phrase, and the body. The preamble generally sets the stage for the rest of the claim and may define the general technical environment of the invention. For example, an independent claim directed to an improved type of telephone may have the preamble: "A telephone ...." Alternatively, an independent claim for the same invention may have the preamble: "An apparatus for improved telecommunication ...." The preamble is not usually considered to be a legally limiting constraint on the invention and, therefore, preambles tend to vary widely—even within the same industry.

Next, the transitional word or phrase is used. There are basically three transitions: "comprising" or "which comprises," "consisting of," and "consisting essentially of." "Comprising" is an open term; construed by the courts as being a shorthand way of saying "including the following elements but not excluding others." For example, a claim to a combination comprising A + B also covers a combination having A + B + C. On the other hand, the term "consisting of" is a closed term. Returning to the example, a combination consisting of A + B does not cover the combination A + B + C. The final term, "consisting essentially of," is part open and part closed in the sense that such a claim covers the recited elements alone or such elements plus any other elements that are not directly related to the claimed invention. In general, patent attorneys use the open term "comprising" in order to cover

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the invention as broadly as possible. A "consisting" transition is usually only used in the context of a chemical composition.

The body of the claim follows the transitional word or phrase and lists the main elements of the invention. It is here, in the body of the claim, that an invention's novel and non-obvious characteristics are particularly claimed. Because claims must be written in single-sentence format, punctuation is also important. Modern claims typically follow a set format whereby the preamble is often separated from the transitional term by a comma while the transitional term is separated from the body by a colon. Each element of the invention in the body of the claim may be set forth in its own separate paragraph, which may, in turn, be set apart from other paragraphs by a semicolon or comma. The functional connections and interoperation of elements are also described in the body, either in a separate dedicated paragraph or in each of the element paragraphs.

Dependent Claims

Dependent claims add additional limitations to the claim from which they depend or further define one or more elements of such claim. Dependent claims may depend on an independent claim or another dependent claim. Dependent claims that depend upon more than one claim are generally referred to as "multiply dependent claims," which are discussed in more detail below.

In practice, dependent claims are often used to focus in on the inventor's preferred embodiment of the invention (e.g., the actual product design that the inventor intends to use). In a typical patent application, claim 1 is an independent claim that broadly describes the invention, and claim 2 is a claim dependent on claim 1 and that adds one or more limitations to claim 1 or further defines one or more elements of such claim.

Subsequent dependent claims may introduce different or additional limitations that correspond to different embodiments of the invention. Indeed, the expressions "in one embodiment," "in a preferred embodiment," "in a particular embodiment," "in an advantageous embodiment," or the like often appear in the descriptions of patents and patent applications and are used to identify a particular implementation or method of carrying out the invention. These alternative embodiments may correspond to a set of dependent claims or could conceivably form the basis of an independent claim. It is not uncommon to have

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many more dependent claims than independent claims in order to protect the preferred embodiment(s) of the invention as well as any possible variations.

The Advantages of Dependent Claims

Each dependent claim is, by law, narrower than the independent (or parent) claim upon which it depends. Accordingly, it might appear that there would be little purpose to the dependent claim. However, dependent claims do have their advantages.

First, dependent claims provide valuable fallback positions for patent attorneys, both when negotiating with patent examiners and in litigation. Because it is difficult, if not impossible, to know with a fair degree of certainty if a patent claim is valid (because of unknown prior art), there is always some risk that an independent claim will be found invalid. Nevertheless, even if the independent claim is determined to be invalid, a dependent claim may still survive and may still be broad enough to bar competitors from valuable commercial territory.

Second, a dependent claim may clarify and/or further limit independent claim language. Independent claims are typically written with very broad terms—sometimes too broad or sometimes a bit vague or unclear. Broad terms in independent claims that appear ambiguous or vague may be clarified by dependent claims that further define those terms. Also, under the *doctrine of claim differentiation,* a claim is presumed to cover different subject matter than each other claim. In the case of a term that could be construed broadly or narrowly, a dependent claim specifically drawn to a narrower interpretation should result in a determination that the scope of the parent claim is directed to the broader interpretation. As construed by the courts, the doctrine of claim differentiation dictates that it would be "improper for the courts to read into an independent claim a limitation explicitly set forth in a dependent claim."[1]

Multiply Dependent Claims

While the United States patent laws allow for multiply dependent claims, they are generally disfavored because of cost considerations. Multiply dependent claims typically reference more than one other claim (e.g., "The method of claims 1 or 2, further comprising..."). In this regard, specific claims must be referenced and not merely some unspecified set of other claims. A claim reciting "the method of any of any other claim" or "the

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method of all previous claims" is incorrect. Also, claims must be referenced in the alternative, using "or" rather than "and" (e.g., "the method of claims 1 and 2" is incorrect). Such a claim is counted for filing-fee purposes in the United States according to the number of other claims that are referenced. Thus, if the claim depends from three claims, such claim is counted for fee purposes as three dependent claims. In light of the excess-claim fees currently imposed by the U.S. Patent and Trademark Office (USPTO), this claim strategy can quickly become expensive. Multiply dependent claims are, however, commonly used in other jurisdictions, including Europe.

Claim Categories (or Types)

Claims can be categorized in terms of what is being covered. The most common claim types are apparatus (or product, device, system, article, or composition) and method (or process). However, there are quite a few different claim categories that may be used to patent an invention.

Apparatus Claims

Apparatus claims typically refer to a physical entity—i.e., an apparatus, product, device, system, article of manufacture, or composition. Many apparatus claims use these terms in the preamble to identify the claimed subject matter as such. For instance, the preamble of an apparatus claim for an improved telephone might read: "a telephone apparatus ..." or "an apparatus for telephone communication ..." Alternatively, the preamble may refer to a telephone product, system, device, article, etc. Still further, the preamble of an apparatus claim may simply recite: "a telephone ..."

Apparatus claims typically focus on the structure of the invention in the body of the claim. For example, the size, orientation, and/or location of physical components may be recited. Apparatus claims also describe how each component connects to, and interacts with, the other components of the invention. Of course, the overarching aim of apparatus claims, as with all other claims, is to specify the invention in such a way as to clearly demarcate its novel and non-obvious features.

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Method Claims

Method (or process) claims typically recite some novel and non-obvious activity. The activity may refer to a method of manufacturing a device or a method of using a device. However, under *In Re Bilski,* 545 F.3d 943 (Fed. Cir. 2008) (*certiorari* granted), a method must transform an article or be tied to a particular machine in order to be patentable. Methods that do not meet the machine-or-transformation test (e.g., certain types of software or business methods) may not be patentable in view of the *Bilski* case.

Method claims are identified by the preamble. Method claims recite: "a method ..." or "a process ..." Additionally, the transitional phrase may refer generally to the steps of the method—e.g., "a method for making a telephone, the method comprising the steps of: ..." The novel and non-obvious steps of a claimed method are recited in the body of the claim.

Claim Considerations

Each claim type has its own pros and cons. The drafter must consider carefully the advantages and disadvantages of a particular claim type while preparing the patent application. For example, from a practical standpoint, it may be much more difficult to determine whether a manufacturer is infringing a method claim than an apparatus claim. To determine infringement of the apparatus claim, one may only need a sample of the final manufactured product, but to evaluate infringement of the method claim, it may be necessary to have access to the actual manufacturing facility.

On the other hand, apparatus claims generally protect against all uses of a claimed product, while a method claim may only protect against one particular method of use. Still further, products protected by apparatus claims must be appropriately marked with the patent number in order to obtain damages before actual notice of the patent is provided to the infringer. Marking may be a nontrivial expense in some cases—potentially making it a worthwhile endeavor to avoid the requirement entirely by relying on method claims alone. While courts have been inconsistent in their application of the marking statute when a combination of claim types is present, courts generally agree that patents with only method claims are not subject to the marking statute. These are just a few examples of the considerations that go into deciding on types of claims to pursue.

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Claim Coverage and Claim Validity

Claim coverage and claim validity are two competing considerations in claim drafting. Ideally, an independent claim is drafted broadly to cover the current invention as well as foreseeable variations and trivial improvements, so that the patent claim cannot be easily designed around. However, the broader a claim is, the more likely it is that the claim may be found invalid under statutory requirements of novelty and non-obviousness.

Claim Coverage

The breadth of coverage offered by a patent claim generally depends on the elements the claim recites. In general, the broader the claim coverage, the fewer elements, or steps, required to prove infringement. For instance, a broad claim might cover a telephone with the elements x and y, while a narrower claim may only cover telephones containing the elements x, y, and z. Likewise, a claim for a method of making a telephone that recites the steps a, b, and c will be broader than one reciting the steps a, b, c, and d. In essence, broad claim coverage enables the patent to be asserted against a wider range of devices or processes, because fewer elements or steps are needed to find infringement.

Claim Validity

Unfortunately, patents with broader claim coverage often face significant obstacles regarding claim validity. The validity of a claim refers to its compliance with applicable statutory and judicial guidelines. Of particular importance in the United States are the statutory requirements of novelty and non-obviousness.

Novelty requires that patent claims present new improvements over known devices or methods, inventions, patents, and publications—collectively termed the prior art. In order for a claim to be considered novel, there must be no single item of prior art that teaches all of the claimed elements. Thus, a claim for a telephone with elements w, x, y, and z may be considered novel over an item of prior art teaching a telephone with elements x, y, and z. Likewise, the telephone claim may be considered novel over an item of prior art disclosing a telephone with elements v, w, x, and y. However, the claim would not be novel over an item of prior art teaching elements w, x, y, and z (or v, w, x, y, and z).

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In addition to being novel, a claim must meet the statutory requirement of non-obviousness. An obviousness inquiry seeks to determine whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the claimed subject matter pertains. Obviousness is similar to novelty in that it compares the elements found in the prior art with the elements in the invention being claimed. Unlike novelty, however, obviousness is not restricted to considering the elements taught in a single item of prior art; instead, the teachings of multiple items of prior art may be combined to invalidate a claim.

In practice, obviousness and novelty go hand in hand in the USPTO. Generally, claims are first analyzed by an examiner for novelty and may be rejected if a prior art reference teaching all the elements of the claim can be found. Assuming a claim can overcome the novelty hurdle (meaning there is no single prior art reference teaching all of the elements of the claim), an obviousness inquiry may then commence, wherein the claim may be rejected if there are multiple prior art references that can be combined to teach all elements of the claim.

The Specification

By law, sufficient detail must be provided in the written description, or specification, of the patent to support the claims. Specifically, under 35 U.S.C. § 112, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The patent specification is the portion of a patent application that describes the invention for which patent protection is sought. The specification generally consists of a background section, a summary of the invention, a summary of any figures or drawings, and a detailed description of the invention. In the United States, an abstract section that summarizes the disclosure is also required to aid in searching. By law, the specification must set forth a description sufficient to enable one of ordinary skill in the art to which the subject matter pertains to practice the "best mode" of the invention without undue experimentation.

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The specification section is important because it is the first place a court looks when construing a patent claim. Courts recognize that, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."[2] Because courts so often look to the specification to illuminate the meaning of claims, often the claims are drafted first, and the specification afterwards, so that the drafter already knows what claim terms must be included in the specification.

Also, unlike the claims of a patent, the specification section usually cannot be modified once it is filed (subject to a few narrow exceptions). Consequently, it is important to include all relevant information the first time around. Practitioners may also describe several different variations, or embodiments, of the invention that correspond to different dependent or independent claims. However, references to the "invention" should be limited, in favor of allusions to "embodiments" or "aspects." Additionally, the specification should avoid disclosing embodiments that are not claimed, as the resulting dedication to the public of this subject matter may later hamper efforts to stop infringers.

Prosecuting a Patent

Patent prosecution refers to the negotiation process between a patent applicant (and his/her representative) and a patent examiner at a patent office. Patent prosecution is distinct from patent litigation, which relates to the legal action relating to patent infringement. However, actions taken by patent applicants in the prosecution process can have significant effects on subsequent litigation.

The Prosecution Process

At a high level, patent prosecution can be divided into pregrant prosecution and postgrant prosecution. Pregrant prosecution involves negotiations with the patent office for the grant of patent claims. Postgrant prosecution involves issues such as opposition proceedings and postgrant amendments. This article focuses on pregrant prosecution.

There are several phases of pregrant prosecution. First, the patent application is prepared, which includes the drawings, the specification, the claims, and usually some associated paperwork. Next, the application is filed with the appropriate patent office. This may

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be the USPTO, the European Patent Office, or some other patent office. Once the application is filed, the applicant officially has a patent pending. At about eighteen months after initial filing in a patent office, the patent application is usually published and becomes publicly available. At around the same time, the patent office in question will begin to search for applicable prior art and examine the patent application to determine if it should issue as a patent. The bulk of pregrant prosecution issues arise during the search and examination phase.

During a patent examination, the examiner will compare the prior art results obtained in the search to the claims filed in the application to determine whether the claims are allowable. In the case of the USPTO, if the examiner finds that the application does not comply with the statutory requirements of novelty and non-obviousness or that the application is objectionable for some other reason (e.g., deficiencies in the specification), the examiner may prepare and send the applicant an office action requesting that the applicant address particular issues. The applicant may respond to the office action by arguing in support of the application and/or by making amendments to the application.

Alternatively, the applicant may decide to abandon the application. If the applicant does respond to the office action, the examiner may then consider the applicant's arguments and/or amendments and reply with the same grounds for rejection, different grounds for rejection, an allowance granting some or all of the claims, or with some combination of the above. This negotiation process between the patent office and the applicant is repeated until the patent issues, or the application is abandoned.

Prosecution History Estoppel

Prosecution history estoppel refers to a legal presumption concerning concessions in the scope of claim coverage. Generally, estoppel attaches during the course of prosecution because of arguments or amendments made in response to an office action. In particular, "a patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claims."[3] Once the applicant has narrowed his or her claim through argument or amendment, an estoppel is presumed that prevents enforcement of a broader claim version.

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A narrowing amendment, if made for a reason related to patentability, will give rise to a presumption that the claim does not cover certain devices or methods. Presumptions arise when: a preexisting claim limitation is narrowed by amendment, a new claim limitation is added by amendment, or a dependent claim is rewritten into independent form to include all of the limitations of the original independent claim and the original independent claim is cancelled.[4]

For instance, if a claim reading: "a telephone comprising: element a and element b, wherein a is attached to b by a screw," is amended to read "a telephone comprising: element a and element b, wherein a is attached to b by a Phillips head screw," then a court may presume the applicant has conceded claim coverage of telephones that attach a to b by a non-Phillips head screw. However, the presumption of surrender may be rebutted if the patentee can demonstrate certain facts that prevent the estoppel from being applied.[5] "The scope of the patentee's concession is determined on a limitation-by-limitation basis."[6]

While it is almost impossible to avoid creating some sort of prosecution history estoppel, there are several strategies applicants may undertake to minimize estoppel effects. In this vein, practitioners often adhere to the old adage "less is more." A practitioner will typically limit amendments defining a term in one claim that may illuminate the meaning of a term in another claim. Also, it is advisable to avoid acknowledging that different claim terms are synonymous, as is often tempting when arguing that claims distinguish over the prior art.

Likewise, you should minimize as much as possible comments that interpret the claims or describe what the invention is. Where feasible, it is desirable to indicate to the examiner that any amendments being made are being made to better define the invention, not to overcome the prior art. Practitioners are also well-advised when distinguishing over the prior art to recite the exact language of the claims and do not paraphrase. Also, you should not comment regarding distinctions over prior art unless absolutely necessary. Gratuitous comments defining over the prior art can limit the scope of the claims.

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Conclusion

While it may be relatively easy to produce a patent application that scrupulously complies with statutory and judicial guidelines, following the guidelines while, at the same time, building in interpretative adaptability and breadth may be a far less trivial matter. There are numerous issues related to preparing and prosecuting a patent application that can have ripple effects on the patent's viability in downstream litigation or licensing negotiations. A well-prepared and prosecuted patent may be used to attract investors, prevent competitors from copying valuable products or processes, negotiate fruitful licensing agreements, or obtain damages for patent infringement.

On the other hand, patent applications that are thrown together quickly and prosecuted poorly, without an eye toward future litigation, may result in nothing more than a waste of valuable time, energy, and resources. Thus, it is of paramount importance for applicants seeking patent protection to understand what goes into a well-written patent application and to make sure their patent counsel understands as well.

For more information about patents, see Volume 3 of the 3rd Edition of the Association for University Technology Managers Technology Transfer Practice Manual.

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Aligning the Activities of a Technology Transfer Office with the Social Mission of a Life Sciences Research Institute in Portugal: Opportunities and Challenges for a New Office

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Introduction

This paper outlines the opportunities, concerns, and strategies associated with setting up a technology transfer office (TTO) in Portugal, at a publicly funded life sciences research institute, the Instituto Gulbenkian de Ciência (IGC). First, it discusses the lessons learned from North American models of TTO formation and how best to accomplish the translation of science into valuable assets for the benefit of society. Next, it gives an overview of the history and current landscape of technology transfer in Portugal. Finally, the paper explores the opportunities and challenges in setting up a TTO at the IGC.

The Role of the Technology Transfer Office

The primary role of the technology transfer office (TTO) is the mobilization of university-based research into practical and societal applications. In this sense, the mission of a TTO

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should mirror the broader societal and academic mission of its host university to mobilize innovative research and knowledge for the benefits of society. One way to accomplish this goal is for TTOs to facilitate and broker the relationships between researchers and external stakeholders, such as other researchers, their institutions, industry, venture capital, and local or regional economic development interests. Such activities are particularly important in the life sciences sector where there are close and complex relationships between research centers and other stakeholders, especially the biotechnology industry. Indeed, many biotechnology companies spawned from research institutions as spin-off companies, and many prominent biotechnology clusters are located near universities (Boston University, Stanford University, and Duke University).

The history of the TTO and the rise of the modern biotechnology industry are closely linked and often associated with the passing of the *Bayh-Dole Act* in the United States (1980) that enabled universities to hold intellectual property rights in publicly funded research products and processes.[1] The *Stevenson-Wydler Act* was the equivalent for government departments.[2] These acts were closely followed by a United States Supreme Court ruling that a genetically modified bacterium constitutes patentable subject matter. This landmark decision in *Diamond v. Chakrabarty* allowed the patenting of products such as gene sequences or life forms, a necessary condition for the life sciences industry to prosper.[3] Most countries in the industrialized world have since followed the U.S. model of enabling publicly funded research institutions, researchers, or some combination of the two to hold intellectual property rights in the products and processes of publicly funded research.

Presently, most research institutions in the United States have a TTO or its equivalent, and technology transfer professionals have formed a close network through organizations such as the U.S.-based Association of University Technology Managers (AUTM).[4] In its most recent survey on the state of technology transfer in the United States, well over a hundred universities plus colleges reported statistics to AUTM.[5] AUTM provides reported data to its members and compiles aggregate reports for public dissemination. However, the AUTM metrics and their equivalents have been criticized as being overly focused on input/output measures such as number of disclosures of inventions from researchers in an institution to the TTO, number of patents filed, number of patents granted, license reve-

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nue generated for the institution, and number of spin-off companies created (regardless of profitability and longevity).[6] Unfortunately, such metrics have come to dominate science policy at a broader level, since they are easily synthesized and understood by institutional and governmental policymakers, even if they do not capture the broader societal benefits of publicly funded research institutions.

This issue of how to measure the success and societal contributions of specific technology transfer strategies has recently received more attention. TTOs such as the University Industry Liaison Office (UILO) at the University of British Columbia have undertaken more comprehensive reviews of their activities considering broad-based societal, academic, economic, financial, and political impacts.[7] In addition, the UILO has taken a global view in determining its social value. It has instituted a global access policy[8] not only for neglected diseases research and global health as advocated by AUTM[9,10] and illustrated through the Better World Project,[11] but for all university innovation. Such policies, among other things, call for differential pricing structures and access principles for developing and developed countries.

Such innovative metrics and activities illustrate the real utility of TTOs, especially considering the small return on investment for most TTO activities based on traditional metrics, especially in smaller research institutes or less economically developed regions. For example, no Canadian technology transfer office is self-sustaining over the long term based on licensing royalties, with the exception of specific years where long-term licensing revenue is elevated due to one big hit. It is naïve, therefore, to believe that the primary role of a TTO is to generate revenue for its host institution, or, in many instances, that a TTO can even generate enough revenue to be financially self-sustaining.

Thus our starting premise for establishing a new TTO at a life sciences institute, the Instituto Gulbenkian de Ciência, in Portugal is that the activities and mission of the office should align with the broad social mandate of the institute. The following discusses the opportunities and challenges in setting up such an office.

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Technology Transfer in Portugal

Portugal's exports have been steadily moving from low technology products to medium- and high-technology goods.[12] Moreover, in 2008, corporate research and development (R&D) expenditures (0.61 percent GDP) exceeded state R&D expenditures for the first time.[13] The growth in business sector expenses for R&D indicates an effort from the private sector to increase Portugal's scientific development and technology capabilities. Currently, Portugal offers a highly competitive system of fiscal incentives for R&D, offering tax deductions of up to 82.5 percent of the investment in R&D.[14]

This significant progress was driven by several initiatives that tackled the country's shortcomings with regard to technological development.

One important area where these initiatives have been active is knowledge transfer between industry and the academic sector. As in most developed countries, science and technology policy in Portugal has moved toward facilitating exchanges between government, publicly funded research institutions, and industry, including the enhancement and modernization of intellectual property rights and of the national intellectual property system.

Historically, one of the engines behind Portugal's recent progress in technology transfer has been the National Institute for Industrial Property (INPI, Instituto Nacional da Propriedade Industrial). INPI is the national institution responsible for management, policy, and education on intellectual property. Since 1999, INPI has been actively implementing an original initiative aimed at establishing a network between itself, entrepreneurs, patent agents, and other stakeholders within the innovation system. INPI has focused on developing strategic partnerships with business associations, universities, technological centers, and incubators.

The tangible outcome of this initiative was the establishment of offices to support intellectual property rights known as GAPI (Gabinetes de Apoio a Propriedade Industrial). From 2001 to 2002, fifteen GAPI units were established serving diverse organizations and institutions such as business associations and universities.[15] Five more GAPIs were established between 2003-2005. It is important to understand that, prior to this initiative, most

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institutions in Portugal did not have any intellectual property (IP) management or knowledge transfer departments, so these GAPIs were an important springboard for Portuguese technology transfer. The GAPIs became the precursors to many of the TTOs currently active in Portugal.

GAPI funding came from both European programs and INPI. Besides providing professional and logistic support for each GAPI, these funds also promoted capacity building in the best practices for management of intellectual property rights and technology transfer as well as global networking through the participation of GAPI professionals in international workshops. A new GAPI initiative is in progress and will encompass companies, startups, as well as universities and other R&D institutions.[16]

As a major upside, this initiative successfully brought together two formerly disassociated communities in Portugal: intellectual property lawyers and managers and the research and development community. However, on the downside, many of the problems in Portuguese technology transfer can be traced to how the GAPI initiative was initially implemented. The GAPI units were autonomous from INPI and their organization and institutional policies were defined by their host institution, meaning there was no standardized format or guidelines for these offices. As a consequence, Portugal, a very small country, now has twenty TTOs.

These TTOs have completely different models of operation and compete with each other. Clearly, for a country with limited resources, it would be highly beneficial to avoid organizational redundancies across different TTOs and centralize technology transfer, thus reducing institutional costs. However, due to the GAPI legacy of highly fragmented TTOs with very different operational models, a centralized TTO is extremely difficult to implement.

Some of these problems are currently being tackled by UTEN (University Technology Enterprise Network), a joint five-year effort between the University of Texas and Portugal that started in 2007. This follows an initiative of the Portuguese government to establish several international partnerships, not only with the University of Texas at Austin, as well as, with the Massachusetts Institute of Technology, Carnegie Mellon-University, Harvard

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Medical School, and the Fraunhofer-Gesellschaft. The UTEN network in particular aims to bolster Portuguese R&D institutions and establish thematic networks in Portugal, the transfer of technology to commercial ventures, and the introduction of Portuguese companies to the U.S. market. UTEN aids in establishing Portuguese small-medium enterprises (SMEs) and startups in the U.S. market by building contacts with venture capitalists and synergies with U.S. companies, good examples of such interactions are Bioalvo, Fluidinova, and YDreams Portuguese SME that UTEN has helped to establish a presence in the United States in 2007.[17]

UTEN has, so far, managed to identify technology-based business opportunities, offer training to technology transfer officers, and create a fluid network between all Portuguese TTOs. Therefore, although the idea of a centralized TTO for Portugal may still be distant, there has been significant progress in aligning most Portuguese TTOs' goals and practices.

So far we have focused on government and universities. In Portugal, however, industry also poses some interesting challenges. Since R&D has thus far played a small role in Portuguese industry, it is not surprising that the private sector has a certain lack of interest in engaging in interactions with academic institutions. This, in turn, makes the TTO's job more challenging in that it has to educate both researchers and industry partners about the value of technology transfer. Furthermore, this lack of sophistication in the private sector can make attracting venture capital for startups very difficult since high-technology companies are viewed as risky endeavors by investors. Nevertheless, funding for high-technology startups is becoming more available, namely through private/public funds programs.

If we take all these factors together, then we can safely say that, although much progress has been made in Portugal, there is still significant room for improvement.

The Challenges and Opportunities in Setting up a TTO in Portugal

Keeping in mind the initial discussion on the role of a technology transfer office in a publicly funded life sciences research institution and the Portuguese policy goal of facilitating technology transfer for the benefit of Portuguese industry and broader society, we now discuss the specific case of establishing a technology transfer office at the Instituto

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Gulbenkian de Ciência (IGC). The policies and practices of such a TTO should, ideally, align with the mission of the IGC.[18] The mission of the IGC includes promoting science and serving the Portuguese research community, pursuing modern biomedical research in both content and technological basis, as well as producing internationally competitive science.[19] It has strong postgraduate education programs and is a leading life sciences research institute in Portugal. It is a highly academic institute with a history of scientific excellence.

This mission is based on the broader mission of Fundação Calouste Gulbenkian (FCG), a private foundation, which established and supports the IGC. The FCG has a very clear mission of improving Portuguese and global society. Consistent with this, it is involved in and fosters co-operative projects based on the United Nations millennium goals[20] (end of poverty, universal education, gender equality, child health, maternal health, combat HIV/AIDS, environmental sustainability, global partnerships) with Portuguese-speaking African countries and East Timor.

Hence, due to its mother institution, the IGC carries a very strong social mission. This has led to an internal culture of Mode 1 research and of little interest in generating revenues through IP licensing. However, recently the IGC has started to show interest in high social-impact technology transfer initiatives as it is becoming clear that technologies that do not leave the lab have smaller social contributions.

So, for a TTO to be aligned with the IGC's goals it needs to take into account the institute's concern with excellence in scientific research and the societal mission of the institute.

What kind of TTO, then, can be developed that incorporates both these elements? The policies will need to be carefully crafted to encourage high-quality applied scientific innovation in the life sciences. Thus, part of the mission of a TTO must address the possibility of facilitating or directly generating, through licensing revenues, additional resources for research.

Having a TTO within a research institution serves an important educational function for research faculty and students by (1) providing training on identification of research with

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translational potential; (2) providing training on IP protection, entrepreneurship, and business development; and (3) allowing access to networks that include entrepreneurs, investors, and industry. These initiatives, in turn, stimulate scientific innovation within the institute by increasing the perceived impact of research findings. Currently we are pursuing this in two ways: we are addressing the doctoral students directly, through courses on technology transfer and its importance, and we are meeting with the principal investigators directly on a one-on-one basis in order to educate and build long-term, trust-based relationships.

Such a traditional role for a university TTO, however, should not be the only goal, especially within an institution with a strong public-good mission. Any new policy must also recognize that technology transfer to industry via intellectual property rights and licensing is only one of the mechanisms to mobilize institutional research for the public good. A number of TTOs at institutions such as University of California, Berkeley, and the University of British Columbia have established global access policies to facilitate, for example, the transfer of technology to developing countries. In these circumstances, revenue generation should not be the primary concern, but rather take second place to the dissemination of useful products and processes. In this sense, it is very important for the TTO to value the overall social impact of a certain project over its immediate returns for the institute.

The final issue is the pragmatic one of implementation. The answer to this question is intimately related to the size of the institution, or, in other words, to its critical mass and power to engage the discovery and dissemination of new technologies. The constraints imposed result from the costs of seeking patent protection and the ongoing issue of generating successful commercial outcomes. Thus, the management of limited resources must be a priority.

One means for a TTO at a smaller institution such as the IGC to bypass the resource issue is to establish collaboration with an already fully functional TTO from another organization. In such an event, creativity in partnering will be important so that it can answer the expectations of both parties. This type of engagement makes sense if both parties are willing to start a long-term relationship since the outcomes of technology transfer have a lag time of several years from disclosure to being available to society.

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To start a collaboration of this sort, a careful choice of collaborator will be essential. It is important to consider whether the mission of a candidate TTO organization aligns with goals of the FCG/IGC. The desired scenario would be to find a partner such that the IGC would engage in work collaboration as if it were an additional department of that organization. To align with the FCG/IGC's public interest mandate, as much as possible, this partner TTO should favor technology transfer by encouraging nonexclusive licenses and dissemination of innovation in general and, in particular, to developing countries at a lower cost. Willingness to adopt innovative models of IP management, such as supporting initiatives for patent pooling, are also considerations in selecting a partner TTO.

Other important factors to consider are accountability and transparency of the TTO in reporting on and justifying its activities to key stakeholders, including the public. So far, however, finding an appropriate partner has proven difficult, since most large international TTOs are reluctant to make such an effort for an institute with a small output in IP.

An alternative to partnering with a larger, established TTO is to change the focus of the technology transfer away from more traditional models used in larger institutions. Traditional TTOs tend to manage large IP portfolios and generate revenues through licensing agreements. Since the IGC has limited resources for securing and marketing a large volume of patents, an attractive option is to only secure IP for a few select projects that fit well with the institute's mission. These projects would have to be entrepreneur-driven to minimize the load on the IGC's resources and would need to have the potential for high societal impact to fit with the institute's social mission. In summary, spin-offs that may be for profit or nonprofit driven by researcher/entrepreneurs or by external entrepreneurs. The role of the TTO, in this case, would be to work as an in-house entrepreneur while offering support, training, and networking opportunities to the researchers.

We believe this model of an entrepreneurship-driven TTO, in supporting entrepreneurial initiatives with a strong focus in social impact, addresses a need that is present in institutes other than the IGC, and we have initiated talks with another institute in Portugal to offer our services.

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In conclusion, the North American experience has contributed in the shaping up of technology transfer in Portugal, of which the UTEN network is an embodiment. There are many challenges in setting up a TTO in a developing European country, including resource and cultural challenges. Starting a TTO is a tremendous opportunity to build an institution from the ground up, learn from the experience of other organizations, and truly align the mission of the TTO with the social and scientific goals of its host institution and country.

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Research Tool Patents: Have Reports of Their Death Been Greatly Exaggerated?

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Introduction

Judge Pauline Newman of the Court of Appeals for the Federal Circuit characterized a research tool as "a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device *(citation omitted)*, or a biochemical method such as the PCR (polymerase chain reaction). It is as subject to the patent right as is any other device or method, whether it is used to conduct research or for any other purpose.[1]"

Research tool patents are a mainstay of many life science companies. In fact, some companies center their entire business plans around the use or sale of particular research tools. The value of research tools in life science research is unquestionably high; however, recent developments in patent law and tightening budgets have forced companies and universities to decide whether to devote precious resources to drafting and prosecuting research tool patents. The purpose of this article is to set out the current state of the law and discuss whether it makes sense to attempt to obtain and enforce research tool patents.

Legal Considerations

The Hatch-Waxman Act

The United States' patent system is founded on a basic quid pro quo: Rather than keeping an invention secret, if an inventor agrees to provide the public with a description of his or her novel and nonobvious invention that is sufficient to permit those skilled in the art to make and use the invention then the inventor will be granted a 20-year monopoly right on the use of that invention. The extent of this monopoly right is limited to the right to exclude others from making, using, selling, or offering for sale the patented invention. This right to exclude, however, does not come without exceptions.

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One such exception is found in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act.[2] The Hatch-Waxman Act includes provisions designed to remedy two unintended problems with the patent system experienced by companies developing products that are subject to U.S. Food and Drug Administration (FDA) approval.[3] The first problem was a shortening of the effective life of a patent caused by the extended premarket regulatory approval period required for many products.

For example, most companies developing therapeutic products will file for patent protection very early in the development process, typically well before clinical trials begin. As a result, the 20-year term of the patent is ticking away while the product is in clinical trials or awaiting FDA approval. Often therapeutic products have as little as 5 to 10 years of patent life remaining at the time of market approval. To remedy this first problem Congress allowed companies to regain a certain percentage of the time spent gaining regulatory approval in the form of a patent term extension on a single patent covering the approved product (or method of using the approved product).

The second problem addressed by the Hatch-Waxman Act occurred at the opposite end of the patent lifecycle. While innovator companies were losing early portions of their patent term because of the regulatory process, they were gaining effective patent protection beyond the end of the patent's life. For example, if a company wanted to market a generic version of a patented drug, it had to wait until the patents covering the drug (or methods of using the drug) expired before initiating the development process or be subject to a lawsuit for patent infringement.[4]

Even for a generic drug, which does not require full-fledged clinical trials, the development and regulatory process takes years. This period during which the generic manufacturer was gaining regulatory approval was a de-facto extension of the patent holder's monopoly right. Congress attempted to remedy this problem with the passage of 35 U.S.C. § 271(e)(1) (271(e)(1)), which states that it is *not* an act of infringement "to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[5]" This allows generic manufacturers to initiate clinical test-

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ing prior to the expiration of the patents without the fear of an infringement suit. It is this exception to a patent holder's right to exclude that presents potential issues for the owners of research tool patents.

35 U.S.C. § 271(e)(1)

According to 271(e)(1), any use of a "patented product" that is "reasonably related" to the development of data to be submitted to the FDA does not infringe a patent claiming the product. This exception has been interpreted to extend to all products subject to FDA approval, including medical devices.[6]

The Supreme Court assessed the scope of activities that are reasonably related in *Merck v. Integra*.[7] The Court concluded that the exception from infringement covers activity by a drug maker if the drug maker has a reasonable basis for believing that a patented compound may work through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA. The Court explicitly noted that the issue of whether the exception from infringement applied to research tool patents was not before the court.[8]

The decision in *Merck v. Integra* unleashed a storm of speculation as to whether patents to research tools would now fall under the exception to infringement. Many commentators speculated that the broad language used in the Supreme Court's decision (and the underlying Federal Circuit decision) signaled that the courts would find that using patented research tools to generate data to be submitted to the FDA would be exempt from claims of patent infringement under 271(e)(1).[9]

This question is immensely important to the life science industry because research tools are such an integral part of many companies' businesses. For example, assume that Company A is a pharmaceutical company developing novel compounds that activate the XYZ receptor. Company B has a patented method for screening compound libraries for their ability to activate to the XYZ receptor, which allows the development process to be shortened by 50 percent.

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Company B's business is built on providing services using its patented method. If research tools are exempt from patent infringement, then Company A is free to implement Company B's patented method without obtaining a license or paying a royalty and without Company B's consent. Effectively, Company B is out of business. Many scenarios such as this can be (and have been) hypothesized.

Unfortunately, neither the Supreme Court nor the Federal Circuit offered much guidance on the issue, leaving the life science community to speculate as to the enforceability of research tool patents.

Proveris v. InnovaSystems

In August 2008 the Federal Circuit provided some limited guidance into the question.[10] Proveris Scientific Corp. owns a patent claiming an apparatus for characterizing aerosol sprays commonly used in various drug-delivery devices, such as nasal spray pumps and inhalers. Data generated by this device was required to be submitted to the FDA in order for companies to gain approval for certain inhaler-based drug-delivery systems. The product was marketed to drug manufacturers and the FDA as a tool solely useful in generating data for the FDA approval process, but the patented device itself was not subject to FDA approval.

InnovaSystems made and sold a similar product. Proveris sued InnovaSystems alleging infringement of its patents. InnovaSystems claimed that the product was exempt from infringement under 271(e)(1) because it generated data that was reasonably related to the generation of data that would be submitted to the FDA. The Federal Circuit disagreed with InnovaSystems.

The court essentially found that the problems intended to be remedied by the Hatch-Waxman Act did not affect the makers of products that were not subject to the FDA approval process, so they shouldn't be entitled to the benefits. The court stated:

> *Because Proveris' patented product is not subject to a required FDCA[11] approval process, it is not eligible for the*

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> *benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1).*[12]

The court's decision in *Proveris* appears to set up a simple if/then test to determine whether a product is a patented invention under 271(e)(1). If the product is not subject to FDA approval, then infringers of patents covering those products are not exempt from claims of infringement under 271(e)(1).

Proveris *and the Future of Research Tool Patents*

On its face, the *Proveris* decision seems to be good news for those that develop or market research tools. Since the vast majority of research tools are not subject to FDA approval, it would appear that infringers of patents claiming research tools are not entitled to hide behind 271(e)(1). If this is true, then those patent holders can effectively sue to stop infringement of these patents. Also, the value of research tool patents are significantly increased since licenses to these patents may be needed by a significant number of companies using the patented tools. However, many research tools may also have uses as therapeutics, which complicates the analysis.

For example, assume that researchers at the University of Neverland have developed and patented a new cell line. The cell line can be used to screen for molecules having a desirable characteristic, such as the ability to inhibit cell de-differentiation making it a potentially valuable research tool. Further, assume that the cell line can also be used as a cell therapeutic for Parkinson's disease.

Bigpharma learns of the new cell line developed at the University of Neverland and decides to use it to screen its small molecule library for lead compounds for development. Is this activity exempt from infringement?

It is not necessary to obtain premarket approval from the FDA to screen small molecules or sell products for screening small molecules for a given activity. Accordingly, Bigpharma

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is not hurt by the regulatory requirements for clinical testing that might delay entry of their product into the market. Since it is not hurt by the regulatory requirements, Congress did not intend for it to be benefited by the Hatch-Waxman Act. Therefore, Bigpharma is not entitled to the exemption from infringement provided by the Hatch-Waxman Act, and using Neverland's cell line for screening is an infringement.

Now consider the case where Bigpharma decides to use the cell line to develop a therapeutic product.[13] Now it is necessary to obtain premarket approval from the FDA to use the new cell line as a therapeutic. Accordingly, Bigpharma is hurt by the regulatory requirements for clinical testing that will delay entry of its product into the market. Since it is hurt by the regulatory requirements, the allegedly infringing activity is within the class of activities Congress intended to be addressed by the Hatch-Waxman Act. Therefore, it is entitled to the exemption from infringement provided by the Hatch-Waxman Act and this use of the cell line is not an infringement.

In addition to cell lines, similar problems can be envisioned with other research tools that can also be used as therapeutics. These may include antibodies that can be used for diagnostic or research purposes and as a therapeutic agent. The same can be said for nucleotides, which can be used as gene therapy agents as well as research tools. Even chromatography resins, which obviously are primarily used in laboratory research and manufacturing, have been used as therapeutic agents as metal chelators.

As is demonstrated by the preceding analysis, sometimes one use of a technology may be exempt from patent infringement, while other uses of the same technology may not. But, does this matter from a technology transfer perspective?

In the case of the clear use of a technology as a research tool a potential user will have to take a license or be subject to a claim of patent infringement since it is outside of the protection provided by the Hatch-Waxman exception. Thus, it makes sense for the University of Neverland to commit the resources to obtaining a patent with claims covering the technology. In this situation patenting inventions that are pure research tools (i.e., that have no therapeutic potential), is still a viable option. In fact, failure to protect these technology could result in significant loss of potential revenue.

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In the situation where the technology is used as a therapeutic agent, even though the potential infringer's initial activities fall within the Hatch-Waxman exemption and are not subject to an infringement suit, the university should still consider investing in the patenting of the therapeutic technology. Bigpharma will still likely be required to license the technology assuming the initial evaluation is positive.

Even though the early development work may be performed without the risk of patent infringement, as soon as the company markets the product it will emerge from the protection of 271(e)(1) and will be subject to a patent infringement suit. As such, it is very unlikely that a company would elect to develop the technology without a license. Thus, even in the case where some uses of a patented product may be immune from infringement suit, it still makes sense for the university to obtain patent protection.

Conclusion

After the Supreme Court's decision in the *Integra* case, there was significant concern in the life sciences community that the use of research tools may be exempted from infringement by 271(e)(1), leaving many biotechnology and service organizations with no recourse against infringers. Some commentators predicted dire consequences for large sectors of the life science industry. The recent *Proveris* case appears to signal that 271(e)(1) will not exempt the use of research tools that do not require FDA approval from patent infringement claims.

Moreover, even though the initial use of some research tool patents may be exempt from an infringement suit, such patents will likely have value because of their later commercial potential. As a result, research tool patents should become much more attractive to technology transfer offices, entrepreneurs, and development partners. Reports of the death of the research tool patent have been greatly exaggerated.

For more information on research tools, see "Research Tools Policies and Practices: Perspective of a Public Institution," by Uri Reichman, PhD, MBA; Susan E. Ano, PhD; and Steven M. Ferguson, MBA, CLP, in the 3rd Edition of the AUTM Technology Transfer Practice Manual.

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Notes

1. *Integra v. Merck*, 331 F.3d 860, 878 (Fed. Cir. 2003), reversed by *Merck v. Integra*, 545 U.S. 193 (2007).
2. Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc (2000), and 35 U.S.C. §§ 156, 271, 282 (2000).
3. It is generally recognized that the Hatch-Waxman Act was intended to address problems in the development of therapeutic products and generic versions of those products, but subsequent decisions have expanded the scope of the statutes beyond therapeutics. (See e.g., *Eli Lilly & Co v. Medtronic, Inc.,* 496 US 661 (1990)).
4. Recall that unlike many other countries, the United States does not recognize a research exemption to patent infringement. (For example, see *Madey v. Duke University,* 307 F.3d 1351 (Fed. Cir. 2002)).
5. 35 USC § 271(e)(1). The Hatch-Waxman Act also sets out a legal framework that is designed to speed up the introduction of generic drugs by giving generic manufacturers an incentive to challenge patents covering brand name drugs. The first to file an abbreviated new drug application is awarded a six-month period to exclusively market the generic drug.
6. *Eli Lilly & Co v. Medtronic, Inc.*, 496 US 661 (1990), see also *AbTox, Inc. v. Exitron Corp.,* 122 F.3d 1019 (Fed. Cir. 1997). Note that there is some question whether 271(e)(1) covers products that are not eligible for patent term extension under 35 USC § 156, but the AbTox case seems to suggest that all products subject to FDA approval are considered "patented products" for the purposes of 271(e)(1). (See also, *Proveris Scientific Corp. v. InnovaSystems,* Inc., Federal Circuit docket no. 2007-1428, decided August 5, 2008.)
7. *Merck KGAA v. Integra Lifesciences I, LTD,* 545 US 193 (2005).
8. *Id*. FN 7.
9. See, for example, Wolrad Prinz zu Waldeck und Pyrmont, 14 *Mich. Telecomm. Tech. L. Rev*. 367 (2008), Paul Wiegel, *Boston College Intellectual Property & Technology Forum*, November 29, 2007.
10. *Proveris Scientific Corp. v. InnovaSystems, Inc.,* 2008 WL 2967100, Federal Circuit docket no. 2007-1428, decided August 5, 2008.

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11. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code).
12. *Proveris* at page 16.
13. This analysis assumes that the activity is "reasonably related" to developing information for submission to the FDA for approval. The scope of activity that is "reasonably related" was addressed in *Integra* and a detailed discussion of what activities meet this definition is beyond the scope of this paper.

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Licensing Transgenic Mice and Other Research Tools: A Practical Guide

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Introduction

Research Tools

Research tools are reagents that are used to aid in the research process. They can be live materials such as cell lines and transgenic animals or other materials including DNA, viruses, vectors, and proteins. The main focus of this chapter is to discuss licensing of transgenic animals for internal research purposes and licensing of antibodies to a company for distribution as a product line. That being said, much of what is covered can translate into licensing of other research tools for either internal research purposes or for sale and distribution. We provide template license agreements along with this chapter, however, it should be noted that these agreements are considered samples only, and we update them on a frequent basis. (See appendices.)

Rationale: Why License Research Tools

Whether licensing for internal use or for distribution as a product, the licensee is obtaining something of value created by your institution. A license agreement or material transfer agreement (MTA) stipulates the conditions under which that tool can be used or sold. We tend to use a license agreement for this purpose to incorporate more robust protection for the institution in the form of indemnity and governing law provisions, among others.

Access to research tools for internal activities is important to companies. They use a variety of research tools in their research and product development efforts just as faculty members do in their laboratories. Companies prefer accessing research tools that have been used and proven by others to perform as claimed by the developers. Thus, some research tools don't generate interest until months or years after they are first published.

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Licensing of research tools can also be viewed as a service to your faculty member. When licensing a tool for sale and distribution you are removing the burden of distribution from the faculty member's laboratory.

In both licensing scenarios, you are aiding in the advancement of research by enhancing the access to reagents.

Patenting Research Tools

One main reason to patent inventions in a nonprofit, academic, research institution technology transfer office (TTO) is to attract a licensee. In general, patenting of research tools is not necessary and does not make economic sense.

Licenses for internal research use are typically nonexclusive, allowing as many users to obtain the tool as possible. The licensees do not care if the tool is patented because it isn't an end product; it is just one of many reagents used to get to the product.

To attract a licensee for a research tool, the licensing fees must be kept reasonable (i.e., lower than the cost of generating that tool in house). Thus the fees paid for the license might not exceed the cost of a patent, making recovery of patent costs unlikely. This is particularly true with animal models where it is sometimes difficult to judge the popularity of a model when it first becomes available, which is also the time you would have to file a patent application. Antibodies face the same challenge; there are usually a finite number of laboratories studying the protein of interest, and, thus, these labs represent a majority of the market for that antibody.

Other considerations regarding patenting are policing of the use of the tool and patent enforcement. A few questions to ask yourself are: How would my institution police use of a research tool? Companies using a mouse model, for example, might not publish their studies. How likely would it be that my institution would choose to enforce a patent on a potential infringer in the case of a research tool? What are the perceived damages to the institution? If the damages are substantially lower than the cost of enforcement, perhaps a patent is not warranted to begin with. The costs of pursuing patent protection for research tools almost always outweigh any potential benefits.

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One exception to this might be a platform research tool (i.e., a novel cloning system that is markedly better or more efficient than current approaches) that will be sold and distributed by a company, particularly one with a large market. In this case, the license may be exclusive in nature, and the licensee will likely desire patent protection to secure its competitive advantage. Another exception might involve a transgenic animal model that is used as a platform technology. This could be a model of drug metabolism that is being used in a service business to screen for drug-drug interactions and toxicity. However, under any circumstances, reservation of rights for use of the tool by other academic institutions is imperative so that your institution can provide the tool to academic investigators.

Ownership

When reviewing the background information on your research tool, is it important to learn what elements were used to create it and the sources of the elements. It is typical that multiple elements might be combined to create a new, more useful tool. These result in tools that incorporate elements from other entities. Alternatively, the tool could be generated in collaboration with another entity. These situations can be handled in a number of ways starting with consulting with the other entity.

In a few instances we have a jointly owned mouse model where both institutions have a live colony. We have executed an agreement where both institutions can license the model of interest on request, and revenue is divided per the terms of the agreement. This allows each institution to be responsive to requests and capitalize on relationships with licensees; either those of the TTO or of the faculty member. In other cases, we have executed a standard in-license of another institution's material and/or intellectual property. These are cases where the material was obtained or intellectual property was used but not necessarily through collaboration. This provides the ability to license out the tool and provide some revenue back to the other institution. We've also executed a simple letter agreement allowing an institution to license a tool incorporating an element developed by our institution.

A practical, pragmatic approach is essential when dealing with issues created by different institutions owning elements of a research tool. Access to research tools by both academic and commercial entities can be unnecessarily delayed when the owners of the tool cannot agree upon terms to facilitate its distribution. Treat the other institution as you would

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wish to be treated, and keep in mind that a research tool in general is not a blockbuster technology.

Other Encumbrances

There are other broad tool/element research-use licenses being offered to institutions by for-profits; two of which have generated particular interest among TTOs. One is the Cre-Lox technology used to facilitate genetic recombination events that modify the genome of a cell or animal. The United States patent covering this technology expired in 2007. The other, known as Oncomouse, is a family of patents covering the use of a gene to cause a propensity to develop cancer in an animal model or in cell lines derived from that model (U.S. Patents 5,087,571 and 5,925,803). The concept to bear in mind for these is that you should be aware of any agreements that impose obligations on your institution with respect to elements used to create the tool.

Licensing Animal Models

Introduction to Animal Models

When referring to animal models, we are focusing on mammals; there are others that include the fruit fly, *Drosophila melanogaster,* and the nematode, *Caenorhabditis elegans,* but these models are rarely licensed. The most common mammalian model used in research is the mouse, but other animals are used such as rats, rabbits, and larger mammals.

Animal models are typically made by altering the genome of the animal to confer onto that animal, and successive generations, a particular trait. Since we generally do not patent animal models, we consider them a controlled research tool in that we control access to the model via a material transfer agreement for academic requestors and a license to for-profits. As stated above, we keep the fees low enough that it is more attractive to license such models than to recreate them. In addition, our models typically have the benefit of being validated through the research programs of faculty members and others they have sent the model to, thus the licensee can have confidence in what they are licensing.

There are cases where an animal model is generated by other manipulation, for example, surgery. Although not impossible, these are more difficult to license because they tend to be expensive and time-consuming to create, as the trait is not carried through successive

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generations. Also, once published, the manipulation can be replicated by others who wish to do so. Depending on the number of animals used in an experiment and the willingness of the faculty member, animal models of this nature may be amenable to a sponsored research project.

Basic Terms Regarding Animal Models

Following are some basic terms regarding animal models that will be used in further discussion regarding the specifics of license agreement language.

Knockout: A knockout animal is a genetically engineered mouse in which one or more genes have been turned off through a gene knockout. Typically the endogenous gene is knocked out via insertion of a highly similar piece of DNA, the transgene, a portion of which is removed or replaced with another sequence thereby removing or replacing the sequence of interest. The result renders the endogenous gene nonfunctional. The genetic manipulations for producing a knockout mouse are typically done using mouse embryonic stem cells (ES cells), which are then implanted into mouse embryos to generate mice carrying the knockout.

Knock-in: A knock-in animal is similar to the above but some element has been inserted or knocked into the DNA to confer an altered characteristic on the gene or sequence of interest. Whereas knockouts are used to study the effects of silencing a gene, knock-ins are developed for the opposite reason: to study the effects of expressing an additional genetic element. One example of this strategy is to insert a polyglutamine expansion sequence into a gene which, when expanded, displays a toxic or disease phenotype, such as can be observed by adding polyglutamine residues to the Huntingtin gene product to produce a Huntington's disease-like phenotype.

Genotype: The genetic constitution of a cell, organism, or individual, usually with reference to a specific characteristic or as compared to what is considered normal or wild type. Simply put, the genotype we typically reference is the exact genetic change or transgene that has been inserted into the animal model.

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Phenotype: Any observable characteristic of an organism, such as its morphology, development, biochemical, or physiological properties, or behavior. With respect to animal models, the phenotype is a usually a description of how the model differs from wild type.

Heterozygote: When the animal model has different alleles or sequences occupying the position of interest on each of the homologous chromosomes. In the case of animal models, the individual has one copy of the altered sequence and one copy of the original wild-type sequence.

Homozygote: The animal model carries two identical alleles or sequences occupying the position of interest in each of the homologous chromosomes. In the case of animal models, the individual has two copies of the altered sequence.

Understanding Your Animal Model

You don't have to become an expert in animal models, but technology licensing professionals should have some basic information about the mouse model to aid in discussions with potential licensees and licensing. During your interview with the faculty member, consider asking them the following questions:

1. Have you published the animal model? Have other colleagues published on it? Many times companies aren't interested in using a model until it has been validated through research that has been published.
2. What will it cost in time and money to prepare and ship the model? Some institutions can only charge certain costs internally for example, or they may have to breed up for shipment so your faculty member will incur some cost in supplying the animals.
3. Status of the model? Live colony, frozen ES cells, embryos, or sperm? If they have to be reconstituted, how long will this take? Do they have impaired breeding capabilities or require a special diet? These are factors that should be revealed to any potential licensee.
4. What exactly will be supplied: Heterozygotes or homozygotes and how many? We ask the faculty member what is most convenient for him or her and limit supply in most cases to two of each gender or two males. In addition, a genotyping protocol, sometimes including reagents, will be sent. All of this is specified in the agreement so there is no question of what will be supplied.

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A few additional questions that might be answered by your vivarium director or veterinarians are:

5. What is the standard shipping process, and how long is it? Typically there is some time delay for veterinarian reports to be generated, transferred, and approved. Can an outside entity, the licensee, pay directly for shipping costs? Vet costs?
6. Are the animals pathogen free? If they are not, be upfront about this with potential licensees. Many vivariums will not accept animals that don't meet certain health guidelines.
7. Is there any verification process for transfer regarding completion of the MTA or license? There is a checklist of items required to be completed prior to transfer of animals from the vivarium, and we have added a requirement for an executed material transfer agreement or other appropriate document to that checklist.

Animal Model License Structure

As mentioned, animal models are typically licensed nonexclusively, and the agreements have many elements in common with all research tool licenses. With respect to all research tool licenses, it can't be stressed enough to keep it simple, expedient, and be pragmatic. If you have a popular model, create a template for that model so that you can send out a license immediately upon request. Also if you consistently have companies request changes that are acceptable, consider incorporating that language into the original template. Our theory is that we have bigger deals to haggle over so these should be as simple as possible.

That being said there are elements in the license that require some thought.

Subject technology definition: Define the model by the transgene it carries, whether knockout or knock-in. It should not be defined by the phenotype or by a common name. Many animals display the same or similar phenotypes, and some common names are phenotypes. The quaking mouse model is a common name for a specific strain, but many mouse models have a quaking phenotype. Also, incorporate language such that any crossbred animal or cell lines that carry the transgene are to be considered subject technology.

The grant of license: Should restrict sale or transfer to third parties and restrict patenting the model or any use of the model. We include a provision allowing transfer to and use by a service provider, since many companies outsource their colony management and ani-

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mal research activities. Due to frequent requests, we have incorporated language stating that ownership of research results generated by the licensee with the use of the licensed model resides with the licensee. Another requested clause is one stating that the licensee can use the animal model for drug-screening purposes.

Payments: Fee structure is obviously influenced by the general policies of the TTO. Our licenses provide for an upfront fee and an annual maintenance fee. We also require a material handling fee, which is used to reimburse the faculty member's lab for some of the costs incurred in the process of preparing and shipping the animals. We distribute this fee directly to the lab account. This handling fee is also used in cases where the developer of the mouse model no longer has the model, but a colleague maintains a colony and is willing to prepare and ship it.

License fees for mouse model licenses vary widely and will depend on a number of factors. For example, is the fee a one-time fee or are there annual maintenance fees? Does the animal model possess a phenotype that fits within a broad or narrow field, and what is the market size for that field? In our experience and with input from a few other TTOs, upfront fees range from $20,000 to more than $100,000. Upfront fees at the higher end of the range may be in the case of a one-time payment or in the case of an animal model that fits within a large market.

We do not seek any sort of reach-through payment on royalties of a drug/therapeutic discovered via the use of the licensed animal model. This issue is a nonstarter for most potential licensees because they will typically employ a variety of research tools throughout the drug-development process, and if those tools have royalty burdens attached to them, this will strongly discourage their use.

Transfer of animal model: As mentioned, it is important to clearly state exactly what you are transferring and how many. You should also include a timeline for animal model transfer that is generous and takes into consideration the starting material: live colony, frozen embryos, etc. We use sixty days as a minimum in those cases where we have a live colony, regardless of whether we will need to breed up specifically for the transfer.

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Also, we've learned to link the animal transfer timeline to receipt of payment rather than agreement execution. That way the faculty member doesn't initiate any activity and incur any costs associated with the transfer until after the upfront payment has been secured. In addition, there have been rare occasions where a licensee will, at a later date, want to obtain additional animals of that licensed model. We accommodate this in our license agreement to ensure this provision is at our discretion and that any marginal costs incurred will be recovered.

Termination: If termination of the agreement results in the licensee no longer being able to use the animal model, you should request a certificate or other verification of the colony being terminated at the licensee's facilities. Typically this can easily be provided.

Confidentiality: Often the confidentiality provision can be streamlined since there will be no confidential information transferred. This is often the case when the development and use of an animal model has been described in a peer-reviewed publication. On request, we replace with a clause that states that a confidential disclosure agreement will be appended to cover any requests for confidential information.

Distributors for Animal Models

There are a few distributors that will maintain and provide mouse models generated by your faculty members. Those that are most familiar amongst academics include Jackson Labs (JAX) (http://www.jax.org/), the Mutant Mouse Regional Resource Centers (MMRRC) (http://www.mmrrc.org/), and the Mouse Models of Human Cancers Consortium (MMHCC) Repository (http://mouse.ncifcrf.gov/). Distributors that focus on high-volume distribution include Taconic (http://www.taconic.com/).

We have a distribution agreement with JAX under which it distributes the animal model, but any for-profit requestors are directed to the TTO to obtain a license prior to any distribution. In return, a portion of the license fees are paid to JAX. MMRRC and MMHCC each have its own mechanisms for handling such relationships. In those licenses where the distributor is responsible for providing the mice, it is important to specify that shipping fees and schedule are determined by the distributor. Taconic has, in the past, in-licensed animal models for distribution under a standard product-for-sale license. It then distributes to all requestors. Taconic has other distribution mechanisms, including flexible options for distribution of newer or lower volume use animal models.

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Animal Model Template Agreement

See "Appendix A: Template Non-Exclusive License Agreement: Mouse Model License for Internal Purposes."

Licensing Antibodies

Introduction to Antibodies

Antibodies are valued by the research community because they are very powerful tools for probing the nature and function of a protein of interest. Antibodies are immunoglobulin proteins produced by the B-cells in response to an antigenic stimulus. Antibodies interact with antigens in a very specific fashion that is dependent on the amino acid sequence of the hypervariable region of the antibody. Amino acid sequence variation in antibodies is generated by a process called V(D)J recombination in which different combinations of variable genes, diversity genes, and joining genes are linked to produce a single antibody molecule that binds a specific antigen. Further diversity is generated by a process called somatic hypermutation, which changes the sequence within the variable regions of immunoglobulin genes. The number of combinations that can be produced by these processes is almost limitless, and it is this ability to generate variation that is behind the power of the antibody as a research tool.

Basic Terms Regarding Antibodies

Technology licensing professionals who work with antibodies need an understanding of some of the basic terms of the antibody trade that they are sure to encounter as they become involved with antibody licensing. You don't have to become an expert on antibody technology to successfully license antibodies, but some basic antibody literacy will be very helpful.

Monoclonal antibody: An antibody that is derived from a single antibody-producing cell. Monoclonal antibodies are monospecific, meaning that they recognize and bind to a single epitope on their target antigen. In the laboratory, monoclonal antibodies are made by a process in which a mouse is immunized with an antigen of interest and antibody-producing cells are isolated from the spleen of the animal and fused with cells from a myeloma cell line. The fusion process results in the formation of an immortalized antibody-producing cell

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called a hybridoma that secretes the antibody into the culture media. A hybridoma can be propagated in cell culture indefinitely, thus it can serve as a limitless source of the antibody of interest.

Polyclonal antibody: A population of mixed antibodies targeted to a single antigen. Such a population may contain multiple different antibodies that bind to different epitopes on the antigen of interest. Polyclonal antibodies are produced by immunizing an animal (typically a rabbit) with the antigen of interest, followed by harvesting serum from the immunized animal. The antibody response in the animal is often enhanced by the use of an adjuvant, which is a nonspecific stimulator of the immune response. The harvested serum (antisera) will contain a population of mixed antibodies against the target antigen. The supply of a polyclonal antibody is limited by the amount of serum harvested from the immunized animal.

Western blot: A laboratory technique in which an antibody is used to detect the presence of its target protein on a solid membrane support. A protein sample isolated from cells is resolved via SDS-PAGE gel electrophoresis, and the proteins in the gel are transferred to a solid membrane. This membrane is probed with an antibody that recognizes a specific protein and is detected by the use of a secondary antibody that is linked an enzyme that acts on a substrate to produce a detectable signal (light or color). Western blotting can be used to determine the size of a protein, and its relative amount.

Immunofluorescence or immunohistochemistry: A laboratory technique that can be used to determine the tissue distribution and cellular localization of an antigen of interest. In this technique, a tissue section is probed with an antibody that recognizes the antigen of interest, and it is detected by the use of secondary antibody linked to an enzyme or fluorochrome that produces a detectable signal (light or color).

Immunoprecipitation: A laboratory technique in which the protein antigen of interest can be selectively removed from a solution (cell extract) using an antibody that binds to the antigen. This technique can be used to facilitate the concentration of a single protein of interest from a solution containing many different proteins. The precipitation step oc-

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curs when a secondary reagent coupled to a solid support is added to the solution. This secondary reagent is often protein A/G agarose beads, which nonspecifically bind antibody molecules. The beads are pelleted from the solution by centrifugation, which concentrates the protein of interest. Immunoprecipitation can be used to identify other proteins that bind to the antigen of interest, since they will often co-precipitate with the target protein.

Enzyme-linked immunosorbent assay (ELISA): ELISA is a biochemical technique that can be used to detect the presence and relative quantity of an antigen in a sample. A sample containing an unknown amount of the target antigen is affixed to a solid support (most often a 96-well polystyrene plate). An antibody against the target antigen is added to the plate and allowed to bind. Excess antibody is washed away and detection is facilitated by an enzyme linked to the antibody that produces a detectable fluorescent signal when a substrate is added. The intensity of the fluorescence produced can be used to determine the relative quantity of the antigen of interest.

Understand Your Antibody

Technology licensing professionals should have a clear understanding of the antibody reagents that they are licensing and should be prepared to answer basic questions about the antibody. During your interview with the faculty member, consider asking him or her the following questions:

1. Have you published a manuscript describing the use of this antibody? Did this publication result in requests for this antibody from other investigators? Note: If such a manuscript has been published, this is often your best marketing tool, particularly if it was published in a high-impact journal. Many of the questions in this list will often be answered in the manuscript.
2. Is this antibody directed against a target protein that is of interest to only a handful of academic labs, or is it one that will have broad appeal to a wide cross-section of the research community?
3. Why is the target protein important, and how can this antibody reagent be used to address unanswered questions about the target?
4. Is this antibody a polyclonal or monoclonal? What assays can this antibody be used for?

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5. How much of this antibody do you have, and can you supply an aliquot to a potential licensee?
6. What, exactly, was the immunogen used to develop the antibody?
7. What epitope on the target antigen is recognized by the antibody? Many times this has not been determined and might not be important for research purposes.
8. Did you obtain materials used in the development of this antibody from a third party? For example, did you obtain the peptide used to immunize the rabbit from another laboratory?

Antibodies as Research Tools vs. Therapeutics

The majority of antibodies produced in academic laboratories will have utility as research tools. They will be valued by other academic and/or industry scientists who want to study the target protein and its function within the cell and the organism.

Antibodies have also come into favor as therapeutic agents, particularly in the oncology field, where they can be used to bind to and suppress the function of a protein target that is involved in maintaining the growth or survival of a tumor cell. Only a very small number of antibodies produced in academic labs will have therapeutic potential, and they will not be our focus. The terms and license structure for therapeutic antibodies differ drastically from that of a research tool antibody license.

Should I Patent this Antibody?

For reasons discussed above, research tool antibodies should not be patented. Even if the antibody is wildly popular in the research community (few are), it is unlikely that the costs of patenting could ever be recovered via royalties from antibody sales. And, since the majority of research tool antibody licenses are nonexclusive or semiexclusive in nature, there is nothing to be gained by obtaining a right to exclude others from practicing your antibody or methods of using it. Therapeutic antibodies that may be used to diagnose and treat human disease are the exceptions, but these are rarities in the academic community.

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Antibody License Structure

Licenses to companies that supply antibodies to the research reagent marketplace are almost always nonexclusive or semiexclusive, and their structure is typical for nonexclusive licenses with some elements that are specific to antibodies.

The subject technology definition: Under this definition, the licensor will be specifying exactly what it will be supplying to the licensee. Be sure to be clear and unambiguous. You may be supplying:

a) Frozen vials of hybridoma cell line—in the case of a monoclonal antibody. Specify the content and quantity of vials (normally no more than two).
b) Ascites fluid—in cases where the antibody is a monoclonal, but hybridoma cells aren't being supplied.
c) Serum from an immunized animal in the case of a polyclonal antibody. It is important to specify the quantity of serum being supplied. Check with your faculty member to be sure that he/she can supply the requested quantity.
d) In case of a polyclonal antibody, specify the immunogen that was used to generate the antisera. In case of a monoclonal antibody, you will most likely refer to the cell-line designation given to the hybridoma.

The licensee may take your antibody and combine it with another substance (an enzyme tag, etc.); therefore it is important that the subject technology definition encompass any derivatives that the licensee may develop.

An example subject technology definition:

> The term "Subject Technology" shall mean [(i) two vials of the hybridoma cell line designated _____, or (ii) fifty milliliters (50 mls) of polyclonal sera that recognizes target protein/epitope _____ and (iii) X micrograms of plasmid for expression construct of target protein/epitope and (iv) all protocols, documents, know-how and confidential information] developed by the Developers as of the Agreement Date and supplied by University (identified in Appendix A), together with any progeny, mutants or derivatives thereof supplied by University or created by LICENSEE.

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The field definition: Because you are licensing the antibody to a company that supplies reagents to the research community, the field definition should specify that the license grant is specifically for this purpose and does not allow the use of the antibody in humans for any diagnostic or therapeutic purpose.

The license grant: Will specify whether the license is nonexclusive or semiexclusive in nature. Under a semiexclusive license, the licensor agrees to license the subject technology to predetermined number of licensees, typically three. This strategy can be used to negotiate better terms from a research reagent supplier because it knows that its competition will be somewhat limited.

Marketing efforts/diligence: The licensor should seek a commitment from the licensee to introduce the licensed antibody to the market within a set period of time after execution of the license agreement. Companies that supply antibodies to the research market will run their own quality-control analysis on the licensed antibody to be certain that it performs acceptably. The licensor should stipulate that the licensed antibody be marketed to the same degree of diligence that the company uses to market its existing product line.

Payments: A typical license to a research reagent company will involve a royalty on net sales of the antibody and an upfront payment. The royalty rate can range from 10 to 25 percent and is typically higher than that seen for other university technologies because, in the case of an antibody, the licensor is supplying the licensee with the product that will be sold (granted, it will often be diluted and reformulated by the licensee). A well-characterized monoclonal antibody that is in demand by researchers in a particular field of study might command a royalty rate at the upper end of the scale, whereas polyclonal sera raised to a target protein of interest to a small segment of the research community might reside at the lower end of the scale. Because many research reagent suppliers offer hundreds of antibodies to the market and they often don't know which ones will end up being the hot sellers, they will typically resist hefty upfront payments. Our experience has shown that modest upfront payments can be obtained (1$ to $5,000). Semiexclusivity can be used as a tool to obtain a more favorable payment structure.

We would recommend requiring licensees to report and pay royalties on a semiannual or annual basis. Most antibody research tools generate rather modest sales, and it does not

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make sense to require the licensee to report royalties on a quarterly basis. This is particularly true if your institution distributes income as it is received.

Transfer of subject technology: Under this section, the timeline for supplying the antibody to the licensee will be specified. Talk with your faculty member to be sure that this obligation can be met. If the antibody is a polyclonal antibody, there is the possibility that the faculty member may need to collect and characterize antisera from the immunized animal.

Provision of licensed products to faculty member: In many cases, licensees may be willing to provide reasonable quantities of the antibody product back to the lab of the faculty member that developed it. This is a matter of negotiation, but is worth seeking.

Antibody Template Agreement

See "Appendix B: Template Semi-Exclusive License Agreement: Antibody License to Research Reagent Supplier."

Conclusion

A very important point worth reiterating is to make licenses for research tools simple and easy to execute. This can include having templates that are specific to the type of tool being licensed so they can be sent out promptly upon request. Having a general knowledge of what you are licensing and the mechanics of how it is transferred helps speed the process. Taking time to go back to your faculty member to answer each question a potential licensee might ask slows the process down.

Also be pragmatic, both when working with your fellow academic co-developers and with the potential licensee. View these licenses as a service to your faculty member and a means to get the technology out into the research community; they are not blockbuster technologies.

We have found that incorporating these suggestions into office practice will greatly increase your ability to get your research tools out into the greater research community. Doing this in an effective manner will enhace the profile of your TTO, your intitution, and the faculty members.

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Appendix A:

Template Non-Exclusive License Agreement: Mouse Model License for Internal Purposes

This Non-Exclusive License Agreement (hereinafter called "Agreement"), to be effective as of the ___ day of ____, 2008 (hereinafter called "Agreement Date"), is by and between UNIVERSITY (hereinafter called "UNIVERSITY"), a _____ nonprofit corporation having its principal place of business at _____, and _____, a corporation organized under the laws of _____ and having a principal place of business at _____, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WITNESSETH:

WHEREAS, UNIVERSITY is the owner of the Mouse Model, as defined below; and

WHEREAS, UNIVERSITY is willing to grant a fee-bearing, worldwide, non-exclusive license to the Mouse Model to LICENSEE on the terms set forth herein; and

WHEREAS, LICENSEE desires to obtain said non-exclusive license under the Mouse Model.

NOW, THEREFORE, for and in consideration of the promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto expressly agree as follows:

1. DEFINITIONS AS USED HEREIN

1.1 The term "Affiliates" shall mean any corporation, partnership, joint venture or other entity which LICENSEE, directly or indirectly, owns or controls by LICENSEE's ownership of at least fifty percent (50%) of the entity's common stock or other ownership.

1.2 The term "Confidential Information" shall mean any proprietary and secret ideas, proprietary technical information, know-how and proprietary commercial

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information or other similar proprietary information that are owned by UNIVERSITY. The term "Confidential Information" is further defined in Section 12 below.

1.3 **The term "Developers"** shall mean _____, employees of UNIVERSITY.

1.4 **The term "Mouse Model"** shall mean the mouse model carrying the _____ transgene which was developed by the Developers as of the Agreement Date.

1.5 **The term "Party"** shall mean either LICENSEE or UNIVERSITY, and "Parties" shall mean LICENSEE and UNIVERSITY.

2. GRANT OF LICENSE

2.1 **License Grant.** UNIVERSITY hereby grants to LICENSEE a non-exclusive, worldwide right and license in and to the Mouse Model, to make, have made and use solely for research, [drug discovery] and development purposes in research laboratories at LICENSEE. This grant does not include (i) the right to sell or offer to sell the Mouse Model, (ii) the right to sublicense the Mouse Model or (iii) the right to file patent applications on the Mouse Model or for the use of the Mouse Model without UNIVERSITY's prior written approval, which approval shall be in UNIVERSITY's sole discretion. Such right and license shall include, but not be limited to, the right to generate pure-bred progeny of the Mouse Model and the right to generate progeny of the Mouse Model bred to other strains of mice ("Cross-Bred Progeny"), provided that the pure-bred progeny and Cross-Bred Progeny are used only for research purposes and not sold to third parties. Any mice or cell lines carrying the _____ transgene will be considered a Mouse Model and subject to this Agreement, even if said mice or cell lines have been bred or otherwise modified to have other special properties.

2.2 **Government Reservation.** Rights under this Agreement are subject to rights required to be granted to the Government of the United States of America pursuant to 35 USC Section 200-212, including a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject inventions throughout the world.

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Optional:

2.3 Service Provider. In addition to the rights granted in Paragraph 2.1, LICENSEE shall have the right under the license granted in this Agreement to transfer the Mouse Model to third party contract service providers ("Service Provider") for the sole purpose of breeding and maintaining [and conducting research using] the Mouse Model for LICENSEE. LICENSEE warrants that it has (or will enter into prior to transfer of the Mouse Model) agreements with the Service Provider binding the Service Provider to obligations of confidentiality and non-use consistent with the provisions of this Agreement. Such agreement with Service Provider shall also prohibit transfer of the Mouse Model to third parties.

2.4 Ownership of Results. LICENSEE shall retain exclusive ownership of all research results ("Research Results") arising from its use of the Mouse Model under this Agreement including but not limited to, any data, know-how, technology, biological materials (except those considered a Mouse Model under Paragraph 2.1) discoveries and inventions. No express or implied license is granted to UNIVERSITY for the use of any Research Results. LICENSEE shall be free to publish, for any purpose, any Research Results and shall have no obligation to supply any Research Results to UNIVERSITY.

3. PAYMENTS AND REPORTS

3.1 License Execution Fee. As partial consideration for the rights conveyed by UNIVERSITY under this Agreement, LICENSEE agrees to pay UNIVERSITY an initial, non refundable, license execution fee of _____ dollars ($_____). Such payment shall be delivered to UNIVERSITY concurrent with the execution of this Agreement (except if the invoice language is included per Paragraph 3.10).

3.2 Annual Maintenance Fee. In addition to the foregoing license execution fee, LICENSEE agrees to pay to UNIVERSITY an annual non refundable maintenance fee of _____ dollars ($____), which shall be due and payable on the first anniversary and on each subsequent anniversary of the Agreement Date (except if the invoice language is included per Paragraph 3.10).

3.3 Material Handling Fee. In addition to the foregoing fees, LICENSEE agrees to pay to UNIVERSITY a non refundable material handling fee of _____ dollars ($____). Such payment shall also be delivered to UNIVERSITY upon execution of the Agreement (except if the invoice language is included per Paragraph 3.10).

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3.4 **Failure to Make Payment.** Should LICENSEE fail to make any payment whatsoever due and payable to UNIVERSITY hereunder, UNIVERSITY may, at its sole option, terminate this Agreement as provided in Section 6.

3.5 **Payment Terms.** All payments due hereunder are payable by check or wire transfer in United States dollars and shall be deemed received when the complete payment is credited to UNIVERSITY's bank account. Until all funds are received by UNIVERSITY, the payment by LICENSEE is not considered to be complete. No transfer, exchange, collection or other charges, including any wire transfer fees, shall be deducted from such payments.

3.6 **Late Payments.** Late payments shall be subject to a charge of one and one-half percent (1.5%) per month, the interest being compounded annually, or two hundred fifty dollars ($250.00), whichever is greater. LICENSEE shall calculate the correct late payment charge, and shall add it to each such late payment. Said late payment charge and the payment and acceptance thereof shall not negate or waive the right of UNIVERSITY to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment. LICENSEE shall indemnify UNIVERSITY for all attorneys' fees and costs UNIVERSITY incurs in obtaining a full payment of that which is owed to UNIVERSITY.

3.7 **Payment Address.** If payments are sent by check, they shall be sent to the address listed in Paragraph 10.1. If payments are sent by wire transfer, they shall be sent using the wiring instructions sent by UNIVERSITY.

3.8 **Notification of Merger or Acquisition.** In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, LICENSEE shall notify UNIVERSITY in writing within thirty (30) days of such event.

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Optional:

3.9 Licensee Entity Status. If LICENSEE does not qualify as a "small entity" as provided by the United States Patent and Trademark Office, LICENSEE must notify UNIVERSITY immediately.

3.10 Invoice Procedures. Any amounts payable to UNIVERSITY hereunder shall be made in full within thirty (30) days after receipt by LICENSEE of an invoice covering such payment. The Parties understand and agree that one (1) invoice will be sent to LICENSEE by UNIVERSITY for each fee due. The invoice shall be in the form in Appendix ___. Any additional fees, such as taxes, wire or transfer fees, will not be included in the invoice, but payment of such fees shall remain the responsibility of LICENSEE and shall not be deducted from the payment due UNIVERSITY. Subsequent invoices, if requested by LICENSEE, shall be subject to an administrative fee of five hundred dollars ($500), in addition to the original payment due to UNIVERSITY plus any interest charges incurred due to delays in payment, if applicable. The calculation and payment of such interest payments shall not be invoiced and shall be the sole responsibility of the LICENSEE. Invoices shall be sent via facsimile to the address listed in Paragraph 10.1. If LICENSEE requires an original invoice, such invoice shall be sent via overnight courier using LICENSEE's courier _____ (Name Courier) account number _____.

4. TRANSFER OF MOUSE MODELS

4.1 Upon receipt of the license fee described in Paragraph 3.1, UNIVERSITY shall provide LICENSEE with the following biological materials: ____(_) homo/heterozygous females and ____ (_) homo/heterozygous males of the Mouse Model according to the following delivery schedule: Within ____ (___) days UNIVERSITY will ship Mouse Models to LICENSEE. UNIVERSITY will use reasonable efforts to provide the Mouse Models to LICENSEE according to the delivery schedule. However, the Parties understand and agree that there might be times when UNIVERSITY can not provide the Mouse Models exactly on schedule due to problems inherent in husbandry and transport.

4.2 The Mouse Models shall be sent to the address below, via UNIVERSITY's or an approved overnight courier. LICENSEE shall be responsible for paying the ship-

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ment costs, and shall arrange payment in coordination with customary animal shipment processes, using either LICENSEE's account number for such courier or credit card number as available.

Company Scientist
Company Name
Address
City, State, Zip

Phone _____
E-Mail _____

Alternate

4.1 Upon receipt of the license fee described in Paragraph 3.1, UNIVERSITY shall notify _____, distributor of the Mouse Model, that LICENSEE and UNIVERSITY have executed the Agreement and grant permission to _____ to ship LICENSEE's order of the Mouse Model. Shipping price and schedule are determined by _____.

5. TERM AND EXPIRATION

Unless earlier terminated as hereinafter provided, this Agreement shall extend for the life of the last to expire patent issued on the Mouse Model and shall then expire automatically, or if no patent issues on the Mouse Model, this Agreement shall continue in full force and effect for a period of ten (10) years from the Agreement Date. After such expiration, LICENSEE shall be granted a fully paid non-exclusive license to the Mouse Model.

6. TERMINATION

6.1 Termination by University: Breach In the event of default or failure by LICENSEE to perform any of the terms, covenants or provisions of this Agreement, LICENSEE shall have thirty (30) days after the giving of written notice of such default by UNIVERSITY to correct such default. If such default is not corrected within the said thirty (30) day period, UNIVERSITY shall have the right,

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at its option, to cancel and terminate this Agreement. The failure of UNIVERSITY to exercise such right of termination, for non-payment of fees or otherwise, shall not be deemed to be a waiver of any right UNIVERSITY might have, nor shall such failure preclude UNIVERSITY from exercising or enforcing said right upon any subsequent failure by LICENSEE.

6.2 **Termination by University: Insolvency.** UNIVERSITY shall have the right, at its option, to cancel and terminate this Agreement in the event that LICENSEE shall (i) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (ii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iii) a receiver or trustee is appointed for LICENSEE and LICENSEE shall, after the expiration of thirty (30) days following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings.

6.3 **Termination by Licensee.** LICENSEE shall have the right to terminate this Agreement by giving written notice thereof to UNIVERSITY no later than sixty (60) days prior to any anniversary of the Agreement Date, such notice to be effective as of the impending anniversary date. Following the effective date of such termination notice, LICENSEE shall have no further obligation for payment of licensing fees hereunder. For clarification, if LICENSEE provides written notice of termination to UNIVERSITY fifty-nine (59) or fewer days prior to the anniversary of the Agreement Date, LICENSEE shall be obligated to pay the annual maintenance fee for such anniversary date per Paragraph 3.2, even though such payment would occur after the notice of termination.

6.4 **Effects of Termination.** In the event of any termination of this Agreement, all rights to the Mouse Model shall revert to UNIVERSITY. At the date of any termination of this Agreement, LICENSEE shall immediately cease using the Mouse Model and LICENSEE shall immediately destroy the Mouse Models and send to UNIVERSITY a written affirmation of such destruction signed by an officer of LICENSEE.

6.5 **No Refund.** In the event this Agreement is terminated pursuant to this Section 6, or expires as provided for in Section 5, UNIVERSITY is under no obligation to refund any payments made by LICENSEE to UNIVERSITY, as set forth in Section 3, prior to the effective date of such termination or expiration.

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6.6 Survival of Termination. No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination. The obligations of Sections 3, 6, 9, 10, 11, 12 and 13 shall survive termination of this Agreement.

7. ASSIGNABILITY

This Agreement may not be assigned.

8. GOVERNMENTAL COMPLIANCE

8.1 Compliance with Applicable Laws LICENSEE shall at all times during the term of this Agreement and for so long as it shall use the Mouse Model comply with all laws, including, but not limited to, the Animal Welfare Act, that may control the import, export, manufacture, use and other commercial exploitation of the Mouse Model or any other activity undertaken pursuant to this Agreement.

8.2 Export Control Regulations. The Mouse Model is subject to, and LICENSEE agrees to comply in all respects with, U.S. law including but not limited to U.S. export controls under the Export Administration Regulations (15 C.F.R. Part 734 et seq.) and U.S. economic sanctions and embargoes codified in 31 C.F.R. Chapter V. LICENSEE agrees that LICENSEE bears sole responsibility for understanding and complying with current U.S. trade controls laws and regulations as applicable to its activities subject to this Agreement. Without limitation on the general agreement to comply set forth in the first sentence of this Paragraph 8.2, LICENSEE agrees not to sell any goods, services, or technologies subject to this Agreement, or to release or disclose or re-export the same: (i) to any destination prohibited by U.S. law, including any destination subject to U.S. economic embargo; (ii) to any end-user prohibited by U.S. law, including any person or entity listed on the U.S. government's Specially Designated Nationals list, Denied Parties List, Debarred Persons List, Unverified List, or Entities List; (iii) to any foreign national in the U.S. or abroad without prior license if required; or (iv) to any user, for any use, or to any destination without prior license if required.

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9. DISPUTE RESOLUTION

Note: *Insert your university's dispute resolution language as applicable.*

10. ADDRESSES

10.1 University Address for Payments. All payments shall be made payable to "UNIVERSITY" and shall be sent to the address below, and shall reference the applicable reference numbers listed on the front page of the Agreement.

10.2 Licensee Address for Payments. For questions about payments, UNIVERSITY can contact LICENSEE at the address below:

Title
Name
Address

Telephone No. _____
Facsimile No. _____
E-Mail _____

10.3 Addresses for Notices. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, or (iii) facsimile transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing or (b) when a facsimile printer reflects transmission.

In the case of UNIVERSITY:

In the case of LICENSEE:

10.4 Use of Reference Number(s). Each such report, notice or other communication shall reference the applicable reference numbers listed on the front page of the Agreement.

11. INDEMNITY & WARRANTIES

Note: *Insert your university's indemnity and warranty language as applicable.*

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12. CONFIDENTIALITY

Note: *Consider applicability of this language. If the mouse model has been published, licensee should not be subject to a duty of confidentiality.*

12.1 Access to Confidential Information. LICENSEE shall not, directly or indirectly, divulge or reveal to any person or entity the Confidential Information of UNIVERSITY without UNIVERSITY's prior written consent or use such Confidential Information except as permitted hereunder. LICENSEE shall maintain the Mouse Model in strictest confidence and use the same only in accordance with this Agreement. Employees, agents or subcontractors of LICENSEE shall be given access to the Confidential Information only on a legitimate "need to know" basis and after agreeing to be bound in writing to not divulge or reveal the Confidential Information. The public disclosure with the permission of UNIVERSITY of any one component of that which was identified as or constituted the Confidential Information of UNIVERSITY shall not prevent the other components from retaining their status as Confidential Information and the property of UNIVERSITY. Confidential Information shall include any and all information that is produced or results from the disclosure of Confidential Information by UNIVERSITY to LICENSEE during the course of the relationship that is the subject of this Agreement.

12.2 Exclusion. Such obligation of confidentiality shall not apply to information which LICENSEE can demonstrate: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no fault of LICENSEE; (iii) was known to LICENSEE prior to disclosure thereof by UNIVERSITY; (iv) was lawfully disclosed to LICENSEE by a third party which was not under an obligation of confidence to UNIVERSITY with respect thereto; (v) LICENSEE was compelled to disclose by law or legal process; or (vi) was approved for public release by prior written permission of UNIVERSITY.

12.3 Court Order. LICENSEE may make disclosures of Confidential Information required by a Court Order, provided LICENSEE first gives a timely opportunity to UNIVERSITY to participate in the proceeding to the extent that the proceeding permits such participation.

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13. ADDITIONAL PROVISIONS

13.1 Use of UNIVERSITY Name. LICENSEE agrees that it shall not use in any way the name of "UNIVERSITY College of Medicine" or any logotypes or symbols associated with UNIVERSITY or the names of any of the scientists or other researchers at UNIVERSITY without the prior written consent of UNIVERSITY.

13.2 UNIVERSITY's Disclaimers. Neither UNIVERSITY nor any of its faculty members, researchers, trustees, officers, employees, students, directors or agents assume any responsibility for the manufacture or use of the Mouse Model by LICENSEE.

13.3 Independent Contractors. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

13.4 Defense of Infringement Action. UNIVERSITY shall not be liable for any losses incurred as the result of an action for infringement brought against LICENSEE as the result of LICENSEE's exercise of any right granted under this Agreement. The decision to defend or not defend shall be in LICENSEE's sole discretion.

13.5 Non-Waiver. The parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

13.6 Reformation. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or com-

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munity or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

13.7 Force Majeure. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure, that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

13.8 Entire Agreement. The terms and conditions herein constitute the entire agreement between the Parties and shall supersede all previous agreements, either oral or written, between the Parties hereto with respect to the subject matter hereof. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

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IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Agreement Date.

LICENSEE	UNIVERSITY
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

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Appendix B: Template Semi-Exclusive License Agreement: Antibody License to Research Reagent Supplier

This Semi-Exclusive License Agreement (hereinafter called "Agreement"), to be effective as of the ___ day of ____, 2008 (hereinafter called "Agreement Date"), is by and between UNIVERSITY (hereinafter called "UNIVERSITY"), a _____ nonprofit corporation having its principal place of business at _____, and _____, a corporation organized under the laws of _____ and having a principal place of business at _____, and its Affiliates (hereinafter, collectively referred to as "LICENSEE").

WITNESSETH:

WHEREAS, UNIVERSITY is the owner of the Subject Technology as defined below; and

WHEREAS, UNIVERSITY is willing to grant a royalty bearing, worldwide, semi-exclusive license to the Subject Technology to LICENSEE on the terms set forth herein; and

WHEREAS, LICENSEE desires to obtain said semi-exclusive license under the Subject Technology.

NOW, THEREFORE, for and in consideration of the promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto expressly agree as follows:

1. DEFINITIONS AND RECITALS

1.1 The term "Affiliates" shall mean any corporation, partnership, joint venture or other entity which LICENSEE, directly or indirectly, owns or controls by LICENSEE's ownership of at least fifty percent (50%) of the entity's common stock or other ownership.

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1.2 **The term "Confidential Information"** shall mean any proprietary and secret ideas, proprietary technical information, know-how and proprietary commercial information or other similar proprietary information that are owned by UNIVERSITY. The term "Confidential Information" is further defined in Section 16 below.

1.3 **The term "Developers"** shall mean _____, employees of UNIVERSITY.

1.4 **The term "Field"** shall mean the market for research reagents that are not to be used for diagnostic or therapeutic purposes in humans.

1.5 **The term "Licensed Product(s)"** shall mean all products that incorporate, utilize or are made with the use of the Subject Technology.

1.6 **The term "Net Sales"** shall mean the gross amount of monies or cash equivalent or other consideration which is billed, invoiced or received (whichever occurs first) for sales, leases or other modes of transfer of Licensed Products by LICENSEE, less:

(i) customary trade, quantity or cash discounts and rebates to the extent actually allowed and taken;

(ii) amounts repaid or credited to customers by reason of rejections or returns made within six (6) months of the first sale or transfer of the relevant Licensed Product;

(ii) to the extent separately stated on purchase orders, invoices or other documents of sale, taxes and/or other governmental charges (except filing fees) which are actually paid by or on behalf of LICENSEE or sublicensees for the production, sale, transportation, delivery or use of a Licensed Product; and

(iv) reasonable charges for delivery or transportation of Licensed Products to customers through the use of third party delivery or transportation services, if separately stated.

The term "Net Sales" in the case of non-cash sales, shall mean the fair market value of all equivalent or other consideration received by LICENSEE for the sale, lease or transfer of Licensed Products.

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1.7 **The term "Party"** shall mean either LICENSEE or UNIVERSITY, and "Parties" shall mean LICENSEE and UNIVERSITY.

Note: *List specific subject technology that will be sent to licensee. Be clear and specific regarding quantities of materials to be supplied.*

1.8 **The term "Subject Technology"** shall mean [(i) the ____ hybridoma cell line, or (ii) fifty milliliters (50 mls) of polyclonal antisera raised against _____ antigen and (iii) all protocols, documents, know-how and confidential information] developed by the Developers as of the Agreement Date and supplied by UNIVERSITY (identified in Appendix C), together with any progeny, mutants or derivatives thereof supplied by UNIVERSITY or created by LICENSEE.

1.9 **The term "Semi-Exclusive"** shall mean that UNIVERSITY has unilaterally decided that in addition to the reservation of rights or power to grant research licenses set forth in Paragraph 2.2 below, it will grant licenses under the Subject Technology to up to, but no more than, three (3) commercial entities in the Field. Such up to three (3) licenses are referred herein as being "semi-exclusive."

2. GRANT OF LICENSE

2.1 **License Grant.** Subject to the reservations of rights set forth in Paragraph 2.2, UNIVERSITY hereby grants to LICENSEE a semi-exclusive, worldwide, right and license under the Subject Technology to make, have made, use, market, sell, offer to sell, lease and import Licensed Products in the Field. This grant does not include the right to sublicense the Subject Technology.

2.2 **Restriction on License.** UNIVERSITY shall at all times reserve the following rights:

(i) UNIVERSITY's right to make or use the Subject Technology for non-commercial research, patient care, teaching and other educationally related purposes;

(ii) the right of the Developers to make or use the Subject Technology for non-commercial research purposes at academic or research institutions;

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(iii) UNIVERSITY's right to grant non-exclusive licenses to the Subject Technology to other academic or research institutions for non-commercial research purposes;

(iv) the right to make and use the Subject Technology by academic and research institutions for non-commercial research purposes;

(v) to right to grant any non-exclusive license(s) to the Subject Technology that UNIVERSITY is required by law or regulation to grant to the United States of America or to a foreign state pursuant to an existing or future treaty with the United States of America;

(vi) the right to grant semi-exclusive licenses to the Subject Technology to two (2) other commercial entities in the Field; and

(vii) the right to grant licenses and other rights to the Subject Technology to commercial entities outside the Field.

2.3 Government Reservation. Rights under this Agreement are subject to rights required to be granted to the Government of the United States of America pursuant to 35 USC Section 200-212, including a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject inventions throughout the world.

3. MARKETING EFFORTS

LICENSEE shall use reasonable efforts, as defined herein, to effect assiduously the introduction of Licensed Products into the commercial market as soon as practicable. Such efforts shall include, but not be limited to:

(i) first sale of Licensed Products within eight (8) months of the Agreement Date;

(ii) publishing and distributing a product circular for the Subject Technology; and

(iii) the production of the Licensed Products and the marketing and support of the Licensed Products with at least the same diligence as LICENSEE employs and to at least the same level that LICENSEE achieves for comparable products and services marketed by LICENSEE.

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4. PAYMENTS

4.1 License Execution Fee. As partial consideration for the rights conveyed by UNIVERSITY under this Agreement, LICENSEE shall pay UNIVERSITY a license fee of _____ ($X,XXX). Such payment shall be delivered to UNIVERSITY concurrent with the execution of this Agreement (except if the invoice language is included per Paragraph 4.3).

4.2 Royalty on Net Sales. In addition to the foregoing, LICENSEE shall pay UNIVERSITY a royalty of _____ percent (___%) of Net Sales. Collectively the royalty payments that are the subject of this Paragraph 4.2 are termed "Royalties" for purposes of this Agreement and shall be payable as provided in Section 5.

4.3 Failure to Make Payment. Should LICENSEE fail to make any payment whatsoever due and payable to UNIVERSITY hereunder, UNIVERSITY may, at its sole option, terminate this Agreement as provided in Section 10.

Note: *If licensee requires an invoice, use this language:*

4.4 Invoice Procedures. Any amounts payable to UNIVERSITY hereunder shall be made in full within thirty (30) days after receipt by LICENSEE of an invoice covering such payment. The Parties understand and agree that one (1) invoice will be sent to LICENSEE by UNIVERSITY for each fee due. The invoice shall be in the form in Appendix ___. Any additional fees, such as taxes, wire or transfer fees, will not be included in the invoice, but payment of such fees shall remain the responsibility of LICENSEE and shall not be deducted from the payment due UNIVERSITY. Subsequent invoices, if requested by LICENSEE, shall be subject to an administrative fee of five hundred dollars ($500), in addition to the original payment due to UNIVERSITY plus any interest charges incurred due to delays in payment, if applicable. The calculation and payment of such interest payments shall not be invoiced and shall be the sole responsibility of the LICENSEE. Invoices shall be sent via facsimile to the address listed in Paragraph 14.2. If LICENSEE requires an original invoice, such invoice shall be sent via overnight courier using LICENSEE's courier _____ (Name Courier) account number _____.

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5. REPORTING

5.1 First Sale of Licensed Product. LICENSEE shall report to UNIVERSITY the date of first sale of Licensed Products within thirty (30) days of occurrence.

5.2 Royalty Report. LICENSEE shall submit to UNIVERSITY within thirty (30) days after June 30 and December 31, a written report on a form provided by UNIVERSITY (a current version of which is attached as Appendix D) setting forth for such six (6) month period at least the following information:

(i) the number of Licensed Products sold by LICENSEE in each country;

(ii) total billings for such Licensed Products;

(iii) the gross amount of monies or cash equivalent or other consideration which is received for sales, leases, licenses or other modes of transfer of Licensed Products by LICENSEE;

(iv) the identity and amount of any non-monetary consideration received for sales, leases, licenses or other modes of transfer of Licensed Products by LICENSEE;

(v) deductions from the gross amount which LICENSEE believes is applicable to determine the Net Sales thereof; and

(vi) the amount of Royalties due thereon, or, if no Royalties are due to UNIVERSITY for any reporting period, the statement that no Royalties are due.

The royalty report shall be certified as correct by an officer of LICENSEE. After termination or expiration of this Agreement, LICENSEE will continue to submit royalty reports and payments to UNIVERSITY until all Licensed Products made, used, marketed, leased or imported under the Agreement have been sold.

5.3 Payment to Accompany Royalty Report. LICENSEE shall pay to UNIVERSITY with each such royalty report the amount of Royalties and other payments due with respect to such six (6) month period. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which Subject Technology is utilized for each Licensed Product included in the royalty report by citing the applicable reference number listed on the front page of the Agreement.

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5.4 Payment Terms. All payments due hereunder are payable by check or wire transfer in United States dollars and shall be deemed received when the complete payment is credited to UNIVERSITY's bank account. Until all funds are received by UNIVERSITY, the payment by LICENSEE is not considered to be complete. For sales of Licensed Products in currencies other than the United States, LICENSEE shall use exchange rates published in The Wall Street Journal on the last business day of the six (6) month period that such payment is due. No transfer, exchange, collection or other charges, including any wire transfer fees, shall be deducted from such payments.

5.5 Late Payments. Late payments shall be subject to a charge of one and one-half percent (1.5%) per month, the interest being compounded annually, or two hundred fifty dollars ($250.00), whichever is greater. LICENSEE shall calculate the correct late payment charge, and shall add it to each such late payment. Said late payment charge and the payment and acceptance thereof shall not negate or waive the right of UNIVERSITY to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment. LICENSEE shall indemnify UNIVERSITY for any and all attorneys' fees and costs incurred by UNIVERSITY to a full payment of that which is owed to UNIVERSITY.

5.6 Payment Address. If payments are sent by check, they shall be sent to the address listed in Paragraph 14.1. If payments are sent by wire transfer, they shall be sent using the wiring instructions sent by UNIVERSITY.

5.7 Notification of Merger or Acquisition. In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, LICENSEE shall notify UNIVERSITY in writing within thirty (30) days of such event.

6. TRANSFER OF SUBJECT TECHNOLOGY

6.1 Upon receipt of the license fee described in Paragraph 4.1, UNIVERSITY shall, within thirty (30) days thereof, provide LICENSEE with the materials described under Paragraph 1.8, Subject Technology.

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6.2 The Subject Technology shall be sent to the address below, via ____ overnight courier using LICENSEE's courier account number _____.

Company Scientist
Company Name
Address
City, State, Zip

Phone _____
E-Mail _____

7. USE/PROVISION OF LICENSED PRODUCTS TO CONTRIBUTORS

LICENSEE shall, throughout the Term of this Agreement as defined below, provide to the Developers reasonable quantities of Licensed Products free of charge, subject to availability of sufficient stock.

8. RECORDS AND INSPECTION

LICENSEE shall maintain or cause to be maintained a true and correct set of records pertaining to the use of the Subject Technology licensed hereunder and the information by which the Net Sales and the Royalties were calculated under this Agreement. During the Term of this Agreement as defined below and for a period of two (2) years thereafter, LICENSEE agrees to permit an accountant selected and paid by UNIVERSITY and reasonably acceptable to LICENSEE to have access during ordinary business hours to such records as are maintained by LICENSEE as may be necessary, in the opinion of such accountant, to determine the correctness of any report submitted and/or payment made under this Agreement. In the event that the audit reveals an underpayment of Royalties by more than five percent (5%) for the period being audited, the cost of the audit shall be paid by LICENSEE. If the underpayment is less than five percent (5%) but more than two percent (2%) for the period being audited, LICENSEE and UNIVERSITY shall each pay fifty percent (50%) of the cost of the audit. Such accountant shall maintain in confidence, and shall not disclose to UNIVERSITY, any information concerning LICENSEE or its operations or properties other than information directly relating to the correctness of such reports and payments.

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9. TERM AND EXPIRATION

Unless earlier terminated as hereinafter provided, this Agreement shall continue in full force and effect for a period of ten (10) years from the first commercial sale of Licensed Products by LICENSEE ("Term"). After such expiration, but not termination, LICENSEE shall have a perpetual, royalty-free license in the Field to the Subject Technology.

10. TERMINATION

10.1 Termination by University: Breach. In the event of default or failure by LICENSEE to perform any of the terms, covenants or provisions of this Agreement, LICENSEE shall have thirty (30) days after the giving of written notice of such default by UNIVERSITY to correct such default. If such default is not corrected within the said thirty (30) day period, UNIVERSITY shall have the right, at its option, to cancel and terminate this Agreement. The failure of UNIVERSITY to exercise such right of termination, for non-payment of Royalties/ fees or otherwise, shall not be deemed to be a waiver of any right UNIVERSITY might have, nor shall such failure preclude UNIVERSITY from exercising or enforcing said right upon any subsequent failure by LICENSEE.

10.2 Termination by University: Insolvency. UNIVERSITY shall have the right, at its option, to cancel and terminate this Agreement in the event that LICENSEE shall (i) become involved in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (ii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iii) a receiver or trustee is appointed for LICENSEE and LICENSEE shall, after the expiration of thirty (30) days following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings.

10.3 Termination by Licensee. LICENSEE shall have the right in its sole discretion to terminate this Agreement upon sixty (60) days' written notice to UNIVERSITY.

10.4 Effects of Termination. In the event of termination of this Agreement, all rights to the Subject Technology shall revert to UNIVERSITY. At the date of any termination of this Agreement, LICENSEE shall immediately cease using any of

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the Subject Technology and LICENSEE shall immediately destroy the Subject Technology and send to UNIVERSITY a written affirmation of such destruction signed by an officer of LICENSEE; provided, however, that LICENSEE may sell any Licensed Products actually in the possession of LICENSEE on the date of termination, provided that LICENSEE continues to submit royalty reports to UNIVERSITY and pays to UNIVERSITY the Royalties on all such sales in accordance with Paragraph 4.2 with respect thereto and otherwise complying with the terms of this Agreement.

10.5 No Refund. In the event this Agreement is terminated pursuant to this Section 10, or expires as provided for in Section 9, UNIVERSITY is under no obligation to refund any payments made by LICENSEE to UNIVERSITY, as set forth in Section 4, prior to the effective date of such termination or expiration.

10.6 Survival of Termination. No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination. The obligations of Sections 4, 5, 8, 10, 13, 14, 15, 16 and 17 shall survive termination of this Agreement.

11. ASSIGNABILITY

This Agreement may not be assigned.

12. GOVERNMENTAL COMPLIANCE

12.1 Compliance with Applicable Laws. LICENSEE shall at all times during the Term of this Agreement and for so long as it shall use the Subject Technology or sell Licensed Products comply with all laws that may control the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of the Subject Technology, Licensed Products or any other activity undertaken pursuant to this Agreement.

12.2 Requirement for U.S. Manufacture. LICENSEE agrees that Licensed Products leased or sold in the United States shall be manufactured substantially in the United States.

Note: *Check to see if federal funding was used to develop subject technology.*

12.3 Export Control Regulations. The Subject Technology is subject to, and LI-

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CENSEE agrees to comply in all respects with, U.S. law including but not limited to U.S. export controls under the Export Administration Regulations (15 C.F.R. Part 734 et seq.) and U.S. economic sanctions and embargoes codified in 31 C.F.R. Chapter V. LICENSEE agrees that LICENSEE bears sole responsibility for understanding and complying with current U.S. trade controls laws and regulations as applicable to its activities subject to this Agreement. Without limitation on the general agreement to comply set forth in the first sentence of this Paragraph 12.3, LICENSEE agrees not to sell any goods, services, or technologies subject to this Agreement, or to release or disclose or re-export the same: (i) to any destination prohibited by U.S. law, including any destination subject to U.S. economic embargo; (ii) to any end-user prohibited by U.S. law, including any person or entity listed on the U.S. government's Specially Designated Nationals list, Denied Parties List, Debarred Persons List, Unverified List, or Entities List; (iii) to any foreign national in the U.S. or abroad without prior license if required; or (iv) to any user, for any use, or to any destination without prior license if required.

13. DISPUTE RESOLUTION

Note: *Insert your university's dispute resolution language as applicable.*

14. ADDRESSES

4.1 University Address for Payments. All payments shall be made payable to "UNIVERSITY" and shall be sent to the address below, and shall reference the applicable reference numbers listed on the front page of the Agreement

Licensee Address for Payments. For questions about payments, UNIVERSITY can contact LICENSEE at the address below:

Title
Name
Address

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Telephone No. _____
Facsimile No. _____
E-Mail _____

14.3 Addresses for Notices. All notices, reports or other communication pursuant to this Agreement shall be sent to such Party via (i) United States Postal Service postage prepaid, (ii) overnight courier, or (iii) facsimile transmission, addressed to it at its address set forth below or as it shall designate by written notice given to the other Party. Notice shall be sufficiently made, or given and received (a) on the date of mailing or (b) when a facsimile printer reflects transmission.

In the case of UNIVERSITY:
In the case of LICENSEE:

14.4 Use of Reference Number(s). Each such report, notice or other communication shall reference the applicable reference numbers listed on the front page of the Agreement

15. INDEMNITY, INSURANCE & WARRANTIES

Note: *Insert your university's indemnity insurance and warranty language as applicable.*

16. CONFIDENTIALITY

Note: *Consider applicability of this language. If subject technology has been published, licensee should not be subject to a duty of confidentiality.*

16.1 Access to Confidential Information. LICENSEE shall not, directly or indirectly, divulge or reveal to any person or entity the Confidential Information of UNIVERSITY without UNIVERSITY's prior written consent or use such Confidential Information except as permitted hereunder. LICENSEE shall maintain the Subject Technology and Patent Rights in strictest confidence and

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use the same only in accordance with this Agreement. Employees, agents or subcontractors of LICENSEE shall be given access to the Confidential Information only on a legitimate "need to know" basis and after agreeing to be bound in writing to not divulge or reveal the Confidential Information. The public disclosure with the permission of UNIVERSITY of any one component of that which was identified as or constituted the Confidential Information of UNIVERSITY shall not prevent the other components from retaining their status as Confidential Information and the property of UNIVERSITY. Confidential Information shall include any and all information that is produced or results from the disclosure of Confidential Information by UNIVERSITY to LICENSEE during the course of the relationship that is the subject of this Agreement.

16.2 Excluded Information. Such obligation of confidentiality shall not apply to information which LICENSEE can demonstrate: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no fault of LICENSEE; (iii) was known to LICENSEE prior to disclosure thereof by UNIVERSITY; (iv) was lawfully disclosed to LICENSEE by a third party which was not under an obligation of confidence to UNIVERSITY with respect thereto; (v) LICENSEE was compelled to disclose by law or legal process; or (vi) was approved for public release by prior written permission of UNIVERSITY.

16.3 Required Disclosure. LICENSEE may make disclosures of Confidential Information required by a Court Order, provided LICENSEE first gives a timely opportunity to UNIVERSITY to participate in the proceeding to the extent that the proceeding permits such participation.

17. ADDITIONAL PROVISIONS

17.1 Use of UNIVERSITY Name. LICENSEE agrees that it shall not use in any way the name of "UNIVERSITY College of Medicine" or any logotypes or symbols associated with UNIVERSITY or the names of any of the scientists or other researchers at UNIVERSITY without the prior written consent of UNIVERSITY, except that LICENSEE may list scientific references that state the names of the scientists and other researchers at UNIVERSITY.

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17.2 UNIVERSITY's Disclaimers. Neither UNIVERSITY, nor any of its faculty members, scientists, researchers, employees, students, officers, trustees or agents assume any responsibility for the manufacture, product specifications, sale or use of the Subject Technology or the Licensed Products which are manufactured by or sold by LICENSEE.

17.3 Independent Contractors. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

17.4 Defense of Infringement Action. UNIVERSITY shall not be liable for any losses incurred as the result of an action for infringement brought against LICENSEE as the result of LICENSEE's exercise of any right granted under this Agreement. The decision to defend or not defend shall be in LICENSEE's sole discretion.

17.5 Non-Waiver. The parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

17.6 Reformation. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or execu-

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tive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

17.7 Force Majeure. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure, that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

17.8 Entire Agreement. The terms and conditions herein constitute the entire agreement between the Parties and shall supersede all previous agreements, either oral or written, between the Parties hereto with respect to the subject matter hereof. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Agreement Date.

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LICENSEE UNIVERSITY

Name: _____ Name: _____

Title: _____ Title: _____

Date: _____ Date: _____

Appendix C
Subject Technology

List the technology, cell lines, biological materials, compounds, methods, documents, materials, tests, and confidential information to sent by UNIVERSITY to LICENSEE.

Appendix D
Royalty Report

REF : _____
Licensee: _____
Reporting Period: _____
Prepared By _____ Date: _____
Approved By _____ Date: _____

Please prepare a separate report for each product line. Then combine all product lines into a summary report.

Product Line Code (SKU): _____

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Country	Units Sold	Exchange Rate	Total Billings (USD)	Gross Sales (USD)	Less Deductions* (USD)	Net Sales (USD)	Royalty Rate	Royalty Amount
USA								
Canada								
Europe								
Japan								
Other								
Total								$
Third Party Royalty Payments (USD)								$
Net Royalty Payable (USD)								$
Sublicensing Revenue (USD)								$
Other Payments — Milestones, Minimum Royalties, Maintenance Fees (USD)								$
Total Payment Due (USD)								$

*Deduction Description:

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Research Tools Policies and Practices: Perspective of a Public Institution

Uri Reichman, PhD, MBA, Susan E. Ano, PhD, and Steven M. Ferguson, MBA, CLP

Uri Reichman, MBA, PhD, is senior advisor for licensing; Susan E. Ano, PhD, is branch chief; and Steven M. Ferguson, MBA, CLP, is deputy director, licensing and entrepreneurship in the Office of Technology Transfer at the National Institutes of Health in Rockville, Maryland.

Introduction

The impact of the 1980 Bayh-Dole Act (35 U.S.C. §200-§212) on commercialization of medical inventions is indisputable. The act gave grant and contract recipients the ability to take title to inventions made under federally funded research. Associated with this ownership was the right to license the inventions to the private sector for commercial development. The Bayh-Dole Act resulted in a dramatic increase in the formation of commercialization partnerships between academia and industry and in the emergence of a great number of startup enterprises, many of them university spinoffs initiated by the academic inventors themselves.

Over the same time period similar legislation for federal laboratories such as the Stevenson-Wydler Act of 1980 and the Federal Technology Transfer Act (FTTA) of 1986 has also likewise resulted in increased commercialization activity based upon research conducted at the federal laboratories themselves.

The potential of profiting from traditional research activities, however, created the perception that academic institutions and their scientists may become reluctant to disclose their research results and freely share research resources developed under government grants, including those from the National Institutes of Health (NIH).

Furthermore, many were concerned that the proliferation in the number of such partnerships, sponsored research, and license agreements could lead to the private sector imposing restrictions adversely affecting academic freedom and the dissemination of research

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resources. A major area of concern was related to biological materials and research tools that are instrumental to scientific discovery and the life blood of biomedical research.

The commercialization concerns above seemed to some to create potential conflict with the basic intent of federal research funding and with the core philosophy of academic research that traditionally encouraged broad dissemination of research results and research resources. These two seemingly conflicting directives, commercialization on one hand and broad dissemination of research results on the other, created some confusion and ambiguities in the research community that required clarification to show how both objectives could be compatibly achieved.

As the primary federal agency for conducting and supporting biomedical research, the NIH felt that it was necessary to provide its grantees with guidance to assist them in balancing commercialization under Bayh-Dole in a way that would not inhibit further research and new scientific discoveries. Accordingly, the agency took upon itself the responsibility of formulating a formal policy regarding dissemination of biomedical research resources. A working group tasked with this mission was established in 1997 under the directive of the then director of the NIH, Harold Varmus, MD.

A first draft of the policy was proposed by the working group and published in the *Federal Register* in August 1997 to obtain comments from the biomedical community as well as the broader public. In view of the feedback, the NIH published its revised final policy notice on December 23, 1999, (http://www.ott.nih.gov/pdfs/64FR72090.pdf). Since its publication, the notice, entitled "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts" (also known as the NIH research tools policy) has served as a useful reference document for the biomedical research community, assisting researchers in developing balanced strategies related to dissemination of research resources, both as providers of such resources and as recipients.

This 1999 *Federal Register* notice was issued as a grants policy, to be incorporated into the NIH grants policy statement. Moreover, following the issuance of these guidelines Congress amended the Bayh-Dole Act to emphasize the obligation of recipients to balance between the above-mentioned two directives as articulated in the policy and the objective

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section of the law as quoted here: "It is the policy and objective of the congress to use the patent system to promote the utilization of inventions arising from federally supported research and development … to ensure that inventions made by nonprofit organizations and small-business firms are used in a manner to promote free competition and enterprise *without unduly encumbering future research and discovery*" (35 U.S.C. §200).

This chapter is presented in three parts. "Part 1: The NIH Research Tools Policy" provides a detailed description of the NIH research tools policy. This part includes different strategies and proposed language that can be used in transactional and collaborative agreements.

"Part 2: NIH Technology Transfer Practices" discusses the practices implemented by the NIH technology transfer community with regard to research tools. Although these NIH intramural research tool practices themselves derive separately from the Stevenson-Wydler Act and the FTTA (rather than the Bayh-Dole Act), they provide some very practical experience in this area based upon the substantial size and large number of inventions coming from the NIH intramural research program.

"Part 3: More on the NIH Patenting and Policy Positions Related to Research Tools" provides examples of policy positions taken by the NIH over the years as they relate to patenting of research tools. This part highlights the NIH's continuing dedication to improving policies related to dissemination of research tools.

The chapter is designed to provide practical advice and specific language related to the dissemination of research tools. The three parts that follow this introduction endeavor to provide sufficient information so that future collaborative research may better lead to expeditious product development without hindrance to academic research and further scientific discoveries in the spirit of the Bayh-Dole Act.

Part 1: The NIH Research Tools Policy

The NIH research tools policy as published in the December 23, 1999, *Federal Register* encompasses four principles and a set of implementation guidelines as summarized below. Before discussing the principles and guidelines it is important to define what research tools are and how they should be utilized.

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What Are Research Tools and How Should They Be Utilized?

Research tools, also called research resources or research materials, are biological or other materials that are:

- primarily useful for research purposes, such as in data related to the elucidation of disease mechanisms or to drug discovery;
- by definition finished products that often do not require further development time and development costs in order to be utilized; or
- broadly enabling inventions, useful in developing multiple products in numerous disciplines, rather than a single project-specific or product-specific use.

Common examples of research tools include:

- antibodies
- expression plasmids and proteins derived from them
- cell receptors
- cell lines
- animal models (e.g., knockout mice)
- laboratory and drug-screening methods or protocols
- certain software

It should be appreciated that certain biological materials can serve dual purposes, i.e., they can be classified as research tools, but they can also be used for commercial applications as therapeutic or vaccine candidates or as diagnostics that require major investment of capital and time for further development and regulatory approval. These distinctions associated with such materials may be accommodated through inclusion of appropriate language in licensing agreements, which is discussed in "The Guidelines" section of Part 1 and in the "Licensing" section of Part 2 of the chapter.

As will be discussed further in this chapter, inventors should seek the assistance of their technology transfer professionals to thoroughly analyze the potential utility of biological materials developed by them in order to be able to choose a strategy that will best comply with the NIH research tool policy as discussed in this chapter while also protecting the interest of the inventors and their institutions.

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The Principles

The first principle of the NIH research tools policy is "Ensure Academic Freedom and Publication."[1] This principle is concerned with the need by NIH recipients to preserve academic freedom even when a partnership with industry is involved. The following points are the essentials of this principle:

- Recipients have the obligations to preserve academic freedom and disclose their research findings in a timely manner through publications, public presentations, and the like.
- Recipients should avoid signing collaborative agreements that unduly limit their freedom to collaborate and publish or that otherwise grant overreaching rights to a third-party provider of research materials.

With respect to preserving academic freedom under sponsored research situations, this point reinforces an earlier NIH guidance to recipients. In July 1994 the NIH published a notice in the *Federal Register* entitled "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts" (59 FR 5567; November 9, 1994, and *NIH GUIDE*, Vol. 23, No. 25, July 1, 1994).

This earlier document emphasizes that for NIH-funded research, it is essential that "Grantees must ensure that the timely dissemination of research findings is not adversely affected by the conditions of a sponsored research agreement."

The first principle discussed here further elaborates on this issue as summarized in the next two bullets:

- In the case of a sponsored research agreement between a recipient and an industrial partner, some reasonable restrictions are acceptable to avoid conflicting obligation with other industrial sponsors. Furthermore, brief delays in publications of research results are acceptable when patent protection is warranted or for the purpose of ensuring that the sponsor's proprietary information is not disclosed.
- Excessive publication delays or requirements for editorial control, approval of publications, or withholding of data when imposed by the commercial partner all undermine the credibility of research results and should be avoided.

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The second principle, "Ensure Appropriate Implementation of the Bayh-Dole Act," emphasizes the obligations of recipients to cooperate with the spirit of Bayh-Dole in dealing with patenting and licensing of new inventions. It highlights the following:

- NIH-funded research is subjected to laws and regulations as codified by the Bayh-Dole Act *(35 U.S.C. 200 et seq.)*.
- In accordance with this act, recipients are expected to (a) maximize the use of their research findings by making them available to the research community and the public and (b) when warranted and suitable, transfer inventions to the private sector for commercialization, which may sometimes require patent protection.
- While the practice of patenting and licensing of inventions is encouraged by the Bayh-Dole Act to stimulate commercialization, there are sometimes other appropriate means of implementing the Bayh-Dole act as stated below.
- Recipients should consider alternative strategies other than seeking patent protection for materials whose primary use is as research tools, as they are by their very nature fully developed and do not require further investment of time and capital be utilized. Such research tools are usually transferred between academic institutions for internal research under material transfer agreements (MTAs) in transactions that do not involve financial compensations.
- Unpatented research tools can also be transferred to the private sector on a nonexclusive basis via internal-use license agreement. Such agreement may include financial compensation. Modifications to NIH policy allow recipients to elect title to such inventions even if unpatented.
- It is also consistent with Bayh-Dole to grant commercial licenses for research tools to companies for the purpose of sales and distributions of such reagents to the research community. Such commercial licenses may in certain circumstances be better justified on an exclusive basis if the technology requires further development by the commercial party to realize the invention's usefulness as a research tool.

The third principle in the NIH Policy, "Minimize Administrative Impediments to Academic Research," is concerned with the transfer of research tools to research groups, whether located at for-profit or not-for-profit institutions. It emphasizes the importance of establishing expeditious processes for the transfer of research resources.

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Furthermore, it advocates and proposes streamlining and simplification of transfer agreements. This third principle expands on the concepts of the first principle regarding collaborative relations between academia and industrial sponsors and the responsibilities of each party. The main points outlined in this principle are as follows:

- To expedite the transfer process, the standard uniform biological materials transfer agreement (UBMTA)[3] is acceptable. This master document can be further implemented by a convenient form of a simple letter agreement (SLA). In addition a freestanding SLA is strongly encouraged for the transfer of patented biological materials. A sample of such an agreement is provided in "The Guidelines."
- When a recipient acquires research resources from another party, the recipient should develop and implement clear policies that articulate acceptable conditions for acquiring resources and refuse to yield on unacceptable conditions that may excessively restrict academic freedom while remaining respective of the legitimate concerns of the for-profit provider.
- For-profit organizations must minimize obligations that seek to impose. In these transfers all providers should avoid imposing reach-through royalty or product rights as conditions on transfer (i.e., rights to products invented through the use of research tools provided by them), unreasonable restraints on publication and academic freedom, and improper valuation of tools.

The fourth principle, "Ensure Dissemination of Research Resources Developed with NIH Funds," is meant to ensure broad and timely dissemination of research tools by recipients. Furthermore, recipients should not agree to limitations in their agreements with third parties that have the potential to restrict the dissemination of NIH-funded research tools.

- Recipients are expected to manage interactions with third parties that have the potential to restrict recipients' ability to disseminate research tools developed, in whole or in part, with NIH funds (research tools obtained from human tissues may require restrictions to ensure consistency with donor consent and protection of human subjects as per 45 CFR Part 46).
- In cases where recipients are involved with transfer or collaborative agreements with third parties, recipients are encouraged to share the principles outlined in the NIH policy notice with these third parties.

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- In instances where the for-profit institution is seeking access for internal-use purposes, recipients are encouraged to transfer research tools developed with NIH funding to such institutions without seeking option rights or royalties on the final product.

The Guidelines

This section provides technology transfer professionals, scientists, and research administrators with practical strategies, procedures, forms, and proposed language related to the four principles discussed above to facilitate their implementation. These proposals are merely guidelines. It is expected that they may be modified depending on specific scenarios.

Disseminating Research Resources Arising out of NIH-Funded Research

As per the discussion above regarding the third principle, a model transfer letter agreement is shown in Exhibit 1.[4] This SLA is primarily suitable for transfer of materials amongst academic institutions and other not-for-profit entities. It is designed for transfers under terms no more restrictive than the well-known UBMTA.[5] If the materials are patented or licensed to an exclusive provider, other arrangements may be used, but commercial license rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate.

Exhibit 1: Material Transfer/Simple Letter Agreement

In response to RECIPIENT's request for the MATERIAL [insert description] _____ the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.

2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.

3. The MATERIAL will be used for teaching or not-for-profit research purposes only.

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4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.

5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.

6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.

8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____ The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

Provider Information and Authorized Signature

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*Provider Scientist:*_____
Provider Organization: _____
*Address:*_____
Name of Authorized Official: _____
Title of Authorized Official: _____
Certification of Authorized Official: This Simple Letter Agreement ____ has _____ has not [check one] been modified. If modified, the modification is attached.

_____
(Signature of Authorized Official) (Date)
Recipient Information and Authorized Signature
Recipient Scientist: _____
Recipient Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____
Signature of Authorized Official: _____
Date: _____
Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____
(Recipient Scientist) (Date)

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Similarly to this model agreement, when for-profit entities are seeking access to NIH-funded tools for internal-use purposes, recipients should ensure that the tools are transferred with the fewest encumbrances possible. The model SLA may be expanded for use in transferring tools to for-profit entities or an internal-use license agreement may be drafted where compensation may be appropriate. For example, NIH has expanded the model (Exhibit 1a)[6] to handle circumstances relating to the transfer of model organisms where crossbreeding may occur. Additionally, animal welfare conditions or other special issues may apply to these transfers.

Exhibit 1a: Additional MTA/SLA Language for Transfer of Transgenic Organisms

This is in response to RECIPIENT's request for the MATERIAL (specifically, the name of the gene or allele mutation that makes the organism(s) unique) _____, found within the _____ (organism strain, species, et.), the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

…

8. If the RECIPIENT anticipates that it will generate cross-bred or genetically-modified organisms incorporating the PROVIDER's modified allele(s), RECIPIENT may transfer such cross-bred or genetically-modified organism(s) to non-profit institutions under the terms of a material transfer agreement that notifies the not-for-profit institution of the existence of PROVIDER's rights to the modified allele(s) and restricts the use of the transferred organism(s) by the not-for-profit recipient to teaching or not-for-profit research purposes only. This Agreement does not transfer any of PROVIDER's patent, invention, or other intellectual property rights in the organism(s) to RECIPIENT. Additionally, to the extent that any other party has any patent, invention or other intellectual property rights in the organism(s), these rights are not transferred to RECIPIENT by PROVIDER…

Consistent with the principles, in situations where recipients are engaged in collaborative and/or sponsored research with third parties, they are expected to craft agreements with such third parties in a way that is consistent with Bayh-Dole and their obligations to the NIH, including their obligations to share research resources with the rest of the research community as freely and openly as possible. Samples of such language are provided below in Exhibit 2.[7]

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Exhibit 2: Sample Language in Sponsored Research Agreements

The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that upon publication, unpatented unique research resources arising out of this project may be freely distributed.

In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions that ensure that the research tool will be available to the academic research community on reasonable terms.

Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials (or parts thereof) or Provider sole inventions) available to other scientists at not-for-profit organizations for use in research, subject to Provider's independent intellectual property rights.

Subject to Recipient's obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights: …

Research tools that do not require extensive research and development (R&D) or capital investment to realize the invention's usefulness as a tool should not be licensed on an exclusive basis unless it is licensed to a commercial research reagents distributor and the distributor is committed to the broad dissemination of such tools. This strategy is sometimes advisable as it can facilitate a wide distribution of reagents in an effective manner.

In certain situations inventions that are biomedical materials can be exploited in multiple ways. They can be developed into vaccines, therapeutics, or diagnostic products on one hand or can be utilized as research tools on the other. In these cases, patenting of the materials may be warranted. A common example for this is antibodies. Antibodies can be developed into therapeutics against a variety of diseases or they can be used to develop laboratory reagents.

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In these situations, regulatory requirements may be necessary and thus entail significant investment of time and capital, therefore justifying exclusive licenses when the cost of commercial development so justifies. At the same time, antibodies can be used as research tools, e.g., in elucidating disease mechanisms or for drug discovery. In such cases, the biological materials may be licensed on different terms for different fields of use, i.e., exclusive license for therapeutics and vaccines, but nonexclusive licenses when licensed as a research tool. This point is further discussed in Part 2 of this chapter, under the "Licensing" section.

Furthermore, the exclusive licensee shall not be permitted to block the broad dissemination of the materials for the research community for research purposes, which may be accomplished through requiring the licensee to grant such research licenses, MTAs, or refraining from enforcing any relevant patents against nonprofit research institutions. Finally, the original licensor or owner of such materials may reserve the rights to grant such research licenses directly. These goals can be accomplished through incorporation of appropriate language into commercial license agreements. Examples of such language are provided in Exhibit 3.[8]

Exhibit 3: Language Directed to Research Licenses

"Research License" means a nontransferable, nonexclusive license to make and to use the Licensed Products or Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for purposes of commercial manufacture, distribution, or provision of services, or in lieu of purchase, or for developing a directly related secondary product that can be sold. Licensor reserves the right to grant such nonexclusive Research Licenses directly or to require Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, Licensor shall consult with Licensee before granting to commercial entities a Research License or providing to them research samples of the materials.

Licensor reserves the right to provide the Biological Materials and to grant licenses under Patent Rights to not-for-profit and governmental institutions for their internal research and scholarly use.

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Notwithstanding anything to the contrary in this agreement, Licensor shall retain a paid-up, nonexclusive, irrevocable license to practice, and to sublicense other not-for-profit research organizations to practice, the Patent Rights for internal research use.

The grant of rights provided herein is subject to the rights of the United States government pursuant to the Bayh-Dole Act and is limited by the right of the Licensor to use Patent Rights for its own research and educational purposes and to freely distribute Materials to not-for-profit entities for internal research purposes.

Licensor reserves the right to supply any or all of the Biological materials to academic research scientists, subject to limitation of use by such scientists for research purposes and restriction from further distribution.

Licensor reserves the right to practice under the Patent Rights and to use and distribute to third parties the Tangible Property for Licensor's own internal research purposes.

Acquiring Research Resources for Use in NIH-Funded Research

Agreements to acquire materials for use in NIH-funded research are expected to address the timely dissemination of research results. Recipients should not agree to significant publication delays, any interference with the full disclosure of research findings, or any undue influence on the objective reporting of research results. A delay of 30 to 60 days to allow for new patent application filing or review for confidential proprietary information is generally viewed as reasonable.

Under the Bayh-Dole Act and its implementing regulations (37 CFR 401), agreements to acquire materials for use in NIH-funded projects cannot require that title to resulting inventions be assigned to the provider. Recipients should therefore make sure that the definition of *materials* in MTAs or similar agreements with third-party providers does not include all derivatives and improvements of provided materials. Conversely, the language of such agreements should specify that recipients do not gain an ownership interest in such third party's provided materials as a result of the recipient's work with the materials. Exhibit 4[9] below provides possible definitions for use in such transfer agreements.

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Exhibit 4: Definition of* Materials *when Recipients Accept Research Tools

"Materials" means the materials provided as specified in this document. Materials may also include Unmodified Derivatives of the materials provided, defined as substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original materials, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

"Materials" means the materials provided as specified in this document. Materials may also include Progeny and Unmodified Derivatives of the materials provided. Progeny is an unmodified descendant from the original material, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

"Materials" means the materials being transferred as specified in this document. Materials shall not include: (a) Modifications or (b) other substances created by the recipient through the use of the Material which are not Modifications, Progeny, or Unmodified Derivatives. Progeny is an unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original Material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original Material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line. [Source: Uniform Biological Materials Transfer Agreement; terms defined therein]

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Recipients are expected to avoid signing agreements to acquire research tools that are likely to restrict their ability to promote broad dissemination of additional tools that may arise from the research. This situation might occur if an agreement gives a provider an unrestricted exclusive license option to any new intellectual property arising out of the project. A new transgenic mouse developed during the project could fall under this license option and become unavailable to third-party scientists as a result.

In signing agreements such as MTAs, memoranda of understanding (MOU), research or collaboration agreements, and sponsored research agreements, recipients should consider adopting standard language that address this issue. The language provided in Exhibit 2 (in the discussion related to sponsored research), can be used in agreements that either acquire materials from or co-mingle funds with nongovernment sources.

Grant Back and Option Rights to Third-Party Material Provider

The points that follow further elaborate on the expectations from recipients in their dealing with providers from for-profit entities.

Agreements to acquire materials from for-profit entities for use in NIH-funded research may provide a grant back of nonexclusive, royalty-free rights to the provider to use improvements and new uses of the material that would infringe any patent claims held by the provider. The agreements may also provide an option for an exclusive or nonexclusive commercialization license to new inventions arising directly from use of the material. These should be limited to circumstances where the material sought to be acquired is unique, such as a patented proprietary material and not reasonably available from any other source.

A nonexclusive grant-back might be used, for example, to protect a for-profit entity that provides a proprietary compound from being blocked from using new uses or improvements of that compound discovered during the NIH-funded project. In providing license options, recipients must ensure that licenses granted to providers under such options are consistent with Bayh-Dole requirements, including the preference for U.S. industry requirements under exclusive agreements and reservation of government rights under 37 CFR Part 401.

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In determining the scope of license or option rights that are granted in advance to a provider of materials, recipients should balance the relative value of the provider's contributions against the value of the rights granted, cost of the research materials provided, and importance of the research results. The rights granted to providers should be limited to inventions that have been made directly through the use of the materials provided.

In addition, recipients should reserve the right to negotiate license terms that will ensure: (1) continuing availability to the research community under reasonable terms if the new invention is a unique research resource, (2) that the provider has the technical and financial capability and commitment to bring all commercially relevant applications in the field of use of the license to the marketplace in a timely manner, and (3) that if an exclusive license is granted, the provider will provide a commercial development plan and agree to benchmarks and milestones for any fields of use granted.

It is expected that agreements to acquire NIH-funded materials from not-for-profit entities for use in NIH-funded research will not include commercialization option rights, royalty reach-through, or product reach-through rights back to the provider. Such materials should be acquired under terms no more burdensome than the SLA or UBMTA, or, if the materials are provided to a for-profit entity, a SLA or MTA that does not request reach-through to either future products or royalties.

If the providing not-for-profit organization is constrained in sharing the material due to a pre-existing sponsored research agreement or license, NIH expects that such a not-for-profit provider to negotiate a suitable resolution with the private research sponsor or licensee. The co-mingling of NIH and sponsored research funds is allowed, however, each recipient is responsible for ensuring that conditions on the use of the sponsored funds do not interfere with the open dissemination of research tools or other terms and conditions of the NIH funding.

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While there is no specific model language provided to recipients pertaining to the guidelines under this section for working with for-profit entities, a useful example can be found from an NIH model agreement used in the intramural research program, the material cooperative research and development agreement (M-CRADA). This specific model can be found at the OTT Web site under "Forms and Model Agreements."[10]

Part 2: NIH Technology Transfer Practices

In addition to its function as a granting institution, the NIH also engages in intramural research and extensive technology transfer activities. As such, in its own biomedical research program, the NIH has adopted for its programs the same policies and guidelines that apply to recipients. These activities will be highlighted here.

For example, the NIH intramural research program utilizes the SLA or UBMTA as model MTAs for transfers of biological materials with a nonprofit research institution. Additionally, as a U.S. government agency, the NIH has the legal authority to grant licenses under license agreement instead of an MTA. Thus for NIH the grant of an explicit license to use biological materials for commercial purposes can only be accomplished through such means instead of an NIH MTA, which would only give the receiving party permission to use the biological materials without an explicit license.

The NIH OTT (www.ott.nih.gov) serves as the patenting and licensing arm for the NIH and FDA intramural programs. As such, OTT works in concert with technology transfer offices within the different institutes and centers at the NIH and U.S. Food and Drug Administration (FDA). The institute- and centers-based technology transfer activities focus on interactions with academic institutions involving MTAs, the initial referral of new invention reports to OTT, and establishing collaborative research with private companies.

The latter aspect involves agreements such as collaborative research and development agreements (CRADAs), M-CRADAs, or clinical trial agreements. CRADA mechanisms grant options to future inventions made under their research plans. A significant portion of the overall NIH technology transfer activities relate to transfer of biological materials. The practices implemented by the NIH with regards to these activities are highlighted below.

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Patenting

The NIH will generally seek patent protection for biomedical inventions that require further investment of capital and time to bring the invention to the point of commercial utilization. Many times these inventions require regulatory approval (such as from the FDA).[11] Inventions related to vaccines, therapeutics, and diagnostics generally fall into this category. Also included are devices and software with medical utility (e.g., imaging devices and instrumentation or software required by such instrumentation for enhanced signal resolution). Such devices usually require clinical trials to receive acceptance in the medical community. Conversely, the NIH will not seek patent protection for biomedical inventions that only have utility as research tools.

As previously noted, the NIH will seek patent protection for biomedical inventions that can be utilized for dual purposes, i.e., commercial product development (e.g., vaccine or therapeutics) and as research tool (e.g., drug screening and discovery), and further discussion regarding licensing of such dual-purpose inventions is discussed in the next section.

Licensing

At the NIH, research tools may be transferred to third parties under a variety of license agreements for government-owned inventions, whether patented or not (37 CFR Part 404), as listed below:

a. patent license agreements for commercialization (i.e., development of integrated drugs screening kits and systems or for sale and distribution of research reagents)
b. unpatented biological materials licenses for commercialization
c. internal-use licenses (patented or unpatented biological material)
d. commercial evaluation licenses

In all of its license agreements,[12] the NIH includes clauses that will ensure the continued ability to broadly disseminate the licensed materials for research applications, even where those materials are licensed exclusively for commercialization. This is accomplished by incorporating in such agreements specific definitions and clauses that preserve the right

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of the NIH to grant research licenses to third parties (academic or commercial), including to CRADA partners, or to require its licensees to do the same, as shown in Exhibit 5[13] (note that in its license agreements, OTT uses the term Public Health Service (PHS) rather than NIH, to also include the FDA, since OTT serves as the invention licensing arm of this agency).

Exhibit 5: Granting of Research Licenses

"Research License" means a nontransferable, nonexclusive license to make and to use the Licensed Products or Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for any purposes relating to or which could lead to commercial manufacture or distribution or in lieu of purchase.

PHS reserves the right to grant Research Licenses directly or to require Licensee to grant Research Licenses on reasonable terms. The purpose of these Research Licenses is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, PHS shall consult with Licensee before granting to commercial entities a Research License or providing to them research samples of materials made through the Licensed Processes.

Licensee acknowledges that PHS may enter into future Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this Agreement. Licensee agrees not to unreasonably deny requests for a Research License from such future collaborators with PHS when acquiring such rights is necessary in order to make a Cooperative Research and Development Agreement (CRADA) project feasible. Licensee may request an opportunity to join as a party to the proposed Cooperative Research and Development Agreement (CRADA).

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This language sometimes causes concerns for potential commercial partners, who view research licenses as a potential mechanism by which an industry competitor may undermine its commercial position. Such concerns are typically addressed through education regarding the intent of the clauses in Exhibit 5 or by incorporating additional language to reassure licensee that PHS will consider its concerns in good faith (for example: "before

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granting such Research License PHS will consider Licensee's concerns in good faith") or to indicate that PHS may revoke a research license if NIH receives adequate evidence that a corporate licensee has extended its efforts beyond the scope of the research license.

Similarly, nonexclusive commercialization or internal-use licenses for nonpatented biological materials include a clause that allows the NIH the right to distribute the licensed materials to third parties for research purposes, as shown in Exhibit 6.[14]

Exhibit 6: Biological Materials License, Distribution of Material to Third Parties
This Agreement does not preclude PHS from distributing the Materials or the Licensed Products to third parties for research or commercial purposes.

The biological material license agreement (BMLA), either for commercialization or for internal use, makes clear distinction between *materials* and *licensed products*. They typically define *materials* as the biological materials provided by the NIH under the license agreement, and *licensed products* as the end products derived from them or in which they are used.

For example, a plasmid will constitute the *material* and the protein it expresses will be the *licensed product*. A similar relationship exists for a hybridoma cell line (material) and antibodies derived from it (licensed product). In a commercialization license, recombinant virus strains may be the material while the vaccine formulation made from it will constitute the licensed product. A commercialization BMLA will typically entail royalty payment on sales of licensed products. As you can see, it is always critical to make definitions as inclusive (or exclusive) as necessary to ensure the ability of the NIH to comply with its own guidelines regarding research tools.

In the spirit of its guidelines, the NIH license agreements encourage publication or presentation of research results stemming from the use of research tools through inclusion of, e.g., the clause of Exhibit 7.[15]

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Exhibit 7: BMLA Internal Use, Publication of Research Results

Licensee is encouraged to publish the results of its research projects using the Materials or the Licensed Products. In all oral presentations or written publications concerning the Materials or the Licensed Products, Licensee shall acknowledge the contribution of Dr. _____ and the PHS agency supplying the Materials, unless requested otherwise by PHS or Dr. _____.

As previously noted, the NIH will consider seeking patent protection for biomedical inventions that can be utilized for dual purposes, i.e., commercial development (e.g., vaccine or therapeutics) and as research tool (e.g., drug screening and discovery). In licensing of such inventions, the level of exclusivity will be commensurate with the field of use as exemplified in the customized sample shown in Exhibit 8.

Exhibit 8: Grant of Rights Language for Dual Purposes

PHS grants and Licensee accepts license grants for the Licensed Patent Rights as follows:

1) An exclusive license to make and have made, to sell and have sold, to use and have used, and to import *Licensed Product(s)* in the *Field of Use* of vaccines [therapeutics, diagnostics] against xxxxx.

2) A nonexclusive license to make and have made, to sell and have sold, to use and have used, and to import *Licensed Product(s)* in the *Field of Use* of research reagents.

3) A nonexclusive license to use *Licensed Product(s)* in *Licensee's* internal drug discovery program.

In agreements of this type, different earned royalty rates could well apply for product sales in the different fields of use. As an example, perhaps 5 percent for the exclusive license, 7 percent for the commercial nonexclusive license, and no earned royalties could be required for the internal use license. In this instance, a higher earned royalty rate might well apply for research reagent sales due to the technology being so much closer to

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a finished product in this field rather than the actual rate being a function of exclusivity or nonexclusivity. NIH license agreements with multiple fields of use (including internal use) typically contain other financial terms (e.g., execution, annual, or benchmark royalties).

Regarding patent costs reimbursement, the NIH will not generally seek such reimbursement for research reagent agreements, including those for internal use by a licensee as well as for commercial sale and distribution of research reagents by a licensee.

A complete collection of the model agreements of the NIH intramural program can be found at the OTT Web site under "Forms and Model Agreements."[16]

Part 3: More on the NIH Patenting, Licensing, and Policy Positions Related to Research Tools

In its leadership role, the NIH has continuously been involved with educating and advising the research community with respect to the interpretation and implementation of the Bayh-Dole Act and of the research tools guidelines as summarized in previous parts of this article. These activities are done through the Office of Policy for Extramural Research Administration (OPERA) as well as at OTT, with OTT as the lead office for the development of technology transfer policy.

The NIH has over the years published its positions regarding various issues related to patenting and licensing of research tools. Links to some of these published documents are provided on the OTT Web site (www.ott.nih.gov/policy) as well as on the OPERA Web site (http://grants.nih.gov/grants/intell-property.htm). There are a variety of useful policy documents and information listed for recipients, ranging from invention reporting requirements to electing title to biological materials. Some of the research tool-related positions of note are summarized below.

Best Practices for Licensing of Genomic Inventions

Genomic inventions include a wide array of technologies and materials such as cDNAs, expressed sequence tags, haplotypes, antisense molecules, small interfering Ranks, full-length genes and their expression products, methods for the sequencing of genomes, quantification of nucleic acid molecules, detection of single nucleotide polymorphisms,

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and genetic modifications. Commercial products that can be developed on the basis of these technologies include nucleic acid-based diagnostics, gene therapy applications, and DNA- and RNA-based therapeutics. With the growing importance of such inventions in product development, the NIH saw a need to provide additional, specific guidance on the topic.

Building on the established research tools guidelines already in place, the NIH published a final version of "Best Practices for Licensing of Genomic Inventions" (which also included guidance on patenting of such inventions) on April 11, 2005, following comments solicited and received from the public as well as grantees and academic, not-for-profit, and private-sector participants in the biomedical research and development communities.[17]

Patenting of Genomic Inventions

The NIH recognized that patent protection for genomic inventions, like other technology areas, tend to include claims that are broad in scope. However, such an outcome could adversely impact further innovations based on the original findings, which is one of the fundamental issues that led to the development of the research tools policy. As described earlier for research tools, the best practices guidelines advocated pursuing patent protection only if significant further investment in R&D by the private sector would be needed. If, as for research tools, this additional investment were unlikely to be needed, then the best practices indicated that patent protection need not be sought.

However, the best practices recognized that in the early stages of development, the commercial embodiments of the invention may not be clear or the need for patent protection may not be clear. Therefore, pursuit of patent protection in the early stages with reassessment prior to further, future filings may be a reasonable strategy. This scenario would best be implemented if there is periodic review of filings at key filing deadlines so these items are reviewed as a matter of course and a separate review strategy does not need to be implemented.

Licensing of Genomic Inventions

Whenever possible, licensing of genomic inventions should be on a nonexclusive basis, which favors and facilitates the widespread availability and accessibility of the invention to the scientific community. However, it is possible that exclusive licensing of genomic inven-

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tions will be appropriate, especially for nontool applications. In these instances, as previously described for research tools in general, it is important to appropriately tailor the scope of the license to allow for expeditious development of as many aspects as possible. As with any commercial development license, regardless of whether it is for research tools or not, the NIH believes in the inclusion of development benchmarks and milestones to allow for license modification or termination should appropriate progress not be made.

NIH/DuPont Memoranda of Understanding Related to Cre-lox and Oncomouse

To ensure dissemination of critical research tools to the research community as broadly as possible the NIH entered into two MOUs with the E.I. DuPont de Nemours and Co.

The first MOU with DuPont, signed July 1, 1998, relates to DuPont's patent concerning cre-lox, a site-specific recombination system that is used as a genetic tool to control site-specific recombination events in genomic DNA.[18] The cre-lox system has usefulness in basic research conducted or funded by NIH as well as utility for commercial application. The MOU grants the NIH with the right to use the patented system for research purposes. It further states that the NIH retains the right to transfer materials covered by the patent rights and made by it in its research program, to non-for-profit institutions including to recipients under an MTA for research purpose. In transferring materials to for-profit organization, the MTA for such entities must include language referring to the rights of DuPont in the inventions, and directing such for-profit recipients to take a license from DuPont. The terms of this MOU agreement were also made available to PHS-funded nonprofit institutions for use in their own agreements with DuPont.

The second MOU, signed in July 1, 1999, relates to patented transgenic nonhuman mammals and cells derived from them containing a recombinant activated oncogene sequence that have usefulness in basic research conducted or funded by NIH as well as utility for commercial applications.[19] The technology developed and patented by Harvard under a sponsored research agreement from DuPont was licensed exclusively by Harvard to DuPont. Under the MOU the NIH is granted the rights to use the Harvard intellectual property to make materials in its internal research.

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Furthermore NIH secured the rights to further transfer such materials under MTA to other non-for-profit research organizations for research purposes. A similar transfer to for-profit entities is also allowed according to the MOU, but the MTA for such entities must include language referring to the rights of DuPont in the inventions and directing such for-profit recipients to take a license from DuPont. The terms of this MOU agreement are also available to PHS-funded nonprofit institutions for use in their own agreements with DuPont.

The relevant biomedical patent rights for the cre-lox (and some but not all of the rights for the transgenic oncomouse patents) have now expired. The NIH strongly prefers that a company not require researchers at nonprofit institutions to take licenses to its patents, but when a company does so, these two MOUs remain useful examples of how the NIH research tool policy can assist researchers that need to utilize new technology with rapidly changing commercial applications.

Stem Cells

In 2001, PHS entered into an MOU,[20] later amended and re-stated in 2008, with WiCell Research Institute Inc. (WiCell), a Wisconsin-based company and an affiliate of Wisconsin Alumni Research Foundation (WARF), with ownership rights in primate embryonic stem-cell line materials developed at the University of Wisconsin. By virtue of funding some nonhuman primate studies conducted at the University of Wisconsin, the U.S. government obtained a Bayh-Dole license under intellectual property owned by WARF. Through the MOU agreement WiCell agreed to make the WARF intellectual property available to PHS-funded research programs for conducting biomedical research, including when materials from third parties were involved. These third-party suppliers were granted a limited, revocable research license for noncommercial research or teaching purposes only when providing materials to PHS research programs.

Additionally, the MOU provided a means for stem-cell line materials to be provided by WiCell to PHS for noncommercial research. The later amendment to the MOU also permitted the use of the transferred materials by PHS in research conducted with companies under the terms of CRADAs as well as the ability to transfer derivatives to third parties.

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The terms of these MOU agreements were also made available to PHS-funded nonprofit institutions for their own agreements with WiCell.

The NIH thus also strongly prefers that nonprofit institutions do not require researchers at other nonprofit institutions take licenses to their patents but when they do, this MOU also remains a useful example of how the NIH research tool policy can assist researchers that need to utilize new technology with rapidly changing commercial applications.

The Research Tool Web (a Guide to Pricing Research Tools)

To assist research institutions without much experience in valuing and licensing research tools to industry, the NIH OTT provided data to Pfizer Japan to establish a free online searchable database called "Research Tool Web" (http://www.research-tool.info/english/index.html) that contains the financial terms for more than 15 years of research tool licensing transactions completed by the NIH for its research tools. Although the company names are not included for confidentiality reasons, the tool along with key financial terms is included in the database. Research tool license agreements for both research tool resellers and research tool internal users are included. The transaction database can be searched for a specific individual tool or entire tool categories, such as animal models or antibodies.

While it is certainly possible to develop pricing models for research tools like the licensing of other inventions—most institutions find comparables to be the most convenient for research tools since transaction prices tend to be moderate based often on make-vs.-buy transactions by the company that is looking to obtain quick use of the tool itself from the research institution and not access to any patent rights. Thus comparable valuations are easy to come up with at large research institutions with a significant track record in research tool licensing. But what if your institution is small or doesn't have much experience to date in research tool licensing?

Thus the establishment of the Research Tool Web database is an effort to better facilitate the licensing of research tools to companies by providing benchmark valuations of research tools that institutions are seeking to distribute. By collecting historical data from

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institutions such as NIH that have a high annual transactional volume for research tools it should be possible to price a new tool transaction in a range that is reasonable and customary. This database can be used by both research tool buyers as well as research tool sellers to help facilitate and accelerate transactions that will bring these tools into rapid use in commercial development programs.

Pfizer's future plans for this database include adding additional languages other than English and Japanese as well as additional transactional terms from both the NIH and other institutions.

Conclusion

This chapter is an attempt to provide the research community with practical advice and guidelines regarding best practices related to the dissemination of research tools. It is critical that researchers select strategies that will balance between the motivation to commercialize research for the benefit of public health on one hand and the need to disseminate research resources to the general public as broadly and quickly a possible so as to encourage further research and discoveries. The chapter provides examples of strategies used at the NIH in its intramural technology transfer activities as well as in its extramural funding activities.

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Notes

1. For more details on these principles, see *Federal Register,* Vol. 64, No. 246, December 23, 1999, page 72091 (accessible at http://www.ott.nih.gov/pdfs/64FR72090.pdf).
2. The full text of these documents can be found at http://frwebgate3.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=00664624263+1+1+0&WAISaction=retrieve and http://grants.nih.gov/grants/guide/notice-files/not94-213.html, respectively.
3. The UBMTA model agreement and implementing letter can be found on the AUTM Web site (http://www.autm.net).
4. See http://www.ott.nih.gov/pdfs/slaform.pdf .

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5. The NIH is also a signatory to the UBMTA. See http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.aspx.
6. See http://www.ott.nih.gov/docs/MTA-TO_NIH_Model_Agreement.doc.
7. See *Federal Register,* Vol. 64, No. 246, December 23, 1999, page 72094 (accessible at http://www.ott.nih.gov/pdfs/64FR72090.pdf).
8. See *Federal Register,* Vol. 64, No. 246, December 23, 1999, page 72095 (accessible at http://www.ott.nih.gov/pdfs/64FR72090.pdf).
9. Ibid.
10. See http://www.ott.nih.gov/docs/Model%20NIH%20Materials%20Cooperative%20Research%20and%20Development%20Agreement.doc.
11. For additional information regarding the NIH patent policy, see http://www.ott.nih.gov/policy/phspat_policy.aspx.
12. For additional information about the NIH licensing policy, see http://www.ott.nih.gov/policy/phslic_policy.aspx.
13. This example can be found in the PHS exclusive patent license agreement (http://www.ott.nih.gov/pdfs/PHS-Patent-License-Exclusive-model-102005.pdf) as well as other model agreements.
14. This example can be found in the PHS biological materials license agreement (http://www.ott.nih.gov/pdfs/PHS-Biological-Materials-Agreement-License-model-102005.pdf) as well as other model agreements.
15. This example can be found in the PHS biological materials internal use license agreement (http://www.ott.nih.gov/pdfs/PHS-Biological-Materials-Agreement-License-Internal-Use-model-102005.pdf) as well as other model agreements.
16. See http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.aspx.
17. For further information see http://www.ott.nih.gov/policy/lic_gen.aspx.
18. http://www.ott.nih.gov/policy/cre-lox.pdf.
19. http://www.ott.nih.gov/policy/OncoMouse.pdf.
20. http://ott.od.nih.gov/pdfs/WiCellMOUhuman.pdf and http://stemcells.nih.gov/staticresources/research/registry/MTAs/Wicell_MOU.pdf.

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Performing a License Agreement Royalty Audit: A CPA's Perspective

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Introduction

The limited lives of legal and regulatory protections act to diminish the value of your intellectual property (IP) over time. Every year a valuable technology sits idle, a portion of that value goes unrealized, never to be recovered. Conceptually, licenses offer the IP owner the ability to stop the bleeding and earn a return on properties that may represent the culmination of years of expense and effort. It is, however, the truly unique nature of the financial relationship created by the typical license agreement that creates an environment ripe to become a distraction or management nightmare. In almost no other financial transaction do obligees (i.e., licensees) have such unbridled control over defining both the magnitude of their obligations and their counterparties' ability to verify those assertions. The royalty audit serves as an essential tool available to licensors in balancing the relationship; and ultimately, making the license much more effective in capturing value for the IP owner.

Defining the Royalty Audit

A royalty audit is an analysis or investigation of a licensee's compliance with the various obligations, financial and otherwise, laid out in a binding contract, namely the license agreement. Financial compliance is generally determined through an examination of the accounting books and records of the licensee and its sublicensees. As such, experienced accountants, including certified public accountants (CPAs), typically possess the skills appropriate to the basic royalty audit functions.

However, because of the legal disputes or litigation that potentially could arise from the royalty audit findings, forensic accountants,[1] who have skills tailored to detecting fraud or

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misrepresentation, often are best-suited to conducting royalty audits and communicating findings in a potentially contentious environment.

Many issues associated with a royalty audit may require supplemental expertise or experience, in addition to the core accounting or financial skills. For example, a technical expert's understanding of a licensed technology may assist in determining whether a licensee's new product embodies the licensed IP or not. Legal training and a knowledge of case law may assist in interpreting ambiguous language in the license agreement.

Finally, someone experienced in the industry of the IP's application may know whether sales of covered products were made to parties that are related to the licensee, and thus, may not reflect arms-length pricing of the covered products. Because these areas of expertise are not as broadly utilized as accounting or financial expertise, it is generally easier to supplement, as necessary, the core royalty audit team of experienced accountants with members of the technology transfer team (e.g., licensing manager, inventor, IP counsel), who probably represent the best and most cost-effective resource for these other skills.

One important disclaimer concerning what a royalty audit is *not*: Within the accounting world, an *audit* is a technical term used to describe an engagement implementing generally accepted auditing standards to express an opinion as to whether financial statements are prepared in conformity with generally accepted accounting principles. This differs from the use of the word *audit* in the licensing industry, where it is a term of art that does not necessarily imply the use of very specific procedures and standards promulgated by a governing body.

If you engage third-party accountants to perform a royalty audit, it should not be surprising to experience the accountants' reluctance to characterize their work as a royalty audit. Instead, such accounting practitioners might refer to their work as a *contract compliance investigation.*

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Justifying the Royalty Audit

The benefit of performing a royalty audit is often reduced to the potential near-term recovery of underreported royalties. However, other advantages can be just as important to a licensor that manages multiple, active license agreements. The range of benefits offered by a royalty audit can include the following.

- *Royalty underpayment recoveries:* The near-term financial benefit of potentially recovering royalties from underreported royalty sales is often a prime motivating factor for initiating a royalty audit. Anecdotal and small-study evidence indicates that it isn't uncommon for recoveries to be on the order of five to twenty times the cost of conducting the audit itself. For an organization reluctant to authorize the resources necessary for an audit, this argument can be persuasive. In addition to the very obvious benefit of receiving a check for underreported historic sales, another more latent benefit is that audited licensees may change their royalty reporting behavior in future periods.

- *Signaling value to licensees:* The signal provided by carrying out audits is a powerful incentive for all of an organization's licensees to engage in desired behavior. First, as auditing increases the probability of catching an intentionally misreporting licensee, there is a greater probability licensees will choose to honestly report their sales of licensed product when a licensor is known to actively engage in auditing its licensees. Second, an audit will typically entail examining multiple years of documentation. Faced with the prospect of having to produce this amount of documentation in support of their royalty payments, licensees will be more likely to put policies and procedures in place that will allow them to generate, organize, and retain documentation necessary to support their claimed royalty sales.

- *Grounds for license amendment or termination:* Given the typical long-term nature of license agreements, economic and other conditions can change dramatically from when agreements were negotiated. Termination provisions in the license agreement can be useful in allowing the licensor to adjust to and take advantage of these new conditions. A royalty audit can develop the evidentiary basis necessary for the appropriate exercise of termination rights. Alternatively, substantial examples of a licensee's noncompliance will improve the licensor's ability to negotiate favorable amendments to the original agreement.

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- *Identifying unauthorized or damaging use of property:* Use of the licensed property in unauthorized applications, countries, or products, or by unauthorized sublicensees, could come at a significant risk or cost to the licensor. In addition to royalties payable for the likely unreported sales, the context of those sales may be made at great legal or reputational risk. The sales made by a licensee in a territory for which it is not licensed may impinge on another licensee with rights to sell in that territory. An unapproved sublicensee may incorporate licensed trademarks in marketing products with which the licensor, for reputational or political reasons, does not want to become associated (i.e., a university name and mascot in the marketing of liquor). While all licensing will entail risks, the unregulated use of the licensed property is risk that cannot be planned for or weighed.

- *Reputational benefits to the technology transfer office (TTO):* Parties that rely on or coordinate with the TTO may perceive a greater benefit to working with the office. University administrators may be more likely to recognize the commercial diligence and professionalism the TTO exercises in ensuring compliance by licensees and attempting to maximize the university's financial return. Inventors, who could have a direct financial interest in the outcome of the royalty audit, feel like they have an ally in protecting their discoveries and future royalty share.

Targeted Auditing

As part of a larger license audit program, decisions concerning which licensees to audit should reflect the consideration of many criteria. Some of the more common considerations follow, listed in order of the precision and immediacy offered by the rationale.

1. Whistleblower from the licensee's organization claims underreported royalties.
2. Analysis by licensor of licensee's product line suggests unreported licensed products.
3. Indications from other participants in the industry that the licensee has new, unreported products incorporating the licensed technology.
4. Past discord or a lack of communication in the relationship with the licensee.
5. Lax or deficient reporting practices by licensee in the past.
6. Licensee reported product volumes trending lower than the overall trend in a growing industry.
7. Evidence that an event or milestone triggering a payment has occurred.
8. Licensee's royalties comprise a significant portion of entire licensing program.

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9. A major accounting system change at the licensee's organization (often reflected in new or differently formatted royalty report support).
10. New licensees who may be developing their information collection and reporting processes.
11. Significant financial deterioration or distress experienced at the licensee organization.
12. Licensee was acquired by another organization.
13. Licensees with limited or no history of entering royalty-bearing license agreements.
14. Random selection.

The types of licensees designated for audit should be evaluated over time for any unnoticed or unintended trends. For example, if as part of a licensing program, a licensor has only selected licensees in its top quartile of royalty generators, the licensor may not be realizing the value of systemic messaging from the audit program because an entire pool of smaller licensees may believe they are not truly subject to potential audit; thus, their incentive to properly report is muted.

Theory Meets Practice: Considerations in Getting to Go

Practical considerations at the outset of the audit program are several and can act to not only limit the ultimate success of the program, but also prevent the program from starting at all. While not a major part of the work, these nuanced, more politically oriented challenges are nevertheless important.

The anticipated cost will likely always be cited as one of the most common repudiations for conducting an audit. Especially in situations where the historic realization of royalties from an intended target is not that large relative to the cost of the audit, not following through on an audit program can be more easily rationalized. For those in an administrative or leadership capacity at a university, who are not typically faced day to day with the commercial nuances of running a technology licensing program, a greater understanding of the economic incentives in licensing and the strategic benefits of the audit will be helpful.

Further, the very reason a target's royalty payments may be relatively (or unexpectedly) small is that there is underreporting of royalties. A valuable perspective to offer is that, unlike financial statement auditing, which even when performed well is purely a cost of complying with regulatory authority, royalty auditing performed well is responsible for generating additional revenue and is not a cost center activity.

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University administrative procedures and politics should be closely managed through the process of receiving approval and funding for the audit. It is quite common that the cost of a royalty audit engagement will exceed typical purchase approval limits of a technology transfer office and force the audit into a formalized purchasing and/or competitive bidding process. Given this, the involvement of the university contracting/purchasing department will likely be necessary.

In addition, approvals from administrators that may be further removed from the business and day-to-day operation of the TTO might be required. Given this remoteness, additional efforts to educate the appropriate personnel to the benefits of the royalty audit may be necessary. Also, if competitive bidding is necessary, timing expectations for the start of the audit should obviously be dialed back.

Finally, once the royalty audit has received the go ahead, a simple notification to the targeted licensee that a royalty auditing process will soon be initiated would likely be a welcomed consideration. Aside from laying the groundwork for a more cooperative audit process, it furthers the good will between the parties for after the conclusion of the audit when the parties will most likely still be involved in a continuing financial relationship. Only in situations where you have reason to believe forewarning would affect the audit, such as where a whistleblower has informed you of a pattern of document destruction or falsification at the licensee, would you likely withhold this consideration. In most cases, isolated instances of missing or corrupted documents will not prevent the true financial details from being identified by a meticulous and skilled auditor.

Audit Process

The audit process can be characterized with a two-word mnemonic, LOST TRACK. This memory device captures the steps for both the planning and execution phases of the audit.

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The components of the LOST TRACK audit process are:

PLANNING PHASE	**L**icense	Develop thorough knowledge of agreement and licensor's interpretations.
	Opposing side	Understand counterparty's positions, disagreements, and historic performance under the license.
	Systems and accounting	Familiarize with licensee's accounting methods, processes, and documentation.
	Timing and documents	Develop and communicate intended timing and documentation requirements of the licensee.
EXECUTION PHASE	**T**est	Test licensee's books and records for agreement with royalty reports.
	Recalculate	Recalculate royalties due based on licensor's understanding of license and auditors testing.
	Analyze	Analyze and attribute source of differences between royalties paid and royalties due.
	Communicate	Communicate to licensor, and possibly licensee, findings.
	Keep pursuing	Keep pursuing recoveries and needed changes to reporting process.

Because the license agreement provides the framework around which all reporting, documentation, and even the parties' relationship is formed, it is necessary to understand the license thoroughly. For defined terms in the agreement or specialized terminology, the auditor should seek out the input of appropriate parties, including the inventor, licensor, drafting attorney, or outside counsel. Also, it is important to understand the licensor's specific interpretations of ambiguous portions of the agreement.

Similarly, the opposing party's viewpoint is informative for designing the audit. Different interpretations, areas of historic dispute, and the licensee's general approach to the license commitment will highlight areas that may require additional procedures or study. Although direct discussion of these considerations with the licensee is potentially most informative, analysis of the royalty reporting documents that have been submitted historically will also provide clues to the licensee's position on the license.

The financial accounting systems, processes, and procedures that the licensee has in place to fulfill its royalty reporting obligations will also determine what will be available for the auditor's review and testing. Understanding these factors will provide shape and real-world meaning to the phrase books and records, as often used in license agreements to describe what must be made available to an auditor.

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There is a definite benefit to specifying, as part of license negotiations, what types of documentation will be available for audit purposes. Following is a list of commonly used, but by no means exhaustive, documents:

- invoices
- general ledgers
- sales registers and sales analysis reports
- audited financial statements and/or income tax returns
- inventory roll-forwards
- sales tax returns
- shipping documents
- price lists, catalogs, and brochures
- purchase records

Based on the completion of the previous steps, the auditor should be able to flush out a preliminary work plan. With this plan, the auditor will be able to provide thorough document requests to the licensee and an indication of how much time may be required on site at the licensee's location. Providing these to the licensee ahead of arrival should smooth the process of executing the work plan and create more ease in the mind of the licensee, who likely will be more cooperative if there is definition as to his or her commitment during the audit.

With planning complete, the execution of the audit begins with testing of the accounting records. Depending on the volume of transactions and the risk associated with the particular item being examined, the testing could be performed on a sample or complete review basis. There are many procedures that could be performed in validating the assertions the licensee has made in its royalty reporting; however, some common procedures include:

- reconciling units in royalty reports to inventory roll-forward
- agreeing unit sales in inventory roll-forward to sales recorded in general ledger/ sales register
- tracing selection of units by order/customer/period (depending on reporting detail) to customer invoices and/or shipping documents
- testing for variance between suggested price lists to average prices derived from royalty reports and a selection of customer invoices
- verifying accuracy of exchange rates used in converting any foreign currency denominated sales

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- identifying and developing support for allocations and estimates used for adjustments made to gross sales to arrive at net sales royalty base

Ultimately, the royalties due for the investigational periods should be recalculated. The recalculation is premised on the findings of the testing performed and the appropriate interpretation of the obligations outlined in the license agreement (e.g., unit minimums, royalty floors, tiering of royalty rates, success/milestone payments, etc.). This calculation essentially establishes the bar for financial noncompliance.

Variances between actual royalties paid and those calculated as appropriate should be analyzed and attributed to specific causes, where possible. By aggregating the variances for each cause across all of the investigational periods, the most significant themes can be identified and best addressed with the licensee.

Generally, the findings of a royalty audit are communicated in a written report. As part of this, one common procedure is to allow the licensee to review a draft of the report and include as an exhibit any written rebuttal or explanatory information the licensee desires to provide as part of a final report. This will assist in further defining the nature and extent of the differences between the parties to the license agreement. Additionally, it provides the licensee the opportunity to research the issues in a reasoned and diligent manner, as opposed to a reactionary and defensive manner. In situations where deficient royalty reporting is not intentional, this provides an opportunity to avoid a prolonged dispute in recoupment of deficient payments.

Finally, the pursuit of all deficiencies, financial, reporting, interpretive, and otherwise, is the vital final step in the royalty audit. To preserve and ingrain the benefits of the royalty audit, identified issues need to be brought to a conclusion. An identified problem, known to both parties to the license, which remains unaddressed, will provide a strong signal to the licensee that the licensor is unwilling to disturb the relationship. This simply invites further aggressive interpretations of the license by the licensee. Deficient royalty payments are most comfortably pursued, as they represent tangible value, but they are also most likely to lead to a courtroom setting.

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Audit Design

As part of periodic royalty reporting called for in the typical license agreement, some level of documentation will almost always be required in support of the royalty paid. This may be only an exhibit depicting the final computation of the royalty due or it could be a schedule detailing every invoice issued by product line along with the source documents. Whichever end of the reporting requirements spectrum, the royalty audit will go substantially beyond the reporting requirements in providing comfort to the licensor regarding the level of licensee compliance with the terms of the license agreement. Following are some of the considerations in designing an audit to achieve that comfort.

Guiding Objectives

The audit is designed to achieve two primary objectives: completeness and accuracy. Completeness describes the extent to which the licensee has designated all licensed product sales appropriately for royalty payment, identified those sales to the licensor, and made payment on those obligations. To characterize the completeness of reported licensed sales the auditor will need to gain an understanding of the sales of the licensee more broadly. This would likely entail collecting detailed information on sales that ultimately do not reflect the use of the licensed property.

Because the licensee will often consider this information proprietary and will probably be reluctant to share information it does not consider directly relevant to the licensed property with the licensor, the benefit of using an independent third-party to perform the audit becomes more apparent. Without a direct stake in the outcome of the royalty audit, the third-party auditor may be able to elicit more timely and cooperative assistance from the auditee.

Further, looking beyond the audit, the auditor's involvement potentially provides lasting benefits to the auditee. The auditor's role as a buffer between the involved parties may serve to limit any collateral damage to the ongoing relationship between the licensor and licensee. Finally, the auditor's collection and maintenance of the auditee's documents outside of the licensor's control should serve to limit confidentiality or privacy concerns arising out of the applicability of open records laws to governmental entities and programs.

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Accuracy refers to the computational integrity of how the royalty payments were calculated. More than simply checking the math, this concept reflects considerations such as the use of the correct royalty rate, especially in tiered royalty structures; assessment of required late fees/interest where appropriate; inclusion of success/milestone payments; and consideration of minimum periodic royalties. While achieving certainty on completeness relies very heavily on specialized accounting/auditing skills and experience, many aspects of achieving confidence in accuracy are more accessible to the layman. However, there are likely aspects of legal interpretation that may come into play, as royalty tiers, due dates, and trigger events are given their meaning by contractual language or definitions.

Context Important to Planning

Rather than approaching an audit as a routinized endeavor, a consideration of the specific facts surrounding the targeted licensee will help create a plan that is more efficient in its approach and more exhaustive in its examination of possible areas of dispute. A plan that reflects historic and anticipated areas of disagreement should limit the need to make significant follow-on requests for documents or a return visit to the licensee, both of which can cause further disruption to the licensee's business and diminish the level of cooperation as the perceived intrusiveness of the audit increases. Following are examples of contextual concerns that can have significant influence on the design of the audit plan.

- *License agreement drafting:* The success the legal team had in drafting a license agreement that limited ambiguous terms and addressed with specificity real-world situations goes a long way in defining the scope of the audit. Where differing interpretations of the license's meaning arise, a royalty audit will often require additional documents and procedures to address both interpretations.

  For example, the adjustments to gross sales to arrive at the more common net sales royalty base could be interpreted differently. While returns expense may only be tracked at the corporate level, and thus, this expense may be appropriately allocated to individual product lines according to accounting convention, the license agreement may seem to require that adjustments to gross sales must only be expenses specifically identifiable to the licensed products. This situation may necessitate the need to not only test the allocation calculations of the licensee but also assess whether documentation may be required to make an alternative calculation that attempts to specifically identify returns of the relevant products.

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While many license terms are defined relatively easily and in an unambiguous manner (e.g., license period, unitary royalty rate, periodicity of royalty reporting), other terms lend themselves to different interpretations depending on the party. Some examples include:

- books and records (commonly used to describe the documents that must be made available by the licensee to the auditors)
- retention standards for licensee documents
- basis or criteria for tiered royalties
- identification and reporting of subsequent products that incorporate the licensed property
- procedures for reporting royalty audit results

- *Industry trends:* The nature of the industry in which the licensed property is used will affect the manner in which the royalty audit is conducted. An industry characterized by a high level of product innovation, the regular introduction of new models, and the use of consumer rebates would require an audit more extensive in its testing of product pricing, the treatment of obsolete/excess inventories, and identification of product models containing licensed property.

  Another aspect of the industry important to the audit would be the general trend of industry volumes and the competition in the product space. Expectations for licensed product volumes should be informed by the growth or decline of the area of application of the licensed property. New competitors or new products in a space may be expected to have an effect on the licensee's sales. As such, significant negative average sales price or volume trends may be understandable and not necessarily warrant additional procedures.

- *History of the licensing relationship:* The relationship between the licensor and licensee should provide some of the most salient insight into areas that may need special consideration in the audit design. Areas of disagreement, sensitivity, or reluctance to provide additional detail in the past all provide clues to the auditor for possible additional procedures. In instances where the licensee's sensitivity may be attributable to

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concerns about confidentiality, the independent orientation of an auditor may mitigate some of the concerns expressed in the past. Finally, it may also be the case that the parties have already come to an accommodation concerning the interpretation of aspects of the license agreement; in which case, the auditor should take care to reflect those as directed by the licensor.

The Aftermath

There are a number of small-sample or anecdote-based assessments that provide estimates of licensee noncompliance based on royalty audit experiences. Not surprisingly, because they tend to be drawn from such small and personalized populations, you can see a wide range of probabilities. What is generally agreed, it appears, is that a significant majority of audits find noncompliance by licensees. Perhaps more importantly, however, is the nature of the noncompliance. Upon a finding that a licensee has been willfully and intentionally understating its royalty liability, a licensor will need to reevaluate the licensing relationship and determine whether termination, agreement amendment, or more active enforcement is required. If the noncompliance rationale appears to be something less malicious, less dire options could be sufficient.

An entire continuum of noncompliance rationales exist, running from pure instances of fraud to simple administrative errors in aggregating data or performing calculations. Between these extremes are other examples that could be differently interpreted as lying closer to one extreme or the other. As stressed at the outset of this chapter, the overriding principle driving so many of the deficiencies or problems in the licensing arena is that the financial obligee has such a substantial amount of control over defining what happens. As a result, there is often a nefarious interpretation that could be made for many fact patterns.

For example, while a sales department may simply have overlooked communicating to royalties payable personnel the need to add a newly introduced product stock-keeping unit (SKU) to their sales report accounting system queries, a more willful interpretation is that the licensee believed the licensor was not monitoring SKU-level product offerings of their licensees. Often a specific interpretation cannot be confirmed from the documentary evidence and only a range of possibilities, based on the totality of the evidence and the licensor's experience with the licensee, can be gained.

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While an exhaustive list of findings is not possible, following are some of the more common identified reasons for noncompliance:

- fraud or reckless misinterpretations of contractual language
- sales or transfers to related parties that do not reflect full price to consumer or arms-length pricing
- unintentional misinterpretation of license agreement
- omission of new, updated, or changed products
- improper or nonrigorous application of foreign exchange currency conversions
- inappropriate or noncontractual deductions for calculation of net sales (e.g., marketing, commissions, research and development)
- application of rebates, discounts, or other sales incentives to licensed products in advantageous manner
- sale of products outside of geographic, industry, customer, or other constrained authorization areas per the license
- unauthorized and/or deficiently reported sublicensing
- inappropriate attribution of value on bundled product sales
- missing or complete noncapture of required documentation to support royalty reports
- minimums or milestone/success fees not being reflected
- inappropriate withholding of taxes, especially for foreign tax liabilities

Whatever the particular findings from the royalty audit, pursuing the results to a conclusion is vital. Auditing is a backward-looking process, and without action, deficiencies will only continue, if not multiply, in the future.

Addressing deficiencies with the licensee could very well be a more difficult discussion than the original negotiations surrounding the formation of the license. Involving legal counsel, whether internal or external, is important as the context of disputed findings could eventually make it to a courtroom setting. Further, recognizing the financial implications of addressing the findings will help the licensor negotiate more effectively and strategically.

For example, the licensor proving flexible on the payment of a one-time success fee that the licensee argues may only be triggered a year from now, instead of a royalty audit determination that it is currently due, may be beneficial in getting a concession on the

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royalty rate applicable to a particular product. The net effect would be gaining an entirely new revenue stream (the incremental royalty on the particular product) for the concession of a simple timing difference—the cost of having to wait for the payment of the success fee—likely a beneficial trade.

Conclusion

Royalty audits are a valuable tool to the licensor in ensuring that what was bargained for is what is received. Fundamentally an exercise in specialized auditing techniques, the successful royalty audit also typically draws on very differentiated skill sets, including legal, technological, negotiation, and interpersonal. Executed in a professionally disciplined, skeptical, and planned manner, this tool affords the licensor the opportunity to level a playing field over which the licensee has an inordinate amount of control.

Notes

1. Whereas a common credential for an *accountant* or *auditor*, as those terms are commonly used, may be a certified public accountant, forensic accountants will often additionally maintain specialized credentials, such as the certified fraud examiner or certified in financial forensics designations.

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Documents for Spin-Outs and New Ventures

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Introduction

The terms *spin out* and *new venture* are not well-defined and mean a range of things to a number of people. Fundamentally, both terms refer to a company that has licensed technology from a university or research institution in a transaction in which the university or research institution has received equity ownership in the licensee. Some institutions have organized affiliated entities with funds and expertise in organizing and managing new ventures. For simplicity, throughout this chapter, the university, research institution, or affiliate will be referred to simply as the *institution*.

The role of the institution in the new venture can vary greatly. At one extreme, the institution may simply be reacting to a proposal from an existing company or from an entrepreneur desiring to establish a company and utilize the institution's technology, with the institution negotiating some equity ownership as part of the license. At the other extreme, the institution may identify the technology, recruit the initial management, invest the initial capital from a fund available to the institution for this purpose, and actively seek venture or angel funding from sources cultivated by the institution.

Of course, the involvement by the institution can fall anywhere in between these two extremes. Although the institution's role falls along a continuum, for simplicity, this chapter will refer to three situations: (i) institution-organized new ventures, (ii) entrepreneur-organized new ventures, and (iii) early-stage new ventures. Early-stage new ventures are companies with some operating history that plan to refocus their business plan utilizing the institution's technology. These are not really separate categories as much as they are reference points along the continuum of institution involvement in the new venture.

The form documents provided in the Annex to this chapter are prepared for entrepreneur-organized transactions. The institution generally takes a minor or no role in the manage-

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ment or operation of these types of new ventures beyond assistance with further development of the technology. An effort has been made to point out provisions that should be modified in institution-organized transactions in which the institution would be more involved and would control the documentation of the new venture, however, the target reader for this chapter and these form documents is the technology manager experienced with commercialization but not as experienced with taking equity in a licensee and who wants to more closely analyze the issues relating to receiving equity in a new venture.

Because early-stage companies usually have some history of operation, most of the documents in this chapter typically already exist in this situation. The institution usually would not be in a position to propose documents other than the license and possibly the registration rights agreement. Nonetheless, the issues in this chapter will still be relevant to an institution involved in an early-stage transaction.

First Principles

In setting up a program for commercializing technology through new ventures, the institution must first address a number of institution-specific issues. The form documents in this chapter are neutral with respect to many of these issues. It is incumbent upon the institution to consider the form documents within the context of these issues.

Legal Counsel

The new venture is a separate entity and will ultimately need its own legal counsel, different from the institution's counsel, the investors' counsel, and even the entrepreneur's personal counsel. In the institution-organized new venture, it may be appropriate, with appropriate disclosures, to have the institution's legal counsel do the initial legal work to organize the new venture and prepare many of the documents set forth in this chapter, as long as all parties are clear that legal counsel is preparing the documents in his or her capacity as the institution's counsel. Economically, it does not make sense to engage separate counsel to organize the new venture if the institution owns a majority interest in the new venture. Similarly, in the entrepreneur-organized new venture it may be appropriate for the entrepreneur's legal counsel to prepare the various documents, as long as it is clear whom counsel represents.

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State and Federal Law

Needless to say, no institution wants to violate state or federal law. Nor does an institution want to violate its own charter. Accounting for the equity, determining whether the inventors and other institution employees are allowed to receive a portion of the institution's equity, and determining how the inventors and other institution employees are compensated in connection with new ventures are all difficult issues of both law and policy involving state and federal law, analysis concerning the institution's tax-exempt status, if applicable, and other considerations. This chapter is not intended to address any of these issues. The institution must start with these fundamentals, modify the form documents accordingly, and annotate its own set of forms to make sure that provisions required by law are identified as non-negotiable.

Institution Policy

As part of the legal analysis, and overlapping with it, the institution must make sure that the process created with respect to new ventures complies with the institution's policy and conforms to the expectations of the various stakeholders of the institution. Not only is it necessary to make sure that policies are followed, but the success of the institution's program to create new ventures will depend, in part, on whether the stakeholders understand and support the policy.

Why Take Equity?

Although valid questions, it is helpful to stand the questions "Why take equity?" and "How much equity should the institution take?" on their heads. Since Bayh-Dole gives ownership of the technology to the institution, you could start from the perspective that the institution owns 100 percent of the technology (the equity, if you will), and why should the institution give any up? Of course, there are many important reasons to give up equity: to get funding, to attract management, to compensate entrepreneurs for market and technological analysis, etc. The institution's percentage ownership depends, in part, on how many of these key components are already in place at the time that the institution's percentage ownership is being determined.

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In other words, the institution gives up a portion of its 100 percent interest in exchange for these other components. Ultimately, it should be the goal of the institution to commercialize the technology developed in its research laboratories, because the implied purpose for funding research is that it will benefit the community at large. Research that attracts interest and can be licensed to a well-established and well-funded company is easy. Research that is equally important, but takes more effort to commercialize, requires putting a company around the technology, and the institution should organize the company in a way that does not give away the institution's ownership of the technology without appropriate compensation to the institution. Retaining equity is part of that compensation.

Institution's Role in Management

For institutions that have not developed expertise in managing startup companies, management of a new venture can be a high-risk proposition. Coupled with the operational risk is the political risk of having a new venture fail and having the media blame the institution for that failure. New businesses involve high risk and often fail, but the general public may not understand such failure when an institution and its funds are involved. For the most part, the documents in this chapter are drafted based upon the proposition that the institution will remain aloof from management. Institutions with more experience that have created an infrastructure with business and entrepreneurial expertise will want to modify these documents to strengthen the institution's role.

Institution's Role in Financing

Other chapters of the *AUTM Technology Transfer Practice Manual* deal with strategies to provide financing to new ventures through entities affiliated with the institution. (For more on this topic, see "Funding for University Startups," by David Lerner, and "Venture Funding for the University Startup," by India Vincent, Howard Walthall, and April McKenzie, in Volume 4 of the 3rd Edition of the *Association of University Technology Managers Technology Transfer Manual.*) Technology of clear value to an existing company or to a venture investor will not need significant monetary support from the institution, but most technology does not fall into these two categories. The institution will be more successful in creating new ventures if it has a source of funding. The bridge loan note and the stock purchase warrant are to be used by an institution or its affiliate that puts capital into the new venture prior to angel or venture capital funding. These documents are patterned

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after the type of documents that would be required by an angel or venture capital sources that advances funds prior to and in anticipation of the closing of the initial round of funding.

Liquidity Event

The most common failure of an institution inexperienced in the creation of new ventures is to retain equity in a new venture without providing in the new venture's documents adequate means for selling that equity for cash. Investors call this a liquidity event. The institution should have an opportunity to participate in any liquidity event in which either the founders or the investors participate, including the initial public offering of the company, if one should occur. Without contractual provisions in the institution's documents, the institution does not have a right to sell its equity when the new venture goes public, and it doesn't have a right to participate in the sale by the other equity owners. This could result in the founders and the investors selling their equity in the new venture and leaving the institution as a minority owner going forward. For that reason, the documents in this chapter include piggyback registration rights, tag-along rights, and strengthened Rule 144 provisions. Sophisticated investors are usually reluctant to grant the institution these rights, because they want to retain for themselves maximum flexibility, however, they will usually accept these rights in light of the institution's limited role in the management of the new venture.

Inter-Institutional Agreements

An institution that collaborates with other institutions will often find itself in the position of licensing technology in which more than one institution has been involved. The inter-institutional agreement between the institutions should address the relative ownership of any equity to be retained by the institutions in the event of a new venture transaction. More importantly, it is imperative that the inter-institutional agreement designates one of the institutions to have sole authority to negotiate the various new venture documents. It is hard enough to obtain authorization within one institution for the various documents involved in a new venture, and involving the decision process of more than one institution can paralyze the effort to move quickly in the commercialization of technology.

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Institution's Role in New Venture

For an institution to prepare form documents for its new venture transactions, it is important for the institution to determine what its policies are with respect to the various roles that it can play in the life of the new venture. Below are the most likely sources of funding for a new venture.

Funding

All new ventures face the valley of death between the basic research that has been done in the institution and the goal of a commercialized product. This valley of death is littered with companies that have not had the funding to make the journey from proven invention to sellable product. An institution's ability to provide or obtain funding for its new ventures is one of the keys to the institution's success with creating viable new ventures. Of course, there are numerous sources from which to obtain grants and other funds that do not entail giving up equity in the new venture. These sources should always be front of mind in searching for funds, however, they are not the focus of this chapter. Below is a discussion of the primary sources of funds that entail the issuance of equity and the dilution of the institution's interest in the new venture.

Institution Sources

It is not the purpose of this chapter to deal with strategies for an institution to provide capital for its new ventures. Most institutions either have no capital available for funding or have a very small amount of capital for a new venture's initial funding. If there is no initial funding available, then ignore the first two form documents in the Annex to this chapter. If there is initial funding available, then the institution is in a position analogous to that of an angel or venture investor that is willing to provide capital prior to the closing of the first round of funding. The bridge loan note and the stock purchase warrant in the Annex to this chapter are drafted for the situation in which the institution is providing at least some initial capital.

Angel Investors

An angel investor is a wealthy entrepreneur who is willing to risk capital in startup companies, usually because of experience with or interest in the technology being commercialized by the startup. Angel investors are an excellent source of initial capital because their requirements for a return on their investment are usually less than the requirements of

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an institution such as a venture capital firm. Also, an angel investor is often more willing to risk his or her capital because of a desire to solve the social problem addressed by the technology (e.g., a cure for a specific disease or a new form of alternative energy).

Strategic Partners

Strategic partners are also a good source of funding. Although they may have a more institutional approach to the investment than an angel investor, they also may have strategic reasons for the investment that serve as a basis for making a financial deal more favorable to the institution and the new venture (i.e., the return on investment is not the sole reason for the investment).

Venture Capital

This source of capital gets the most attention, and it is often the most successful with respect to a specific investment, however, a venture capital firm's high target for return on investment and its rigorous analysis of the risks involved in a new venture cause the venture capital firm to eliminate the vast majority of new ventures proposed by institutions. Venture capital firms also want exclusive control to manage and seek liquidity for the venture capital firm and usually seek to eliminate even the few rights that the institution seeks with respect to the new venture. As a result, negotiations with a venture capital firm can be very difficult. The institution should jump at the chance of having a venture capital investment in one of its new ventures, however, it should not focus its capital-raising efforts on venture capital firms to the detriment of finding the right angel investor or strategic partner. (For an indepth discussion of how an institution should approach and attract venture capital funding, see "Venture Funding for the University Startup" by India Vincent, Howard Walthall, and April McKenzie in Volume 4 of the 3rd Edition of the *Association, of University Technology Managers Technology Transfer Practice Manual.*)

Equity Participation

In general, in addition to receiving equity in exchange for providing capital to the new venture, participants in a new venture can receive equity for four different roles in the early stages of the new venture.

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Founder's Equity

The initial incorporators of the new venture usually purchase the initial shares issued by the new venture in exchange for a nominal amount of cash or services equal to the par value of the new venture's stock. These are usually referred to as founder's shares, although they are legally no different than any other equity sold to investors by the new venture. In the institution-organized new venture, the institution will receive founder's shares. In the entrepreneur-organized new venture, however, the entrepreneur will receive the founders' shares and the institution's equity will be issued pursuant to the license.

License Equity

Unless the institution is organizing the new venture or providing initial funding, its primary source of equity in the new venture is through the license. Generally, the license should call for issuance of common stock to the institution as partial consideration for the license. There should not be a requirement for the institution to pay any cash for this stock, unless the specific arrangement with respect to the specific new venture calls for support from the institution in the startup costs of the new venture. (For a discussion of the policy considerations concerning an institution accepting equity as consideration pursuant to a license, see "Distribution of Equity as Licensing Income," in "Policies and Procedures for Distribution of Licensing Income" by T. Allen Morris, PhD, MBA, CLP, in Volume 4 of the 3rd Edition of the *Association of University Technology Mangers Technology Transfer Practice Manual.*)

Management Equity

To the extent that the initial managers of the new venture are also the entrepreneurs, then most of the managers' equity in the new venture will come in the form of founders' shares, however, it is important that a portion of the new venture's equity be set aside for the management team. This management equity is generally in the form of shares reserved as part of an incentive compensation plan, so that the management team can earn its equity through its performance as managers.

Investor Equity

Generally, the bulk of the money needed to accomplish the first milestones in the new venture's business plan is raised from investors and is issued in the form of Series A preferred stock. The Series A preferred stock and related documents provide the investors

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with various rights and priorities over the founder's shares and the university's equity, both of which are generally in the form of common stock.

Management

In the institution-organized new venture, the institution will be responsible for recruiting management for the new venture. Some institutions have affiliated entities that provide management during the early stages of the new venture's life. Obviously, providing management significantly increases the institution's risks with respect to the new venture, risk that most institutions are not in a position to take. Most institutions, therefore, will rely upon an independent entrepreneur to provide initial management and recruit the management team for the new venture.

Board of Directors

The new venture's board of directors is responsible for supervising the management team and has certain fiduciary duties to the shareholders of the new venture. Most institutions do not want any of its employees (and indirectly the institution) to undertake these fiduciary duties or to be the target of inquiry in the event that the new venture fails. For that reason, the documents in this chapter call for the institution to have board observation rights with respect to the new venture. Under these provisions, the institution receives all documents provided by the new venture to its board of directors, and a representative of the institution is allowed to attend board meetings, however, the institution's representative does not have a vote in board matters and, therefore, does not undertake any of the obligations or risks of being a director.

Organizational Documents

The purpose of this section is to briefly describe the various documents involved in a new venture. Generally, legal counsel to the new venture will prepare these documents. Forms for these documents are not provided in this chapter. For institution-organized new ventures, the institution would need to prepare forms of these documents, but not in entrepreneur-organized new ventures.

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Choice of Entity

Although special circumstances may call for analysis of this issue, generally, in circumstances where outside investors are to be involved and the ultimate liquidity event is anticipated to be either an initial public offering or a sale of the new venture, investors will expect the new venture to be a corporation, taxed as a C-corp. for federal income tax purposes, and incorporated in either Delaware or the state in which the institution is located.

Certificate of Incorporation

The new venture's organizational document, filed in its state of incorporation, generally will not require any provisions at variance from the standard form used for incorporation of an entity expected to be sold or to eventually go public.

Bylaws

From the institution's standpoint, the new venture's bylaws do not require any special provisions either, except in an institution-organized new venture in which the institution intends to exercise more control over the new venture.

Organizational Minutes

The initial directors of the new venture named in the certificate of incorporation complete the formation of the new venture by having an organizational meeting (or signing a unanimous consent in lieu of meeting) at which they elect the officers, authorize issuance of the founders shares, and take other organizational action. From the institution's standpoint, the new venture's organizational minutes do not require any special provisions.

Subscription Agreement

Many attorneys advise that a new venture require that every shareholder, even the institution and the founders, sign a subscription agreement for the shares. Unless this document can be prepared for little or no additional cost, there is generally little benefit to either the new venture or the institution to require this document.

Shareholder Agreement

Many of the rights that the institution wants in connection with the new venture are best derived from an agreement with the other shareholders rather than through the certifi-

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cate of incorporation or bylaws. These rights include giving the institution an opportunity to participate in all liquidity events and making sure that the founding shareholders who have been issued founder's shares in connection with their various roles continue as shareholders. It is best to sign the shareholder agreement as soon as there is more than one shareholder. This will simplify negotiations with the Series A investor. Although the Series A investor may have its own forms of agreements that may not contain all of the provisions in the attached form, it will generally accept most of the provisions that are already in place and limit its negotiations to items that give it specific problems. The form of shareholder agreement in the Annex to this chapter is intended to be an even-handed document that gives the institution broad ability to participate in liquidity events without encroaching on the Series A investor's ability to manage the company in the manner that it sees fit.

Note two key provisions in the shareholder agreement. Section XV.B requires that all future recipients of equity in the new venture must sign the shareholder agreement as a condition to receiving the equity. In this way, the rights that the institution has negotiated with respect to the other shareholders, such as the tag-along rights discussed below, are not diluted by the addition of shareholders who are not subject to these rights. Also, in Section XV.A, no amendment affecting the institution's rights can be amended without the institution's agreement. These provisions will preserve the institution's right to participate in the liquidity events.

Tag-along rights (and registration rights if they are included in the shareholder agreement rather than being in a separate agreement) are so important to the institution that those rights should not be terminated by a majority of the shareholders. Just because the other shareholders share these rights does not mean that a majority of the other shareholders should be able to take away these rights from the institution. There may be instances in which a Series A investor may require changes to the shareholder agreement, and the institution should be reasonable in negotiating such changes in the interest of improving the success of the new venture, however, the institution should be very reticent to cede to the other shareholders the ability to negotiate or terminate the liquidity rights of the institution.

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Preferred Stock Designation of Rights

This is the document that sets forth the specific rights of the Series A investor. Since this is a document that is specific to each transaction and each Series A investor, there is no form for this document included in this chapter. For the most part, if the other documents in this chapter are in place, the institution should give the Series A investor broad latitude to structure the investment in a manner that meets market demands at the time.

Consulting Agreement

Often a key inventor of the technology will be expected to have a consulting agreement with the new venture. For the institution that intends to leave management of the new venture to the founders and the investors, it should have little input into this document. The institution will want to make sure that the inventor follows the institution's policies with respect to conflicts of interest, of course, and the institution should recommend to the inventor that he or she retain personal legal counsel. Also, if the institution's policies provide for sharing of the institution's equity interest with the inventor, then the institution will want to know how much equity, if any, the inventor will be receiving directly from the new venture, in order to appropriately gauge how much of the institution's equity should go to the inventor.

Patent License Agreement

Most of the legal terms in the institution's form patent license agreement will still apply in the situation where the technology is being licensed to a new venture. There are a number of key issues to address, however, both in the negotiation of the license and in the text of the license itself. The fundamental issue is that the new venture, by definition, is not a viable going concern in which the institution has unqualified confidence that the potential of the technology will be recognized. For that reason, care must be given to the terms of the license so that the technology doesn't become orphaned in a failed company for a significant period of time. This is true both with respect to an institution-organized new venture and with respect to an entrepreneur-organized new venture, because the investor needs to understand the circumstances under which the license could terminate. The third form document in the Annex to this chapter contains examples of these provisions.

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Option to License

One way to test the viability of a new venture and the ability of an entrepreneur to accomplish the promised commercialization of the technology is to begin by giving the new venture an option to license the technology only after a certain milestone is met, such as the raising of a minimal amount of initial capital. An option is appropriate in the instance where the entrepreneur does not have the money on hand to reimburse the institution for basic patent costs, and the institution does not want to spend the time or money to negotiate a license until the entrepreneur has attained certain milestones, which are listed in the option as conditions to the new venture's right to exercise the option. In this instance, since the entrepreneur is unlikely to be able to raise the initial capital without proof for the potential initial investors that the license is forthcoming, the new venture can be given an option that is exercisable once the new venture has raised the initial capital and met the other milestones.

Milestones

Once the new venture is formed and the license has been granted, financial and technical milestones should be included in the license to ensure that the technology is returned to the institution as soon as possible in the event that the new venture begins to fail in its business plan. These milestones are determined on a case-by-case basis, of course, but could include an outside date for a Series A funding round, an outside date for a Series B funding round, the accomplishment of certain test results or regulatory approvals for the product, etc. These milestones should not be punitive, because ultimately the institution wants the new venture to succeed, and the new venture should be given the flexibility to accomplish its business plan. On the other hand, if the technology continues to show promise, but the new venture has misfired either by not being able to raise sufficient capital or by pursuing a dead end with respect to product commercialization, the institution must be in a position to pull back the technology and reload, either with another new venture or with an established licensee.

Royalty

Generally, the institution's methods for determining an appropriate royalty should not change when equity is being received in a new venture. Although in certain situations it may be appropriate to lower the royalty in exchange for additional equity, in general, the

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institution is accepting equity not in exchange for a lower royalty, but because the new venture is a high-risk venture. The equity compensates the institution for licensing to an entity with insufficient capital or management, not as a substitute for royalty payments.

Equity Provisions

More sophisticated institutions may organize the new venture and be the founding shareholder, subsequently adding additional shareholders in exchange for management expertise or capital. More often, however, the new venture is entrepreneur-organized, and the institution is receiving its equity in exchange for the license. It is important that the license contain the equity provisions reflecting that the equity is being received by the institution as partial consideration for the license. In this way, in the case where a dispute arises with respect to the equity or the new venture breaches its obligations to provide certain rights to the institution, the institution can declare a breach of the license. In other words, this formulation of the transaction in effect creates a cross-default between the license and the institution's equity rights and more realistically reflects the intent of the institution in the transaction.

Liquidity

As stated above, the only reason for the institution to receive equity in a new venture is to eventually liquidate the equity in exchange for cash. The following provisions significantly impact the institution's ability to participate in a liquidity event, otherwise the institution risks continuing to own a minority interest in a new venture after the founders and the Series A investors have sold their interests for a significant return on investment.

Registration Rights

When a company registers its common stock in connection with an initial public offering, only the shares sold in the public offering are registered and freely tradable on an exchange. The institution's shares, if they are not sold in the offering, are still restricted shares and subject to limitations on the ability to be sold. This is also true of subsequent public offerings of common stock after the initial public offering, whether the registered shares are to be sold by the company or some of its shareholders.

Also, when there is a public offering of a company's shares, typically an investment banker is involved. The investment banker's job is to assist the company in valuing the stock, find-

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ing purchasers, and making a market in the stock after the offering. Usually the involvement of an investment banker will result in a higher sales price of the stock, especially if the institution has difficulty selling its shares in the open market because it owns a significant number of shares and there is a low number of daily purchasers of the shares in the market.

For these reasons, the institution should require that the new venture provide it with piggyback registration rights. In other words, the institution should have the right to piggy back the sale of some or all of its shares on the back of a sale by the company or other shareholders in a public offering. In the form documents in this chapter, the registration rights are provided for in the Registration Rights Agreement.

In addition to piggyback registration rights, the Series A investors may also negotiate for demand registration rights, giving them the right to demand registration even if the new venture was not planning a registration. Institutions generally do not need demand registration rights, both because the institution usually does not have the expertise to determine when the best time would be to force the new venture to engage in a public offering and because the Series A investors will negotiate vigorously against the institution having a right to trigger a public offering. It is sufficient, for purposes of giving liquidity to the institution, that the institution simply has the right to piggyback onto all public offerings, whether triggered by the new venture or by the Series A investors.

Rule 144

Rule 144 is the federal securities rule providing a mechanism for shareholders of a company that has already had its initial public offering to sell restricted stock to the public without registering the shares for a public offering. Although this rule can be a valuable mechanism for the institution to obtain liquidity, the Rule is limited both in the quantity of stock that can be sold at any one time and in when the right is available. In addition, since there may not be an investment banker making a market at a time when a public offering is not under way, sales under Rule 144 may be at lower prices than are available as part of a public offering. For these reasons, the institution should not allow the right to sell under Rule 144 to be a substitute for piggyback registration rights. The piggyback rights should continue even after Rule 144 sales are available.

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Tag-Along Rights

Section V of the Shareholder Agreement provides the right to shareholders to tag along in the sale by founders or in the sale of a certain percentage of the new venture's shares. This right is one that is often given to the Series A investors, but many institutions fail to consider negotiating for this right. This is one of the most important protections to the institution's right to participate in a liquidity event. If a substantial percentage of the ownership of the new venture is to be sold, then the institution should have the opportunity to participate. Usually this occurs because the Series A investors want to cut their losses and get as much money as possible for selling control of the new venture, in which event the institution could end up as a minority owner of a new venture controlled by a larger entity, often with little hope of ever getting any return from its equity.

Tag-along rights with respect to the founder usually serve a slightly different purpose. The founders are usually expected to serve a key role in the success of the new venture. Because they have paid little for their shares, a premature sale of their equity before the real potential of the technology has been realized could damage the prospects of realizing that potential. Usually, the founders and the institution are in the venture together, so the founders should not have a liquidity event unless the institution has an opportunity to participate.

Drag-Along Rights

Section IV of the Shareholder Agreement allows the owners of a significant percentage of the new venture to require the other shareholders to participate in the sale of the new venture. Although this provision leads to a liquidity event, strictly speaking, it limits the institution's flexibility, since it may put the decision to sell the new venture in the hands of other shareholders. Drag-along rights, however, are usually important to Series A investors, and the institution is often able to preserve its tag-along rights in negotiations with Series A investors by providing drag-along rights to the Series A investors. It is important, however, that the drag-along rights not be triggered by a sale to an affiliate of one of the shareholders, otherwise, this provision could be used to wash out the other shareholders prematurely before the real value of the new venture and the technology have been realized.

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Change-of-Control Provisions

Often a Series A investor will want certain of the institution's rights to terminate in the event of a change of control. These provisions should be resisted. Because the new venture begins with a small ownership base, many transactions can trigger a change of control, even the closing of the Series A financing. It is important that the change-of-control provisions not terminate important rights of the institution prematurely—before a liquidity event and before the full value of the new venture and the technology have been realized.

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Annex: Form Documents

Annex A. Bridge Loan Note

THIS NOTE AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR ANY APPLICABLE STATE SECURITIES LAWS. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND ANY APPLICABLE STATE SECURITIES AND "BLUE SKY" LAWS, OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL OR OTHER EVIDENCE SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED.
BRIDGE LOAN NOTE[1]

$__,000.00 _____, 2010

For value received, Spin-Out, Inc., a _____ corporation (the "Borrower"), whose address is _____, _____, _____ _____, hereby promises to pay to Research Institution, a _____ corporation, whose address is _____, _____, _____ _____, or its nominees or assigns (the "Lender"), the aggregate outstanding principal amount of all advances made to Borrower by Lender, intended to be a principal sum of up to _____ THOUSAND AND NO DOLLARS ($___,000) (such aggregate known herein as the "Principal Amount"), together with interest thereon from the date of each such advance. Lender will make advances to Borrower from time to time pursuant to this Bridge Loan Note ("Note") as requested by Borrower and agreed by Lender, in its sole discretion. Interest shall accrue on the Principal Amount at a rate of ___ percent (_%) per annum, accrued daily and compounded annually. Interest charges will be calculated based upon the actual number of days the Principal Amount is outstanding on the basis of a 365 or 366 day year, as the case may be. In the event of a disagreement with respect to advances or interest, Lender's records shall be determinative.

Payment. The Principal Amount and unpaid accrued interest thereon shall be due and payable upon demand by Lender. All payments shall be made in lawful money of the United States of America at the principal office of Lender, or at such other place as Lender

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may from time to time designate in writing to Borrower. Payment shall be credited first to the accrued interest then due and payable and the remainder, if any, applied to the Principal Amount.

Conversion. The Principal Amount and unpaid accrued interest thereon shall be convertible into shares of any equity securities, including common or preferred stock, or shares of any security convertible into an equity security at a fixed conversion price (in each case, "Equity Securities") issued by Borrower in the Next Equity Financing pursuant to the provisions set forth herein. "Next Equity Financing" means Borrower's next transaction or series of related or unrelated transactions in which Borrower sells Equity Securities in which the gross proceeds to Borrower equal or exceed _____ THOUSAND AND NO DOLLARS ($___,000) (the "Funding Amount") (provided that any debt securities to be converted into shares of Equity Securities at the closing of such transaction shall only be counted once in determining such gross proceeds). In the event that there is more than one closing in the Next Equity Financing, the Next Equity Financing will not be deemed to have occurred until the last closing that causes the aggregate amount of gross proceeds from the closings to equal or exceed the Funding Amount. In the event that more than one offering of more than one type of Equity Securities constitute the Next Equity Financing, then Lender will have the right, in its sole discretion, to convert the Note into any one of the types of Equity Securities sold in the Next Equity Financing, provided that in the event that one of the closings involves a unit offering, Lender may choose to convert into the Equity Securities constituting the unit offered.

Number of Shares. The number of shares of Equity Securities to be issued upon conversion of this Note subsequent to the Next Equity Financing shall be equal to the quotient obtained by dividing (A) the unpaid Principal Amount plus accrued and unpaid interest thereon through the date of conversion by (B) the lowest purchase price per share (or per unit in the case of a unit offering) paid by the investors purchasing the type of Equity Securities into which Lender elects to convert this Note. The issuance of such shares upon conversion of this Note shall be upon and subject to the same rights, terms and conditions applicable to such type of Equity Security in the Next Equity Financing, and Lender shall become a party to any agreements (whether conferring registration rights, tag-along rights, or other rights) that such investors in the Next Equity Financing enter into in connection with the Next Equity Financing.

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If Borrower shall (i) declare a dividend or make a distribution on any of its Equity Securities payable in shares of securities or other assets, (ii) subdivide or reclassify any outstanding shares of Equity Securities into a greater number of shares, or (iii) combine or reclassify any outstanding shares of Equity Securities into a smaller number of shares, the number of shares of Equity Securities issuable upon conversion of this Note after the record date for such dividend or distribution or the effective date of such subdivision, combination or reclassification shall be adjusted so that Lender receives that aggregate number of shares of Equity Securities it would have held after such event if it had converted this Note immediately prior to any such event. Successive adjustments in the number of shares of Equity Securities issuable hereunder upon conversion shall be made whenever any event specified above shall occur.

Exercise. At any time on or after the closing of the Next Equity Financing, Lender shall, in its sole discretion, either (A) elect to convert the unpaid Principal Amount and accrued and unpaid interest thereon into Equity Securities or (B) demand payment in cash of the unpaid Principal Amount plus accrued and unpaid interest thereon. If the Next Equity Financing does not occur on or before _____, 2010, the Lender shall have the option, in its sole discretion, at any time thereafter until the closing of the Next Equity Financing, to convert the Principal Amount and the unpaid accrued interest thereon into shares of the Borrower's common stock. In such event, the number of shares of common stock to be issued upon conversion of this Note shall be equal to the quotient obtained by dividing (A) the unpaid Principal Amount plus accrued and unpaid interest thereon through the date of conversion by (B) $____.[2] Borrower shall notify Lender in writing at least ten (10) business days in advance of any anticipated closing of the Next Equity Financing and shall also notify Lender of each sale of Equity Securities constituting the Next Equity Financing.

Borrower covenants that all Equity Securities issued upon conversion of this Note will be validly issued, fully paid and nonassessable and free from all taxes, liens and charges in respect of the issuance thereof. Certificates for Equity Securities issued pursuant hereto shall be delivered to Lender within a reasonable time after the date on which this Note has been converted. No fractional shares will be issued upon the conversion of this Note. Any fractional share shall be rounded to the nearest whole share, with one-half being rounded upward.

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Prepayment. Borrower may prepay this Note, in whole, at any time after the Next Equity Financing. Borrower shall not have the right to prepay this Note in part without the written consent of Lender. At any time after the Next Equity Financing, Borrower shall give Lender thirty (30) days advance notice of such prepayment, and Lender may, after receiving such notice, exercise its conversion rights hereunder as set forth above, provided that such rights have not terminated pursuant to the provisions hereof.

No Rights as Stockholder. Nothing in this Note shall be construed as conferring on Lender or any other person any voting rights or other rights as a stockholder of Borrower.

Assignment. This Note is not assignable by Borrower without the prior written consent of the Lender, which consent shall not be unreasonably withheld. Subject to the foregoing, the rights and obligations of Lender and Borrower shall be binding upon and benefit the successors, assigns, heirs, administrators and transferees of the parties.

Notice. All notices and other communications under this Note must be in writing. Any notice or communication will be effective upon the earlier of actual receipt or two business days after deposit with next-day courier, pre-paid, addressed to the party to be notified at the address indicated for such party set forth above, or at such other address as such party may designate by 10 days advance written notice to the other party.

Definitions. As used in this Note, the following term shall have the meaning set forth below:

"Applicable Law" means that law in effect from time to time and applicable to this Note which lawfully permits the charging and collection of the highest permissible lawful, non-usurious rate of interest on this Note, including laws of the State of _____ and, to the extent applicable and providing for a higher rate of interest or otherwise controlling, laws of the United States of America.

[Include language conforming to Applicable Law to ensure that the note is not usurious.]

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Legal Expenses. Borrower hereby agrees, subject only to any limitation imposed by Applicable Law, to pay all expenses, including reasonable attorneys' fees and legal expenses, incurred by Lender in converting this Note and in endeavoring to collect any amounts payable hereunder that are not paid when due whether by declaration or otherwise.

Governing Law. This Note shall be governed by and construed in all respects i7n accordance with the laws of the State of _____ as such laws are applied to agreements among residents of such state entered into and to be performed entirely within such states, without regard to conflicts of laws rules.

[Include standard note provisions required or advisable under Applicable Law.]

SPIN-OUT, INC.
By: _____
_____, President

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Annex B. Stock Purchase Warrant

Issue Date: _____, 2010

THE SECURITIES REPRESENTED BY THIS INSTRUMENT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR ANY APPLICABLE STATE SECURITIES LAWS. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND ANY APPLICABLE STATE SECURITIES AND "BLUE SKY" LAWS, OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL OR OTHER EVIDENCE SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED.

SPIN-OUT, INC.

Stock Purchase Warrant[3]

THIS CERTIFIES that Research Institution (the "Holder") is entitled, upon the terms and subject to the conditions hereinafter set forth, at any time on or after the date of this Stock Purchase Warrant (the "Warrant") and on or prior to _____, 2015[4] (the "Expiration Date"), but not thereafter, to subscribe for and purchase from Spin-Out, Inc., a _____ corporation (the "Company"), the number of shares of Equity Securities (defined below) determined pursuant to Section 1(a) (the "Shares") at a price per Share equal to $0.0001 (the "Exercise Price").

I. Exercise of Warrant.

A. *Determination of Number of Shares.* The number of Shares purchasable pursuant to this Warrant shall be 100% of the quotient determined by dividing (i) the highest amount outstanding at any time of principal plus accrued and unpaid interest thereon pursuant to the Note (defined below) by (ii) the lowest purchase price per share paid by investors purchasing the type of Equity Securities in the Next Equity Financing (defined below) into which Holder elects to convert this Warrant. "Note" means that certain Bridge Loan Note, dated _____, 2010, pursuant to which Holder has agreed to lend to the Company up to $--__,000.00. "Next Equity

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Financing" means the Company's next transaction or series of related or unrelated transactions in which the Company sells any equity securities, including common or preferred stock, or any security convertible into an equity security at a fixed conversion price (in each case, "Equity Securities") in which the gross proceeds to the Company equal or exceed _____ THOUSAND AND NO DOLLARS ($___,000) (provided that any debt securities to be converted into shares of Equity Securities at the closing of such transaction shall only be counted once in determining such gross proceeds and provided further that Equity Securities issued upon conversion of the Note shall not be counted in determining such gross proceeds). The Company shall notify Holder in writing at least ten (10) business days in advance of any anticipated closing of the Next Equity Financing and shall also notify Holder of each sale of Equity Securities constituting the Next Equity Financing

B. *Exercise.* The purchase rights represented by this Warrant are exercisable by the Holder in its sole discretion at any time after the closing date of the Next Equity Financing and before the close of business on the Expiration Date by the surrender of this Warrant and the Notice of Exercise annexed hereto, duly executed, at the principal executive office of the Company (or such other office or agency of the Company as it may designate by notice in writing to the Holder at the address of the Holder appearing on the books of the Company), and upon payment of the Exercise Price of the Shares thereby purchased (by cash or by check or bank draft payable to the order of the Company); whereupon the Holder or its designee shall be entitled to receive a certificate for the number of Shares so purchased. The Company agrees that if at the time of the surrender of this Warrant and purchase of the Shares the Holder shall be entitled to exercise this Warrant, the Shares so purchased shall be and be deemed to be issued to the Holder or its designee as the record owner of such Shares as of the close of business on the date on which this Warrant shall have been surrendered.

II. Nonassessable. The Company covenants that all Shares which may be issued upon the exercise of rights represented by this Warrant will, upon exercise of the rights represented by this Warrant, be validly issued, fully paid and nonassessable and free from all taxes, liens and charges in respect of the issuance thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue). Certificates for Shares

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purchased hereunder shall be delivered to the Holder or designee within a reasonable time after the date on which this Warrant shall have been surrendered and exercised as aforesaid.

III. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. Any fractional share shall be rounded to the nearest whole share, with one-half being rounded upward.

IV. Charges, Taxes and Expenses. Issuance of certificates for Shares upon the exercise of this Warrant shall be made without charge to the Holder or designee for any expenses in respect of the issuance of such certificate, all of which expenses shall be paid by the Company, and such certificates shall be issued in the name of the Holder or designee.

V. No Rights as Shareholder. This Warrant does not entitle the Holder to any voting rights or other rights as a shareholder of the Company prior to the exercise thereof.

VI. Loss, Theft, Destruction or Mutilation of Warrant. On receipt of evidence satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of mutilation, on surrender and cancellation of this Warrant, the Company at its expense shall execute and deliver, in lieu of this Warrant, a new warrant of like tenor and amount.

VII. Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall be a Saturday, a Sunday or a legal holiday in the United States, then such action may be taken or such right may be exercised on the next succeeding day not a Saturday, Sunday or legal holiday.

VIII. Adjustments. The Exercise Price and the number of Shares purchasable hereunder, after determination pursuant to Section 1(a), are subject to adjustment from time to time as follows:

A. *Reclassification, etc.* If the Company, at any time while this Warrant, or any portion hereof, remains outstanding and unexpired by reclassification of securities or otherwise, shall change any of the securities as to which purchase rights under this

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Warrant exist into the same or a different number of securities or any other class or classes, this Warrant shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities that were subject to the purchase rights under this Warrant immediately prior to such reclassification or other change, and the Exercise Price therefore shall be appropriately adjusted, all subject to further adjustment as provided in this Section VIII.

B. *Subdivision or Combination of Shares.* In the event that the Company shall at any time subdivide the outstanding securities as to which purchase rights under this Warrant exist, or shall issue a stock dividend on the securities as to which purchase rights under this Warrant exist, the number of Shares immediately prior to such subdivision or to the issuance of such stock dividend shall be proportionately increased, and the Exercise Price shall be proportionately decreased, and in the event that the Company shall at any time combine the outstanding securities as to which purchase rights under this Warrant exist, the number of Shares immediately prior to such combination shall be proportionately increased, and the Exercise Price shall be proportionately eased, effective at the close of business on the date of such subdivision, stock dividend or combination, as the case may be.

C. *Cash Distributions.* No adjustment on account of cash dividends or interest on the securities as to which purchase rights under this Warrant exist will be made to the Exercise Price under this Warrant.

D. *Mergers, Consolidations and Sales.* If there shall occur any consolidation or merger of the Company with another entity, or any reorganization or reclassification of the Equity Securities, then lawful and adequate provision shall be made whereby the Holder shall thereafter have the right to receive upon the exercise of this Warrant such shares of stock, securities or assets as would (by virtue of such consolidation, merger, reorganization or reclassification) be issued or payable with respect to or in exchange for the Shares, had this Warrant been exercised in full immediately prior to such consolidation, merger, reorganization or reclassification, and in any such case appropriate provisions shall be made with respect to the rights and interests of the Holder so that the provisions hereof shall thereafter be applicable, as nearly as may be, in relation to any securities or assets thereafter deliverable upon exercise of this Warrant. No such consolidation or merger shall be

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consummated unless prior to or simultaneously with the consummation thereof the successor entity (if other than the Company) that would result from such consolidation or merger shall assume by written instrument executed and mailed or delivered to the Holder the obligation to deliver to such Holder such securities or assets as, in accordance with the foregoing provisions, such Holder may be entitled to receive.

E. *Notice of Certain Action.* If the Company shall propose: (i) to pay any dividend to the holders of any class of its Equity Securities or to make any other distribution to the holders of any class of its Equity Securities, (ii) to offer to the holders of any class of its Equity Securities rights to subscribe for or to purchase any additional Equity Securities; (iii) to effect any reorganization or reclassification of its Equity Securities, (iv) to effect any other capital reorganization, (v) to effect any consolidation, merger or share exchange or any sale, transfer or other disposition of all or substantially all of its assets; (vi) to file with the Securities Exchange Commission a registration statement covering any class of Equity Securities, or (vii) to effect the liquidation, dissolution, filing, or winding up of the Company, then, in each such case, the Company shall give to the Holder a notice of such proposed action, which shall specify the date on which a record is to be taken for the purpose of such action or the date on which such action is to take place and the date of participation therein by the holders of the Company's Equity Securities, if any such date is to be fixed, and shall also set forth such facts with respect thereto as shall be reasonably necessary to indicate the effect of such action on the Company's rights set forth in this Warrant. Such notice shall be given in the case of any action covered by clause (i) or (ii) above at least ten (10) business days prior to the record date for determining holders of Equity Securities for purposes of such action, and in the case of any other such action, at least twenty (20) days prior to the date of the taking of such proposed action.

F. *Notice of Adjustment.* When any adjustment is required to be made in the number or kind of Shares, or in the Exercise Price, the Company shall promptly notify the Holder of such event and of the number and kind of Shares or property thereafter purchasable upon exercise of this Warrant.

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IX. Restrictions on Transferability of Securities.

A. *Restrictions on Transferability.* This Warrant shall not be sold, assigned, transferred or pledged without the consent of the Company; provided, however, that it may be assigned to any affiliate of **[The Research Institution Parent]** without the Company's written consent.

B. *Restrictive Legend.* Each certificate representing the Shares, and any other securities issued in respect of the Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, shall be stamped or otherwise imprinted with a legend in the following form (in addition to any legend required under applicable state securities laws):

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR ANY APPLICABLE STATE SECURITIES LAWS. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND ANY APPLICABLE STATE SECURITIES AND "BLUE SKY" LAWS, OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL OR OTHER EVIDENCE SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED.

Each holder of Shares and each subsequent transferee consents to the Company making a notation on its records and giving instructions to any transfer agent of the Shares in order to implement the restrictions on transfer established in this Section IX.

C. *Notice of Proposed Transfers.* Each holder of Shares, by acceptance thereof, agrees to comply in all respects with the provisions of this Section IX.C. Such holder agrees not to make any disposition of all or any portion of the Shares unless and until (i) there is then in effect a registration statement under the Securities Act of 1933 (the "1933 Act") covering such proposed disposition and such disposition is made in accordance with such registration statement or (ii) such holder shall have notified the Company of the proposed disposition and shall have furnished the

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Company with a detailed statement of the circumstances surrounding the proposed disposition, and if reasonably requested by the Company, such holder shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration of such shares under the 1933 Act.

X. Miscellaneous.

A. *Governing Law.* This Agreement shall be governed by and construed in all respects in accordance with the laws of the State of _____ as such laws are applied to agreements among residents of such state entered into and to be performed entirely within such states, without regard to conflicts of laws rules.

B. *Waivers and Amendments.* This Warrant and any provisions hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of the same is sought.

C. *Remedies.* The Company acknowledges that the Holder's remedies at law in the event of any default or threatened default by the Company in the performance of or compliance with any of the terms of this Warrant are not and will not be adequate, and that such terms may be specifically enforced by a decree for the specific performance of any agreement contained in this Warrant or by an injunction against a violation of any of the terms of this Warrant.

D. *Reservation of Shares.* At all times after the closing of the Next Equity Financing, the Company shall reserve and keep available the number of Shares determined pursuant to Section I.A, solely for purposes of issuance upon exercise of this Warrant, free from all preemptive rights with respect thereof.

E. *Notices.* All notices and other communications required or permitted hereunder shall be in writing and shall be delivered personally by hand or by courier, mailed by United States first-class mail, postage prepaid, sent by facsimile or sent by electronic mail directed to the party to be notified at the address, facsimile number or electronic mail address indicated for such person on the signature page hereof, or at such other address or facsimile number as such party may designate by ten (10) days' advance written notice to the other parties hereto. All such notices and other communications shall be deemed given upon personal delivery, on the date of mailing, upon confirmation of facsimile transfer or when directed to the electronic mail

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address set forth on signature page hereof charter or bylaws, the Holder agrees that such notice may be given by facsimile or by electronic mail.

F. *Counterparts.* This Warrant may be executed in any number of counterparts, each of which shall be enforceable, and all of which together shall constitute one instrument.

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officers thereunto duly authorized.

SPIN-OUT, INC.

By:_____
_____, President
Address: _____
_____, ____ _____
Attn: President

IN WITNESS WHEREOF, the Holder has agreed to and acknowledged this Warrant.
AGREED AND ACKNOWLEDGED:

RESEARCH INSTITUTION

By: _____
_____, President
Address: _____
_____, _____ _____

Facsimile: _____

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Notice of Exercise

TO: Spin-Out, Inc.

_____

_____, _____ _____

ATTN: Secretary

1. The undersigned hereby elects to purchase _____ Shares (as such term is defined in the attached Warrant) of Spin-Out, Inc. pursuant to the terms of the attached Warrant, and tenders herewith payment of the purchase price in full.
2. Please issue a certificate or certificates representing the Shares in the name of the undersigned or in such other name as is specified below:

_____

(Print Name)

Address:_____

_____

Tax ID No.:_____

3. The undersigned confirms that the Shares are being acquired for the account of the undersigned for investment only and not with a view to, or for resale in connection with, the distribution thereof and that the undersigned has no present intention of distributing or selling the Shares.

_____

(Date) (Signature)

_____

(Print Name)

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Annex C. Equity Provisions of Patent License Agreement

EQUITY PROVISIONS OF PATENT LICENSE AGREEMENT

1. Definitions

"Affiliate" means (i) any business entity more than 50% owned directly or indirectly by Licensee, (ii) any business entity which owns directly or indirectly more than 50% of Licensee, or (iii) any business entity that is more than 50% owned directly or indirectly by a business entity that owns directly or indirectly more than 50% of Licensee.

"Effective Date" means _____, 20__ .[5]

"Equity Recipients" means collectively the Institution [6] and Inventors,[7] as stated in writing from Institution to Licensee. The Institution will inform Licensee in writing of the appropriate allotment of equity amongst the Equity Recipients.

"Funding Event" means one or more issuances by Licensee subsequent to the Effective Date of equity securities (common stock, preferred stock, convertible debt or equity, options, warrants, calls, rights, commitments or other equity securities) for funding purposes for aggregate gross proceeds received by Licensee equal to _____ million dollars ($__,000,000).[8]

"Fully Diluted Basis" means the calculation of percentage ownership shall include all shares of common stock outstanding as of the date in question, assuming conversion of all convertible debt and equity and the exercise of all authorized capital stock rights, including options, warrants, calls, rights, commitments, and agreements of any character as of such date or that Licensee is obligated or committed to issue, deliver, or sell, including any such capital stock rights that an investor has agreed may be authorized to be issued pursuant to any incentive compensation plan after the closing of a financing.

"Subsidiary" means any business entity more than 100% owned by Licensee.

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2. License Grant and Commercialization

2.2 Subsidiaries

Licensee may extend the license granted herein to any Subsidiaries[9] provided that the Subsidiaries agree in writing to be bound by the Agreement to the same extent as Licensee. Licensee agrees to deliver such written agreement to Institution within 30 calendar days following execution.

2.5 Diligent Commercialization

Licensee by itself or through its Subsidiaries and Sublicensees will Actively Commercialize Licensed Products and Licensed Services in the Field in the Territory. Without limiting the foregoing, Licensee will use diligent and commercially reasonable efforts to perform and complete the following milestone events by the deadlines indicated.

Milestone Events[10]	**Deadlines**
Licensee hires CEO and key members of management	Within _____ months of execution
Licensee applies for _____ grant	Within _____ months of execution
Licensee closes the Funding Event	Within _____ months of execution

It shall be considered a breach of the Agreement if Licensee fails to meet the milestone events set forth above by the deadlines indicated or fails to Actively Commercialize Licensed Products or Licensed Services.

3. Compensation

3.5 Equity Consideration for License Grant

(a) As consideration for the rights granted to Licensee by Institution in this Agreement, upon the execution of this Agreement, Licensee will issue to the Equity Recipients_____ fully paid and non-assessable shares of Licensee's common stock.[11] Such shares shall be issued to the Equity Recipients in the proportions specified by Institution. Licensee represents and warrants that such number of shares represent not less than _____ percent (__%) of its capital stock on a Fully Diluted Basis as of the date that such shares are issued.

(b) Licensee hereby represents and warrants that, as of the Effective Date: (i) Licensee is a corporation duly organized, validly existing, and in good standing

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under the laws of the State of _____, (ii) Licensee's authorized equity consists of (a) __ million (__,000,000) shares of common stock, $___ par value per share (the "Common Stock"), of which _____ (_____) have been issued and are outstanding, and (b) __ million (__,000,000) shares of preferred stock, $___ par value per share, of which _____ (_____) have been issued and are outstanding, and (iii) except as set forth on the attached Capitalization Table as Exhibit B, there are no options, warrants, calls, rights, commitments, or agreements of any character to which Licensee is a party or by which it is bound obligating Licensee to issue, deliver, sell, repurchase, or redeem, or cause to be issued, delivered, sold, repurchased, or redeemed, any equity securities of Licensee, and Licensee has no current plans, commitments or obligations to issue any equity securities, with the exception of the Funding Event and this License.[12] Upon Institution's request, Licensee shall provide, from time to time, an updated capitalization table along with a certification from the Licensee's Chief Financial Officer certifying the table's completeness.

(c) Because Licensee needs additional capital in order to carry out its business plan, the Equity Recipients are granted anti-dilution rights as follows: if the Equity Recipients' percentage equity ownership interest on a fully diluted basis falls below _____ percent (__%) before Licensee has completed the Funding Event (the "Anti-dilution Threshold") or as a result of a Funding Event, then Licensee, for no additional consideration, shall promptly issue to the Equity Recipients that additional number of shares necessary to increase the Equity Recipients' equity ownership to an amount equal to the Anti-dilution Threshold.[13] Licensee shall provide Institution with prompt notice if the Equity Recipients hold less than the Anti-dilution Threshold at any time prior to the completion of the Funding Event. Pursuant to such anti-dilution rights, Licensee shall promptly issue Equity Recipients that number of fully paid, non-assessable shares of Licensee's common stock necessary for the Equity Recipients to maintain the Anti-dilution Threshold until the Funding Event, it being understood that in the event a closing occurs that, when aggregated with prior closings, exceeds _____ million dollars ($__,000,000), then Equity Recipients shall receive additional fully paid, non-assessable shares of Licensee's common stock sufficient to maintain the Anti-dilution Threshold up to _____ million dollars ($__,000,000) of gross proceeds.[14]

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(d) Pursuant to an investor rights, shareholders' agreement, or other comparable agreement or agreements mutually agreeable to the Parties and executed concurrently with this Agreement, the Equity Recipients will have Piggy-Back Registration Rights, Tag-Along Rights, and Pre-emptive Rights. Pursuant to a side letter executed concurrently with this Agreement, Institution will have board observation and information rights for so long as Equity Participants and their authorized transferees hold at least _____ percent (__%) of Licensee's common stock on a Fully Diluted Basis. The following definitions shall apply to this Section 3.5(d): (i) *"Piggy-Back Registration Rights"* means the Equity Recipients have the right to have their shares included in any registration statement filed by Licensee for its benefit or for the benefit of another shareholder; (ii) "*Tag-Along Rights*" means that if a founder or other key employee sells any or all of his or her shares or if any shareholder or group of shareholders sells thirty percent (30%) or more of any class of Licensee's outstanding equity securities, then the Equity Recipients have the right to sell their shares in the same proportion;[15] and (iii) *"Pre-emptive Rights"* means Institution has the right to purchase a proportionate share of any new equity issuance by Licensee equal to the Equity Participants' and their authorized transferee's percentage interest in Licensee's outstanding equity securities prior to such issuance (which right is in addition to the Institution's rights with respect to the anti-dilution threshold).[16]

(e) If Licensee transacts any business with an Affiliate of Licensee, other than a Subsidiary, including, without limitation, any contract for service or license or transfer of any intellectual property rights or other asset, then either (i) the terms of such business transaction must be no less favorable to the Licensee than those that could be commercially obtained by the Licensee in an arms-length transaction negotiated with an unrelated party, or (ii) the transaction must not affect the interests of Institution in an adverse manner relative to the effect of the transaction on other shareholders of Licensee, taking into account all interests of such shareholders, including those in capacities other than as shareholders of Licensee. A transaction shall be deemed to satisfy (i) or (ii) if the independent members of Licensee's board of directors who have no interest in such transaction unanimously determine prior to such transaction that (i) or (ii) is met.

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6. Legal Expenses and Prosecution[17]

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Institution, which consent will not be unreasonably withheld. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement.[18] For any permitted assignment to be effective, (a) the Licensee must pay Institution the assignment fee and reimburse Institution any expenses pursuant to Section ___ (Compensation) and ___ (Legal Expenses), and (b) the assignee must assume in writing (a copy of which shall be promptly provided to Institution) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original Party to the Agreement.

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EXHIBIT B
Patent License Agreement

Shareholder	No. of Shares	% on Fully Diluted Basis
Institution		
[Shareholder]		
[Shareholder]		
[Shareholder]		
[Shareholder]		
TOTAL		100%

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Annex D. Shareholder Agreement

SHAREHOLDER AGREEMENT

THIS SHAREHOLDER AGREEMENT (this "Agreement"), dated as of _____, 2010, but to be effective as provided in Section XVII, is by and among Spin-Out, Inc., a _____ corporation (the "Corporation"), and the Shareholders, as defined below. The Corporation and each of the Shareholders, individually, shall be referred to herein as a "Party" and, collectively, the "Parties."

WITNESSETH:

WHEREAS, the Shareholders are the owners of common stock, $_____ par value per share, of the Corporation (the "Common Stock"); and

WHEREAS, the Parties hereto agree that the success of the Corporation requires the active interest and support of its Shareholders and therefore desire to promote the best interests of the Corporation and their mutual interests by imposing certain requirements with respect to the voting and transferability of the shares of Common Stock of the Corporation owned by the Shareholders;

NOW, THEREFORE, for and in consideration of the premises and the mutual covenants hereinafter set forth, and for other good and valuable consideration, the parties hereby agree as follows:

1. Definitions. As used in this Agreement:
   A. "*Affiliate*" shall mean a Person that controls, is controlled by, or is under common control with, the other Person specified.
   B. "*Buy-Out Offer*" means an offer made by any Person who is not then a Shareholder, or an Affiliate of a Shareholder, to purchase for cash[19] all but not less than all of the then issued and outstanding Restricted Shares.
   C. "*Buy-Out Offeror*" means the Person who makes a Buy-Out Offer.
   D. "*Commission*" means the Securities and Exchange Commission, or any other federal agency at the time administering the Securities Act.

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E. "*Exchange Act*" means the Securities Exchange Act of 1934, as amended, or any successor federal statute, and the rules and regulations of the Commission issued under such Act, as they may, from time to time, be in effect.

F. *Founder"* and "*Founders*" means _____.[20]

G. "*Offer*" and "*Offerees*" shall have the meanings ascribed to such terms in Section III.

H. "*Person*" shall include an individual, a corporation, a limited liability company, a partnership, a trust or any other organization or entity.

I. "*Pro Rata Shares*" means that number of Restricted Shares equal to the product of (i) the total number of Restricted Shares available for purchase pursuant to Section III.C, multiplied by (ii) the quotient of (A) the number of shares of Common Stock owned (on an as-converted basis) by such Non-Selling Shareholder, divided by (B) the total number of shares of Common Stock (on an as-converted basis) owned by all Non-Selling Shareholders that exercised their right to purchase Restricted Shares pursuant to Section III.C.

J. "*Remaining Shareholders*" means, with respect to any specific event or transaction, all of the Shareholders other than the Shareholder or Shareholders that are the subject of such event or transaction.

K. *"Restricted Shares*" shall mean all shares of Common Stock owned or hereafter acquired by the Shareholders while this Agreement remains in effect, including without limitation all such stock of the Corporation now owned or hereafter acquired by any Shareholder and the Shareholder's spouse as community property or as separate property, and all references herein to the stock owned by a Shareholder include the community interest of such Shareholder's spouse in such stock. Any obligation of a Shareholder to Sell or offer to Sell Restricted Shares includes an obligation on the part of the Shareholder's spouse to Sell or offer to Sell the spouse's community interest in such stock in the same manner. The termination of the marital relationship of any Shareholder and his or her spouse for any reason shall not have the effect of removing any stock of the Corporation otherwise subject to this Agreement from the coverage hereof.

L. *"Sale"*, "*Sell*" or "*Sold*" shall mean and include any sale, gift or other form of transfer, conveyance, disposal or encumbrance, whether voluntary or involuntary, including any dividend or distribution and the pledging of any security.

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M. "*Securities Act*" means the Securities Act of 1933, as amended, or any successor federal statute, and the rules and regulations of the Commission issued under such Act, as they each may, from time to time, be in effect.

N. "*Shareholders*" shall mean the Persons identified as Shareholders on the signature page attached hereto and any other Persons or entities who become Parties to this Agreement as "Shareholders" pursuant to the terms of this Agreement, and their respective heirs, legal representatives, administrators and successors.

O. "*Significant Shareholder*" shall mean a Shareholder owning more than 10% of the Corporation's outstanding Common Stock on an as-converted basis.

P. "*Third-Party Offer*" means (i) a bona fide offer from a Person who is not then a Shareholder, or an Affiliate of a Shareholder (other than the Corporation), to purchase or otherwise acquire any Restricted Shares from a Shareholder who is not a Founder, or (ii) a bona fide offer from any Person to purchase or otherwise acquire Restricted Stock from a Founder.

Q. "*Third-Party Offeror*" means a Person that makes a Third-Party Offer.

R. "*Parent*" means Research Institution Parent.

S. "*Institution*" means Research Institution.

T. "*Institution Shareholders*" means (i) the "Equity Recipients" as defined in that certain Patent License Agreement between Institution and the Corporation and (ii) any Person to whom an Equity Recipient transfers shares pursuant to Section VI.

II. Transfer Restrictions. No Restricted Shares or any interest therein shall be Sold in any fashion unless such Sale is made in accordance with Sections III, IV, V or VI of this Agreement. Any Sale or attempted Sale not made in compliance with this Agreement shall be void and of no effect.

III. Offer to the Corporation and the Shareholders. Unless such Sale is exempted pursuant to Section VI, no Shareholder shall Sell any Restricted Shares or any interest therein to any Person, except pursuant to the provisions hereinafter set forth in this Section III or in Sections IV or V.

A. Any Shareholder who desires in good faith to Sell any Restricted Shares or any interest therein (such Shareholder being sometimes referred to herein as the "Selling

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Shareholder"), or who has received a *bona fide* offer to purchase such Restricted Shares which said Shareholder desires to accept, shall first make a written offer (the "Offer") to Sell such Restricted Shares to the Corporation, and to the Significant Shareholders other than the Selling Shareholder (the "Non-Selling Shareholders") (the Corporation and the Non-Selling Shareholders being sometimes referred to collectively herein as the "Offerees"), in the order provided in Section III.C below; provided, however, that the terms of this Section III shall not apply to a transaction subject to Section IV of this Agreement.

B. The Offer shall be sent to the Offerees in compliance with the terms of this Agreement and shall set forth:
   1. the number of Restricted Shares and the interest therein that the Selling Shareholder desires to Sell;
   2. the names and identities of any proposed purchasers and a description of the proposed Sale;
   3. the cash consideration per share to be received by the Selling Shareholder in connection with a bona fide sale, or if the consideration is other than cash or partly in cash and partly in the form of other consideration, the nature of the other consideration to be received (with a reasonable description thereof) and the other terms and conditions of such proposed Sale;
   4. the address of the Selling Shareholder at which the Offerees may give any notice required herein;
   5. an offer to Sell the Restricted Shares that are subject of the Offer to the Offerees pursuant to the provisions of this Agreement; and
   6. a Co-Sale Offer pursuant to Section V, if applicable.

   The date of the Offer shall be the third business day after the Offer shall have been mailed or delivered personally to all Parties entitled to receive it.

C. The Offerees shall have the option for 35 days following the date of the Offer to purchase all of the Restricted Shares offered, including Restricted Shares of Tag-Along Offerors pursuant to Section V. As between the Corporation and the Non-Selling Shareholders, the preferential right to purchase all of the Restricted Shares offered pursuant to this Section III shall exist in and be exercisable:

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1. first, by the Corporation, as to any or all of such Restricted Shares, for a period of fifteen (15) days beginning with the date of the Offer;
2. then by each Non-Selling Shareholder its Pro Rata Shares, for a period of ten (10) days beginning with the 16th day after the date of the Offer;
3. thereafter, during the period commencing on the 26th day after the date of the Offer and ending on the 30th day after the date of the Offer, each Non-Selling Shareholder who has exercised its full rights under Section III.C.2, any of the Restricted Shares not acquired by the Offerees pursuant to Section III.C.3, provided that if more than one Offeree seeks to purchase such Shares, they shall be allocated among such Offerees based upon their respective number of Pro Rata Shares; and
4. thereafter, during the period commencing on the 31st day after the date of the Offer and ending on the 35th day after the date of the Offer, as to all of the Restricted Shares not acquired by the Offerees pursuant Section III.C.3, or that said Offerees have not theretofore elected to acquire, by the Offeree who owns the largest number of shares of Common Stock as of the close of business on the 30th day after the date of the Offer.

The Secretary of the Corporation shall give notice promptly to all Offerees of the number of shares which may be purchased at any time by any of them during each of the periods specified above.

D. In order to exercise its right to purchase, an Offeree shall notify the Selling Shareholder within the requisite time period. Such notices shall state the number of Restricted Shares which the Offeree elects to purchase. Each Offeree other than the Corporation shall send a duplicate copy of its notices of exercise to the Corporation.
E. If, at the end of the 35 day option period provided hereunder, the Corporation and the Offerees have not elected to purchase all of the Restricted Shares offered, then the Offerees shall not be entitled to purchase any of the Restricted Shares and the Selling Shareholder may Sell all, but not less than all, of the Restricted Shares to the proposed purchaser named in the Offer, on terms that are no more favorable to

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the proposed purchaser than the terms set forth in the Offer. If the offered Restricted Shares are not Sold within 90 days after the date of the Offer, then, before any Sale of such Restricted Shares, a new Offer covering such Restricted Shares must be made by the Selling Shareholder in accordance with the terms of this Section III.

F. The closing of the purchase of Restricted Shares by the Offeree pursuant to this Section III shall be at 10:00 a.m. local time at the Corporation's office on the fifth business day after expiration of the 35 day option period referred to in Section III.C, or at such other time and place as the Parties may agree.

G. Payment for the Restricted Shares purchased under this Section III by an Offeree, unless otherwise agreed between the selling and purchasing parties and except as provided below, shall be made in cash or by certified cashier's check or checks payable to the order of the Selling Shareholder or such other Person as may be designated by him. In the event the consideration per share to be received by the Selling Shareholder consists, in whole or in part, of non-cash consideration, then each Offeree may, in lieu of paying such non-cash consideration, pay the fair market value of such consideration in accordance with Section XII hereof.

IV. Drag-Along Right.

A. Notwithstanding any other provision of this Agreement, and subject to the provisions of this Section VI [and Section XVII], if any Shareholders receive a Buy-Out Offer, and Shareholders who, at such time, own of record and beneficially more than 75%[21] of the Restricted Shares (a "Controlling Interest") elect to accept such Offer as to their Restricted Shares, then the Controlling Interest shall have the right to require that all Shareholders Sell 100% of their Restricted Shares to the Buy-Out Offeror on the same terms and subject to the same conditions of purchase and sale.

B. The Shareholder receiving a Buy-Out Offer (the "Notifying Shareholder") shall promptly deliver to the Corporation and the Remaining Shareholders a written notice (the "Buy-Out Notice") that contains the information that must be contained in an Offer Notice given with respect to a proposed Sale subject to Section III, and states that the Notifying Shareholder wishes to Sell and cause to be Sold all Restricted Shares held by him pursuant to the terms of the Buy-Out Offer as

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described in the Buy-Out Notice. The date of the Buy-Out Notice shall be the third business day after the Buy-Out Notice shall have been mailed or delivered personally to all Parties entitled to receive it. Solely as among the Parties, the statements made in the Buy-Out Notice shall be irrevocable and binding upon the Notifying Shareholder for a period of 30 days after the date of the Buy-Out Notice, provided that such period shall be ninety (90) days if a Controlling Interest has delivered the appropriate written notice indicating that they wish to Sell Restricted Shares in connection with the Buy-Out Offer within 30 days after the date of the Buy-Out Notice.

C. Each Remaining Shareholder who desires to participate in the Buy-Out Offer shall, within 30 days after the date of the Buy-Out Notice, deliver written notice to the Corporation and the Notifying Shareholder stating that he wishes to Sell and cause to be Sold all Restricted Shares held by him pursuant to the terms of the Buy-Out Offer as described in the Buy-Out Notice. Solely as among the Parties, such statement shall, for a period of 90 days after the date of the Buy-Out Notice, be irrevocable and binding upon the Remaining Shareholder if a Controlling Interest makes the same written commitment.

D. If within 30 days after the date of a Buy-Out Notice, a Controlling Interest has delivered the appropriate written notice indicating that they wish to Sell Restricted Shares in connection with the Buy-Out Offer, then (i) the Corporation promptly shall deliver written notice of that fact to all Shareholders, (ii) the Notifying Shareholder shall advise the Buy-Out Offeror that all communications from the Buy-Out Offeror relating to the Buy-Out Offer must be delivered to all Shareholders and (iii) for a period of 90 days after the date of the Buy-Out Notice, each Shareholder shall be obligated to Sell Restricted Shares to the Buy-Out Offeror pursuant to terms and conditions that are identical for all Shareholders and to those described in the Buy-Out Notice as to the purchase price per Share and terms of payment. Each Selling Shareholder shall pay his own costs and expenses incurred in connection with the sale of his Restricted Shares; *provided, however,* that if any Shareholder did not elect to participate in the sale contemplated by the Buy-Out Offer but was required to do so by the Controlling Interest, then each Shareholder who elected to require all Shareholders to participate in the Buy-Out Offer shall be liable for and pay a pro rata portion of the out-of-pocket costs and expenses incurred by each non-consenting Shareholder in connection with his sale of Restricted Shares (in-

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cluding attorneys' fees and expenses).

E. The Notifying Shareholder promptly shall notify the Corporation and the Remaining Shareholders in writing of any changes in the terms of the Buy-Out Offer as described in the Buy-Out Notice, which subsequent notice shall constitute a new offer for purposes of this Section IV.

V. Tag-Along Right.

A. Notwithstanding any other provision of this Agreement and subject to the provisions of this Section V, if (i) any Shareholders desire to Sell or otherwise dispose of more than 30% of the outstanding Restricted Shares in the aggregate, or (ii) a Founder desires to Sell 10% or more of his Restricted Shares (such Selling Shareholders, the "Tag-Along Offerors"), in each case pursuant to a Third-Party Offer (the "Co-Sale Offer"), then the Remaining Shareholders shall have a co-sale right as set forth in this Section V.

B. Upon the occurrence of a Co-Sale Offer, the Tag-Along Offerors shall promptly deliver to the Corporation and the Remaining Shareholders a written notice (the "Sale Notice") that contains the information that must be contained in an Offer Notice given with respect to a proposed Sale subject to Section III. The date of the Sale Notice shall be the third business day after the Sale Notice shall have been mailed or delivered personally to all Parties entitled to receive it. Solely as among the Parties, the statements made in the Sale Notice shall be irrevocable and binding upon the Tag-Along Offerors for a period of 60 days after the date of the Sale Notice.

C. Each of the Remaining Shareholders shall have 30 days from the date of the Sale Notice to make a demand for the Tag-Along Offerors to cause the Third-Party Offeror to purchase such Remaining Shareholder's Restricted Shares by delivering to the Tag-Along Offerors a notice (the "Co-Sale Notice") duly executed by such Remaining Shareholder and specifying (i) the fact that such Remaining Shareholder is making a demand for the Tag-Along Offerors to cause the Third-Party Offeror to purchase such Remaining Shareholder's Restricted Shares (any such Remaining Shareholder making such demand is herein referred to as a "Participating Shareholder") and (ii) the number of Restricted Shares such Participating Shareholder is requiring the Tag-Along Offerors to cause the Third-Party Offeror to purchase, up

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to the maximum number determined in Section IV.D. Solely as among the Parties, such Co-Sale Notice shall, for a period of 90 days after the date of the Sale Notice, be irrevocable and binding upon the Participating Shareholder.

D. On the closing date as set forth in the Sale Notice, each Participating Shareholder shall deliver to the Third-Party Offeror certificates representing his Restricted Shares duly endorsed for transfer to the Third-Party Offeror or its designee, free and clear of all liens, claims or encumbrances whatsoever, and the Tag-Along Offerors will cause the Third-Party Offeror to pay to such Participating Shareholder the purchase price for the Restricted Shares transferred as set forth in the Sale Notice; provided, that in the event that one or more Offerees have exercised their rights pursuant to Section III, then each such Offeree shall be deemed to be a Third-Party Offeror pursuant to this Section V. The maximum number of Restricted Shares that a Participating Shareholder may require the Tag-Along Offerors to cause the Third-Party Offeror to purchase pursuant to a Co-Sale Notice shall equal the number of Restricted Shares owned by the Participating Shareholder multiplied by a fraction, the numerator of which is the number of Restricted Shares set forth in the Third-Party Offer and the denominator of which is [the sum of (a)] the total number of Restricted Shares owned by the Tag-Along Offerors [plus (b) the total number of Restricted Shares owned by all of the Participating Shareholders].

E. The Tag-Along Offerors promptly shall notify the Corporation and the Remaining Shareholders in writing of any changes in the terms set forth in the Sale Notice, which subsequent notice shall constitute a new offer for purposes of this Section V.

F. In addition to the rights set forth in Section V.A, in the event any Founder desires to Sell less than 10% of its Restricted Shares pursuant to a Third-Party Offer, then the Institution Shareholders shall have a co-sale right as set forth in this Section V. Such Founder shall be deemed a Tag-Along Offeror, such Third-Party Offer shall be deemed a Co-Sale Offer, and the Institution Shareholders have the right to be Participating Shareholders. With respect to such Co-Sale Offer, the Institution Shareholders shall have the same rights and such Founder shall have the same obligations as set forth in Section V.B through V.E of this Agreement.

VI. Exempt Transactions.

A. The prohibition against the Sale of Restricted Shares hereunder shall not apply to the exchange of Restricted Shares pursuant to a plan of merger, consolidation,

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capitalization or reorganization of the Corporation, but any stock or securities received in exchange therefor shall also become Restricted Shares subject to this Agreement; provided, however, that any such stock or securities received in any such merger, consolidation, recapitalization or reorganization shall not become Restricted Shares subject to this Agreement to the extent that the stock or securities received in such merger, consolidation, recapitalization or reorganization are registered under the Exchange Act. A dissolution or liquidation of the Corporation shall not be deemed to be a Sale for purposes of this Agreement.

B. The prohibition against the Sale of Restricted Shares hereunder shall not apply to:
   1. the Sale or other transfer by a Shareholder to an Affiliate of such Shareholder;
   2. the Sale or other transfer by an Institution Shareholder to:
      a. Institution, other component institutions of Parent, or Affiliates of Parent;
      b. employees of, or consultants to, Parent (or any of its Affiliates) in accordance with Parent's intellectual property policies; or
      c. to Persons having rights in the intellectual property licensed by Parent to the Corporation; or

C. the sale or transfer by a Shareholder that is an individual of all or part of such Shareholder's Restricted Shares to:
      a. such Shareholder's spouse;
      b. such Shareholder's or his or her spouse's parents, grandparents, or siblings or any lineal descendants (natural or adopted) of the foregoing individuals, or to an inter-vivos trust established on behalf of any of such individuals;
      c. a guardian of such Shareholder's estate;
      d. an inter-vivos trust primarily for such Shareholder's benefit;
      e. a charitable trust pursuant to a bona fide gift by the Shareholder to such trust; or
      f. the estate, beneficiaries, heirs or legatees of such Shareholder; provided, however, that, in each of the above cases provided (a) through (c) above, any such transferees shall receive and hold the Restricted Shares subject to the terms of this Agreement, and there shall be no further transfer of such Restricted Shares except in accordance with the terms of this Agreement.

D. Except as expressly provided in Section VI.A, any transferee of Restricted Shares, regardless of the method by which said transferee acquired said Restricted Shares, shall be subject to the terms of this Agreement, and shall, prior to the receipt of

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any of such Restricted Shares, agree in writing to be bound by the terms hereof by execution of an Adoption Agreement in the form attached as Exhibit A hereto. Any purported Sale or transfer which does not comply with this provision shall be null and void.

VII. Anti-Dilution Option.

A. With respect to any issuance or portion thereof (other than an Excluded Issuance, as defined below) by the Corporation of shares of its Common Stock, securities convertible into Common Stock or other equity securities or rights to acquire such Common Stock or other equity securities other than an Excluded Issuance (collectively such securities or rights shall be the "New Securities"), Significant Shareholders may elect to subscribe for and purchase for the issuance price offered by the Corporation a portion of such New Securities sufficient to maintain the Significant Shareholder's Ownership Ratio (as defined below).

B. The Secretary of the Corporation shall give each Significant Shareholder thirty (30) days written notice before making any sale or offering of New Securities and shall advise the Shareholder of his or her rights under this Section VII to participate in such offering. The notice shall describe the price and the terms which the Corporation proposes to Sell such shares of New Securities together with a calculation of the Shareholder's Ownership Ratio and the number of shares he would be allowed to purchase under this Section VII to maintain his or her Ownership Ratio after such sale was complete. Each Significant Shareholder then shall have fifteen (15) days after the date of the notice to advise the Corporation in writing whether the Shareholder will exercise his or her rights hereunder and to deliver payment in full for the shares of New Securities he or she elects to purchase. If a Significant Shareholder fails to deliver payment for his or her portion of the New Securities within the requisite time period, the Corporation shall proceed with the offering of such New Securities according to the plan described in the notice delivered to the Significant Shareholders and the Significant Shareholder failing to exercise such rights shall have no further special purchase rights under this Section VII in connection with such offering.

C. For purposes of this Section VII, the following definitions shall apply:

1. "Excluded Issuance" means (A) any shares issued as stock dividends or pursuant to stock splits, recapitalization or other similar events that do not adversely

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affect the Ownership Ratio of the Shareholders; (B) securities issued pursuant to a firmly underwritten public offering; (C) Common Stock issuable directly to, or upon the exercise of any warrants or options held by, employees, directors or consultants of the Corporation as compensation or otherwise, but not in excess of _____ shares (appropriately adjusted for any Recapitalization) in the aggregate; (D) securities issued by the Corporation to Persons who are not Affiliates of a Shareholder as consideration in connection with a bona fide business acquisition, whether by merger, stock purchase, asset acquisition or similar transaction; (E) securities issued to Persons having rights in the technology covered by any license agreement between the Corporation and Parent; (F) securities issued pursuant to conversion or exercise of convertible or exercisable securities outstanding on the date hereof or issued upon satisfaction of the terms of this Section VII; (G) securities issued to Persons who are not Affiliates of a Shareholder that are financial institutions, lessors or vendors in connection with commercial credit arrangements, equipment financings or any exchange of securities for services; and (H) securities issued to a strategic partner who are not Affiliates of a Shareholder in connection with a license agreement, joint marketing agreement or other strategic relationship.

2. "Ownership Ratio" means the ratio of (A) the sum of all shares of Common Stock held by a Shareholder (including for this purpose any shares of Common Stock or other equity securities which could be acquired upon conversion of any securities convertible into Common Stock or other equity securities or exercise of any rights to acquire Common Stock or other equity securities), to (B) all outstanding shares of Common Stock in the Corporation (including for this purpose any shares of Common Stock or other equity securities which could be acquired upon conversion of any of the Corporation's securities convertible into Common Stock or other equity securities or exercise of any rights issued by the Corporation to acquire Common Stock or other equity securities).

VIII. Voting Agreement.[22]

A. So long as this Section VIII is in effect, each Shareholder will vote all of the Shareholder's Restricted Shares and take all other necessary or desirable actions (in his or her capacity as a shareholder of the Corporation), and the Corporation

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will take all necessary or desirable actions as are reasonably requested and are within its control to cause the Corporation's Board of Directors to consist of up to _____ members, and to cause the following individuals to be elected to the Corporation's Board of Directors, whether such election occurs at an annual or special meeting of the Shareholders, or by written consent in lieu thereof, and whether or not such election shall occur because of the existence of a vacancy on such Board arising for any reason whatsoever:

1. ____ individual(s) designated by the Institution ("Institution Designee(s)");
2. _____ individual(s) designated by the holders of a majority of the Common Stock ("Common Stock Designee(s)");
3. _____ individual(s) designated by the holders of a majority of the Series A Preferred Stock of the Corporation ("Series A Designee(s)");
4. additional individuals as necessary; and
5. the Chief Executive Officer of the Corporation.

B. Each Shareholder will vote all of the Shareholder's Restricted Shares, and the Corporation will take all necessary or desirable actions, as are reasonably requested to prevent the removal, with or without cause, of any of the designees named pursuant to Section VIII.A without the prior written consent of the Parties (or a majority in the case of the Common Stock Designee(s) or the Series A Designee(s)) entitled to designate such designee.

C. Each Shareholder will retain at all times the right to vote the Shareholder's Restricted Shares in his or her sole discretion on all matters presented to the Corporation's Shareholders for a vote other than the matters set forth in Section VIII.A and VIII.B above, except as otherwise limited or controlled by the Corporation's Articles of Incorporation or Bylaws, as amended from time to time.

D. Notwithstanding the foregoing, the Corporation's shareholders, including the Shareholders, may, in accordance with the [State Statute], vote to increase the size of the Board of Directors. The vacancies created thereby may be filled as provided in the Corporation's Articles of Formation and Bylaws.

E. Notwithstanding the foregoing, the Institution Shareholders will not be subject to the voting agreement and other provisions set forth in Sections VIII.A and VIII.B above.[23]

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IX. Legend on Stock Certificates. The Corporation will cause to appear on all stock certificates representing the Restricted Shares a conspicuous legend in such form as the Board of Directors may determine, stating that such shares are subject to an agreement which restricts the transferability and voting of the shares and otherwise circumscribes the rights which may be exercised by the holder thereof.

X. Specific Enforcement. In view of the inadequacy of money damages, and in view of the fact that the stock of the Corporation cannot be readily purchased or Sold in the general market, if any Shareholder (a "Breaching Shareholder") or other Person shall fail to comply with the provisions of Sections II, III, IV, V, VI or VIII hereof, the Corporation and the other non-breaching Shareholders shall be entitled, to the extent permitted by applicable law, to injunctive relief in the case of the violation, or attempted or threatened violation, by a Breaching Shareholder or other Person of any of the provisions of such Sections, or to a decree compelling specific performance by a Breaching Shareholder or other Person of any such provisions, or to any other remedy legally allowed to them.

XI. Void Transfers. If any Restricted Shares shall be Sold otherwise than in accordance with the terms and conditions of this Agreement, such Sale shall be void. The Persons who would otherwise have been Offerees hereunder regarding such Restricted Shares shall, instead of treating such Sale as a nullity, have the right, exercisable at any time prior the expiration of six (6) months after first receiving written or other notice of such disposition, to purchase such Restricted Shares at such price and in all other respects as if the Restricted Shares had been disposed of in accordance with the terms and conditions of this Agreement. Such right shall constitute an "adverse claim" within the meaning of such term as used within the meaning of the uniform Commercial Code of any State.

XII. Unique Consideration. If the consideration to be received in any proposed Sale by a Selling Shareholder pursuant to Sections III, IV or V hereof is other than money or promissory notes, and involves a consideration which is unique and the value of which cannot be readily determined by the Corporation and the Shareholders (e.g., stock in a closely held corporation or an interest in land), then the Corporation and the Shareholders may, for the purposes of this Agreement, be deemed to meet the purchase price offer to the Selling Shareholder by paying cash in an amount equal to the fair market value of the unique consideration proposed to be furnished to the Selling Shareholder in the proposed

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transaction. The determination of the value of the unique consideration shall be made by a third Person selected by agreement of the Corporation, and the holders of at least 51% of the outstanding voting stock of the Corporation (and, if applicable, the personal representative of a deceased Shareholder). If there is no agreement on a third party, then the determination shall be made by an independent appraiser selected by the Corporation's Board of Directors. In the event of an appraisal or other determination of value pursuant to this Section XII by a third party or independent appraisal, the time periods provided in Sections III, IV or V hereof shall be extended for such period of time as is reasonably necessary to complete such appraisal or determination of value.

XIII. Spouses. The spouses of the Shareholders, if any, are fully aware of, understand, and fully consent and agree to the provisions of this Agreement and its binding effect upon any community property interest they may now or hereafter own. They agree that the termination of their marital relationship with any Shareholder for any reason or their death shall not have the effect of removing any stock of the Corporation otherwise subject to this Agreement from its coverage. Their awareness, understanding, consent and agreement are evidenced by their signing this Agreement. All stock described in this Agreement shall include the community property interest of the spouse of a Shareholder. Furthermore, each Shareholder agrees that if such Shareholder marries during the term of this Agreement, such Shareholder's spouse shall sign an Adoption Agreement. If such Shareholder's spouse fails or refuses to sign such Adoption Agreement, such Shareholder shall continue to be subject to the restrictions set forth in Sections II, III and VIII, however, such Shareholder shall not be considered a Shareholder or a Significant Shareholder for purposes of exercising rights set forth in Sections IV, V, or VII or for purposes of purchasing shares pursuant to Section III, nor shall such Shareholder exercise his or her rights, if any, to designate directors pursuant to Section VIII. Upon the execution of an Adoption Agreement, such new spouse shall become a party to this Agreement and shall be bound hereby together with all of the then present parties to this Agreement as though such spouse were an original party hereto.

XIV. Notices. All notices, offers, requests, consents and other communications under this Agreement shall be in writing and shall be deemed delivered (i) three business days after being sent by registered or certified mail, return receipt requested, postage prepaid or (ii)

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one business day after being sent via a reputable overnight courier service, guaranteeing next business day delivery, in each case to the intended recipient set forth below:

(a) if to the Corporation, _____, _____, _____ _____ Attention: Secretary; and

(b) if to any Shareholder, to the address as last shown on the stock record books of the Corporation, or, in each case, at such other address as may hereafter have been designated by such Shareholder most recently to the Corporation in writing, with specific reference to this Section.

XV. Amendment; Severability; Subsequent Parties.

A. Except as expressly provided herein, neither this Agreement nor any term hereof may be amended, waived or discharged other than by a written instrument signed by the Corporation and the holders of at least a majority of the Restricted Shares; provided, that no amendment to or waiver or discharge of any provision of this Agreement that would have a materially adverse impact on the rights of Parent, Institution, or their an Institution Shareholder shall be effective without the written consent of Institution. In the event that any provisions hereof are held to be invalid, illegal or against public policy, the remaining provisions hereof shall not be affected thereby. In such event, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible with respect to those provisions which were held to be invalid, illegal or against public policy.

B. Notwithstanding anything herein to the contrary, the Corporation shall not issue any equity securities of the Corporation to any Person unless such Person becomes a party to this Agreement, and this Agreement shall be amended to include any and all future holders of equity securities of the Corporation. In such instances, such Persons and the Corporation shall execute an Adoption Agreement in the form of Exhibit A hereto adding such Persons as a party to this Agreement; provided, however, that an Adoption Agreement may, in the Corporation's sole discretion, exclude a Shareholder from the obligation to vote his, her or its Restricted Shares pursuant to Section VIII of this Agreement.[24] Each Shareholder hereby constitutes and appoints the Corporation such Shareholder's agent and attorney-in-fact with full power and authority, in the name, place and stead of such Shareholder to

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execute such Adoption Agreement on behalf of such Shareholder to evidence such Shareholder's approval of such additional parties to this Agreement. The foregoing power of attorney is hereby declared to be irrevocable and a power coupled with an interest. Upon execution by the Corporation and the additional party of such Adoption Agreement, the additional party shall be considered a Shareholder hereunder, and all shares of capital stock owned by such additional party shall be deemed to be Restricted Shares, and legended accordingly, for all purposes of this Agreement.

XVI. Agreements by Corporation. The Corporation, insofar as is proper or required, consents to this Agreement. It shall not issue, transfer or reissue any of its shares of stock in violation of this Agreement or without requiring proof of compliance with this Agreement. All stock certificates of the Corporation issued to or held by a Shareholder during the life of this Agreement shall be endorsed as stated above.

XVII. Effectiveness; Termination. This Agreement shall become effective as of the date first set forth above, **[provided that it is executed before or after such date by the Corporation and each shareholder of the Corporation] [provided, however, that Section IV of this Agreement shall be effective only when the holders of all of the outstanding shares of Common Stock have agreed in writing to be bound by all the terms of this Agreement].** Except as otherwise provided herein, this Agreement shall terminate upon the earlier to occur of (i) the closing of the first public offering of the Corporation's Common Stock pursuant to a firm commitment underwriting and an effective registration statement under the Securities Act of 1933, as amended; or (ii) the written approval of the Corporation and the holders of at least 75% of the then outstanding shares of voting stock of the Corporation that are subject to this Agreement; provided, that no termination pursuant to subsection (ii) shall be effective without the written consent of Institution.

XVIII. Construction. Each Party has had the opportunity review this Agreement with legal counsel. This Agreement shall not be construed or interpreted against any Party on the basis that such Party drafted or authored a particular provision, parts of or the entirety of this Agreement.

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XIX. Relationship with Bylaws. In the event of a conflict between a provision of this Agreement and the provisions of the Corporation's Bylaws, the provisions of this Agreement shall be controlling.

XX. Miscellaneous. This Agreement (a) constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, among the Parties with respect to the subject matter hereof, (b) may be executed in several counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same instrument, (c) shall inure to the benefit of and be binding upon, the successors, assigns, legatees, distributees, legal representatives and heirs of each Party and is not intended to confer upon any Person, other than the Parties and their permitted successors and assigns, any rights or remedies hereunder, (d) **shall be governed in all respects, including valid interpretation and effect, by the laws of the State of _____, without regard to conflict of laws principles** and (e) the _____ state courts of _____ County, _____ (or, if there is exclusive federal jurisdiction, the United States District Court for _____) shall have exclusive jurisdiction and venue over any dispute arising out of this Agreement, and the parties hereby consent to the jurisdiction of such courts. The captions in this Agreement are for convenience of reference only and shall not affect its interpretation in any respect.

IN WITNESS WHEREOF, the undersigned have hereunto set their hands as of the day and year first above written.

SPIN-OUT, INC.

By:_____

Printed Name:_____

Title:_____

shareholder Signature page to
SPIN-OUT, INC. shareholders agreement
SHAREHOLDERS:

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RESEARCH INSTITUTION

By:_____

_____, President

By:_____

Printed Name: _____

_____

Signature of Spouse (if applicable)

By:_____

Printed Name: INVENTOR

_____

Signature of Spouse (if applicable)

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EXHIBIT A

Adoption Agreement

This Adoption Agreement ("Adoption") is executed pursuant to the terms of that certain Shareholders Agreement, dated as of _____, 20___, by and among Spin-Out, Inc., a _____ corporation (the "Corporation"), and the Shareholders (as defined therein) ("Shareholders"). By the execution of this Adoption Agreement, the undersigned agrees as follows:

1. Acknowledgment. The undersigned acknowledges that it is acquiring certain shares of the Common Stock of the Corporation, subject to the conditions of the terms and conditions of the Shareholders Agreement.

2. Agreement. The undersigned (i) agrees that the shares of the Common Stock of the Corporation acquired by it shall be bound by and subject to the terms of the Shareholders Agreement, and (ii) hereby adopts the Shareholders Agreement with the same force and effect as if were originally a party thereto and named as a Shareholder therein.

3. Notice. Any notice required as permitted by the Shareholders Agreement shall be given to the undersigned at the address listed beside the undersigned's signature below.

4. Joinder. The spouse of the undersigned, if applicable, executes this Adoption Agreement to acknowledge its fairness and that it is in such spouse's best interests and to bind such spouse's community interest, if any, in any shares of the Common Stock of the Corporation, to the terms of the Shareholders Agreement.

EXECUTED and DATED as of _____, 20__.

PURCHASER OR TRANSFEREE:

By:_____
Name: _____
Address:_____

SPOUSE:

By:_____
Name: _____
Address:_____

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Agreed to on behalf of the Corporation and all Shareholders and their respective spouses pursuant to Section XV.B of the Shareholders Agreement.

SPIN-OUT, INC.
(for itself and as Attorney-in-Fact for the Shareholders)

By:_____
Name: _____
Address:_____

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Annex E. Registration Rights Agreement

Registration Rights Agreement

THIS REGISTRATION RIGHTS AGREEMENT (this "Agreement"), dated as of _____ ___, 2010, is entered into by and between Spin-Out, Inc, a _____ corporation (the "Company"), and the Research Institution (the "Institution").

WHEREAS, the Institution requires that the Company grant the rights contained herein as a condition to acquiring the securities of the Company pursuant to the license of certain technology by the Company from Institution of even date herewith;

WHEREAS, the Company's Board of Directors has determined that entering into this Agreement is in the best interests of the Company; and

WHEREAS, the Company and the Institution desire to provide for certain arrangements with respect to the registration of shares of capital stock of the Company under the Securities Act;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained in this Agreement, the parties hereto agree as follows:

I. Certain Definitions.

As used in this Agreement, the following terms shall have the following respective meanings:

"Assignee" means a person to whom Shares have been transferred in accordance with Section IV hereof.

"Commission" means the Securities and Exchange Commission, or any other federal agency at the time administering the Securities Act.

"Common Stock" means the common stock, $_____ par value per share, of the Company.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, or any successor federal statute, and the rules and regulations of the Commission issued under such Act, as they each may, from time to time, be in effect.

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"Initial Public Offering" means the initial public offering of shares of Common Stock pursuant to a firm commitment underwriting and an effective Registration Statement.

"Prospectus" means the prospectus included in any Registration Statement, as amended or supplemented by an amendment or prospectus supplement, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus

"Registration Statement" means a registration statement filed by the Company with the Commission for a public offering and sale of securities of the Company (other than a registration statement on Form S-8 or Form S-4, or their successors, or any other form for a similar limited purpose, or any registration statement covering only securities proposed to be issued in exchange for securities or assets of another corporation).

"Registration Expenses" means the expenses described in Section II.C.

"Registrable Shares" means (i) the Shares and (ii) any other shares of Common Stock issued in respect of the Shares (because of conversions stock splits, stock dividends, reclassifications, recapitalizations, or similar events); provided, however, that shares of Common Stock that are Registrable Shares shall cease to be Registrable Shares upon (i) any sale pursuant to a Registration Statement or Rule 144 under the Securities Act or (ii) any sale in any manner to a person or entity which, by virtue of Section V of this Agreement, is not entitled to the rights provided by this Agreement.

"Securities Act" means the Securities Act of 1933, as amended, or any successor federal statute, and the rules and regulations of the Commission issued under such Act, as they each may, from time to time, be in effect.

"Selling Stockholder" means any Stockholder owning Registrable Shares included in a Registration Statement.

"Shares" shall mean the shares of Common Stock issued to the Stockholders as of the date hereof and any Capital Stock subsequently acquired by the Stockholders.

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"Stockholders" means the Institution and the Assignees.[25]

II. Registration Rights.

A. *Incidental Registration.*

1. Whenever the Company proposes to file a Registration Statement, at any time and from time to time, it will, prior to such filing, give written notice to all Stockholders of its intention to do so. Upon the written request of a Stockholder or Stockholders given within thirty (30) days after the Company provides such notice (which request shall state the intended method of disposition of such Registrable Shares), the Company shall use its reasonable best efforts to cause all Registrable Shares which the Company has been requested to register by such Stockholder or Stockholders to be registered under the Securities Act to the extent necessary to permit their sale or other disposition in accordance with the intended methods of distribution specified in the request of such Stockholder or Stockholders; provided that the Company shall have the right to postpone or withdraw any registration effected pursuant to this Section II.A without obligation to any Stockholder.
2. If the registration for which the Company gives notice pursuant to Section II.A.1 is a registered public offering involving an underwriting, the Company shall so advise the Stockholders as a part of the written notice given pursuant to Section II.A.1. In such event, the right of any Stockholder to include its Registrable Shares in such registration pursuant to Section II.A shall be conditioned upon such Stockholder's participation in such underwriting on the terms set forth herein. All Stockholders proposing to distribute their securities through such underwriting shall (together with the Company) enter into an underwriting agreement in customary form with the underwriter or underwriters selected for the underwriting by the Company. Notwithstanding any other provision of this Section II.A, if the managing underwriter determines that marketing factors require a limitation of the number of Shares to be underwritten, the Company may limit the number of Registrable Shares to be included in the registration and underwriting. The Company shall so advise all holders of Registrable Shares requesting registration, and the number of shares that are entitled to be included in the registration and underwriting shall be allocated in the following manner. The number of shares that may be included in such registration and under-

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writing shall be allocated first to holders of the Company's preferred stock,[26] if any, requesting registration and having registration rights superior to the registration rights of the Stockholders, and then among the Stockholders requesting registration in proportion, as nearly as practicable, to the respective number of shares of Registrable Securities that they held at the time the Company gave the notice specified in Section II.A.1. If any Stockholder would thus be entitled to include more securities than such Stockholder requested to be registered, the excess shall be allocated among other requesting Stockholders pro rata in the manner described in the preceding sentence. If any holder of Registrable Shares disapproves of the terms of any such underwriting, such person may elect to withdraw therefrom by written notice to the Company, and any Registrable Shares or other securities excluded or withdrawn from such underwriting shall be withdrawn from such registration.

B. *Registration Procedures.*

1. If and whenever the Company is required by the provisions of this Agreement to use its reasonable best efforts to effect the registration of any Registrable Shares under the Securities Act, the Company shall:
   a. as expeditiously as reasonably possible furnish to each Selling Stockholder such reasonable numbers of copies of the Prospectus, including any preliminary Prospectus, in conformity with the requirements of the Securities Act, and such other documents as such Selling Stockholder may reasonably request in order to facilitate the public sale or other disposition of the Registrable Shares owned by such Selling Stockholder;
   b. as expeditiously as reasonably possible to register or qualify the Registrable Shares covered by the Registration Statement under the securities or Blue Sky laws of such states as the Selling Stockholders shall reasonably request; provided, however, that the Company shall not be required in connection with this paragraph (b.) to qualify as a foreign corporation or execute a general consent to service of process in any jurisdiction;
   c. as expeditiously as reasonably possible, cause all such Registrable Shares to be listed on each securities exchange or automated quotation system on which similar securities issued by the Company are then listed;
   d. promptly provide a transfer agent and registrar for all such Registrable Shares not later than the effective date of such registration statement;

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f. notify each Selling Stockholder, reasonably promptly after it shall receive notice thereof, of the time when such Registration Statement has become effective or a supplement to any Prospectus forming a part of such Registration Statement has been filed; and

e. notify each seller of such Registrable Shares of any request by the Commission for the amending or supplementing of such Registration Statement or Prospectus.

2. If the Company has delivered a Prospectus to the Selling Stockholders and after having done so the Prospectus is amended to comply with the requirements of the Securities Act, the Company shall reasonably promptly notify the Selling Stockholders and, if requested, the Selling Stockholders shall immediately cease making offers of Registrable Shares and return all Prospectuses to the Company. The Company shall reasonably promptly provide the Selling Stockholders with revised Prospectuses and, following receipt of the revised Prospectuses, the Selling Stockholders shall be free to resume making offers of the Registrable Shares.

3. If, in the judgment of the Company, it is advisable to suspend use of a Prospectus included in a Registration Statement due to pending material developments or other events that have not yet been publicly disclosed and as to which the Company believes public disclosure would be detrimental to the Company, the Company shall notify all Selling Stockholders in writing to such effect, and, upon receipt of such notice, each such Selling Stockholder shall immediately discontinue any sales of Registrable Shares pursuant to such Registration Statement until such Selling Stockholder has received copies of a supplemented or amended Prospectus or until such Selling Stockholder is advised in writing by the Company that the then current Prospectus may be used and has received copies of any additional or supplemental filings that are incorporated or deemed incorporated by reference in such Prospectus. The Company, as expeditiously as reasonably possible, shall advise the Selling Stockholders that use of the then current Prospectus may be resumed or deliver copies of a supplemented or amended Prospectus.

C. *Allocation of Expenses.* The Company will pay all Registration Expenses for all registrations under this Agreement. For purposes of this Section II.C, the term "Registration Expenses" shall mean all expenses incurred by the Company in

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complying with this Agreement, including, without limitation, all registration and filing fees, Nasdaq and exchange listing fees, printing expenses, fees and expenses of counsel for the Company, compensation of the employees of the Company, state Blue Sky fees and expenses, and the expense of any special audits incident to or required by any such registration, but excluding underwriting discounts, selling commissions and the fees and expenses of Selling Stockholders' own counsel.

D. *Indemnification and Contribution.*

1. In the event of any registration of any of the Registrable Shares under the Securities Act pursuant to this Agreement, the Company will indemnify and hold harmless the seller of such Registrable Shares and each of its officers, directors, employees and partners, each underwriter of such Registrable Shares, and each other person, if any, who controls such seller or underwriter within the meaning of the Securities Act or the Exchange Act against any losses, claims, damages or liabilities, joint or several, to which such seller, underwriter or controlling person may become subject under the Securities Act, the Exchange Act, state securities or Blue Sky laws or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in any Registration Statement under which such Registrable Shares were registered under the Securities Act, any preliminary prospectus or final prospectus contained in the Registration Statement, or any amendment or supplement to such Registration Statement, or arise out of or are based upon the omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and the Company will reimburse such seller, underwriter and each such controlling person on at least a quarterly basis for any legal or any other expenses reasonably incurred by such seller, underwriter or controlling person in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any untrue statement or omission made in such Registration Statement, preliminary prospectus or prospectus, or any such amendment or supplement, in reliance upon and

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in conformity with information furnished to the Company, in writing, by or on behalf of such seller, underwriter or controlling person specifically for use in the preparation thereof.

2. In the event of any registration of any of the Registrable Shares under the Securities Act pursuant to this Agreement, each seller of Registrable Shares, severally and not jointly, will indemnify and hold harmless the Company, each of its directors and officers and each underwriter (if any) and each person, if any, who controls the Company or any such underwriter within the meaning of the Securities Act or the Exchange Act, against any losses, claims, damages or liabilities, joint or several, to which the Company, such directors and officers, underwriter or controlling person may become subject under the Securities Act, Exchange Act, state securities or Blue Sky laws or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement under which such Registrable Shares were registered under the Securities Act, any preliminary prospectus or final prospectus contained in the Registration Statement, or any amendment or supplement to the Registration Statement, or arise out of or are based upon any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, if the statement or omission was made in reliance upon and in conformity with information relating to such seller furnished in writing to the Company by or on behalf of such seller specifically for use in connection with the preparation of such Registration Statement, prospectus, amendment or supplement; provided, however, that this indemnity shall be limited by the applicable provisions of the Constitution and laws of the State of _____;[27] provided further, however, that the indemnity contained in this section shall not apply to amounts paid in settlement of any such claim, loss, damage, liability or action if such action is effected without the consent of the applicable Selling Stockholder (which consent shall not be unreasonably withheld); provided further, however, that the obligations of a Selling Stockholder hereunder shall be limited to an amount equal to the net proceeds (after deducting the underwriters' discount but without deduction of other expenses) to such Selling Stockholder of Registrable Shares sold in connection with such registration.

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3. Each party entitled to indemnification under this Section II.D (the "Indemnified Party") shall give notice to the party required to provide indemnification (the "Indemnifying Party") promptly after such Indemnified Party has actual knowledge of any claim as to which indemnity may be sought, and shall permit the Indemnifying Party to assume the defense of any such claim or any litigation resulting therefrom; provided, that counsel for the Indemnifying Party, who shall conduct the defense of such claim or litigation, shall be approved by the Indemnified Party (whose approval shall not be unreasonably withheld); and, provided, however, that the failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Section II.D except to the extent that the Indemnifying Party is adversely affected by such failure. The Indemnified Party may participate in such defense at such party's expense; provided, however, that the Indemnifying Party shall pay such reasonable expense if representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceeding; provided, however, that in no event shall the Indemnifying Party be required to pay the expenses of more than one law firm per jurisdiction as counsel for the Indemnified Party. The Indemnifying Party also shall be responsible for the reasonable expenses of such defense if the Indemnifying Party does not elect to assume such defense. No Indemnifying Party, in the defense of any such claim or litigation shall, except with the consent of each Indemnified Party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect of such claim or litigation, and no Indemnified Party shall consent to entry of any judgment or settle such claim or litigation without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld.

E. *Information by Stockholder*. Each Selling Stockholder shall furnish to the Company such information regarding such Selling Stockholder and the distribution proposed by such Selling Stockholder as the Company may reasonably request in writing and as shall be required in connection with any registration, qualification or compliance referred to in this Agreement.

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F. *"Lock-up" Agreement: Confidentiality of Notices.*

1. Each Selling Stockholder, if requested by the managing underwriter of an underwritten public offering by the Company of Common Stock, hereby agrees that, for a period of not more than 180 days following the effective date of a Registration Statement for the Company's Initial Public Offering, or not more than 90 days for any other Registration Statement, it will not (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, as long as all officers, directors and five percent or greater stockholders of the Company are bound by similar provisions. In connection with this Section II.F, each Stockholder shall execute the form of lock-up agreement as may be requested by the managing underwriters, as long as all officers, directors and five percent or greater shareholders of the Company are bound by similar provisions.
2. The Company may impose stop-transfer instructions with respect to the Registrable Shares or other securities subject to the foregoing restrictions until the end of the applicable lock-up period.
3. Any Stockholder receiving any written notice from the Company regarding the Company's plans to file a Registration Statement shall treat such notice confidentially and shall not disclose such information to any person other than as necessary to exercise its rights under this Agreement.

G. *Rule 144 Requirements.* After the earliest of (i) the closing of the sale of securities of the Company pursuant to a Registration Statement or (ii) the registration by the Company of a class of securities under Section 12 of the Exchange Act, the Company agrees to comply with the following, it being understood that any failure to do so because of circumstances beyond its control shall not be regarded as being a breach of this Agreement:

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1. make and keep current public information about the Company available, as those terms are understood and defined in Rule 144;
2. file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements); and
3. so long as a Stockholder owns any Registrable Shares, to furnish to such Stockholder forthwith upon request a written statement by the Company as to its compliance with the reporting requirements of Rule 144 and of the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements), a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed by the Company as the Stockholder may reasonably request in complying with any rule or regulation of the SEC allowing the Stockholder to sell any such securities without registration;

H. *Termination.* All of the Company's obligations to register Registrable Shares under Section II.A of this Agreement shall terminate five (5) years after the closing of the Initial Public Offering.

III. Board Observation Rights. The Company shall give Institution copies of all notices, minutes, consents and other material that the Company provides to its directors at the same time and in the same manner as given to the directors. The Company shall allow an Institution representative to attend all meetings of the Company's Board of Directors as an observer, except that such representative may be excluded from access to any material or meeting or portion thereof if the Company believes, upon advice of counsel, that such exclusion is reasonably necessary to preserve the attorney-client privilege.

IV. Transfers of Rights. The rights and obligations of the Stockholders hereunder may not be assigned by any Stockholder, except to any person to whom the Stockholder transfers at least _____ Shares, which amount shall be adjusted for any stock split, stock dividend, stock combination, reverse stock split, recapitalization or similar event. Upon such assignment and transfer, such transferee shall be deemed an "Assignee" for purposes of this Agreement; provided that (i) such transferee gives written notice to the

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Company of such transfer; (ii) such transferee agrees in writing to comply with the terms and provisions of this Agreement and assumes all obligations of a Stockholder hereunder; (iii) such transfer is otherwise in compliance with this Agreement and (iv) such transfer is otherwise effected in accordance with applicable securities laws. Except as specifically set forth in this Section IV, the rights of a Stockholder with respect to Registrable Shares as set out herein shall not be transferable to any other person. Except as otherwise provided herein, this Agreement shall inure to the benefit of, and be binding upon, the successors, permitted assigns, heirs, executors and administrators of the parties hereto.

V. General.

A. *Severability.* The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.

B. *Specific Performance.* In addition to any and all other remedies that may be available at law in the event of any breach of this Agreement, the Stockholders shall be entitled to specific performance of the agreements and obligations of the Company hereunder and to such other injunctive or other equitable relief as may be granted by a court of competent jurisdiction.

C. *Governing Law.* This Agreement shall be governed by and construed in accordance with the internal laws of the State of _____[28] (without reference to the conflicts of law provisions thereof). The state courts of ____ County, ____ (or, if there is exclusive federal jurisdiction, the United States District Court for ____) shall have exclusive jurisdiction and venue over any dispute arising out of this Agreement, and the parties hereby consent to the jurisdiction of such courts.

D. *Notices.* All notices, requests, consents, and other communications under this Agreement shall be in writing and shall be deemed delivered (i) two business days after being sent by registered or certified mail, return receipt requested, postage prepaid or (ii) one business day after being sent via a reputable nationwide overnight courier service guaranteeing next business day delivery, in each case to the intended recipient as set forth below:

If to the Company, at _____, _____, _____, _____
Attention: _____, or at such other address or addresses as may have been furnished in writing by the Company to the Stockholders; or

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If to the Institution, at the Office of New Ventures, _____, _____, __ _____, Attention: _____, or at such other address or addresses as may have been furnished in writing to the Company; or

If to the other Stockholders, at their record address as maintained in the Company's stockholder records.

Any party may give any notice, request, consent or other communication under this Agreement using any other means (including, without limitation, personal delivery, messenger service, telecopy, first class mail or electronic mail), but no such notice, request, consent or other communication shall be deemed to have been duly given unless and until it is actually received by the party for whom it is intended. Any party may change the address to which notices, requests, consents or other communications hereunder are to be delivered by giving the other parties notice in the manner set forth in this Section V.D.

E. *Complete Agreement.* This Agreement constitutes the entire agreement and understanding of the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings relating to such subject matter.

F. *Amendments and Waivers.* Any term of this Agreement may be amended or terminated and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), with the written consent of the Company, on the one hand, and Institution, on behalf of the Stockholders, on the other hand; provided, that this Agreement may be amended with the consent of the holders of less than all Registrable Shares only in a manner which applies to all such holders in the same fashion. Any such amendment, termination or waiver effected in accordance with this Section V.F shall be binding on all parties hereto, even if they do not execute such consent. Upon the effectuation of any such amendment, the Company shall promptly give written notice to the Stockholders, if any, who have not previously consented thereto in writing. No waivers of or exceptions to any term, condition or provision of this Agreement,

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in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision.

G. *Pronouns.* Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa.

H. *Counterparts:* Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. This Agreement may be executed by facsimile signatures.

I. *Section Headings.* The section headings are for the convenience of the parties and in no way alter, modify, amend, limit or restrict the contractual obligations of the parties.

[signatures on following page]

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COMPANY:
SPIN-OUT, INC.

By:_____
Print Name:_____
Title:_____

STOCKHOLDERS:
RESEARCH
INSTITUTION

By:_____
Print Name:_____
Title:_____

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Annex F. Board Observation Rights Side Letter

_____, 2010

_____

President
Research Institution

_____

_____, __ _____

Re: Board Observation Rights

Dear _____:

In consideration for Research Institution (the "Institution") entering into the Patent License Agreement (the "License") by and between the Institution and Spin-Out, Inc. (the "Company"), having an Effective Date of _____, 2010, and for other good and valuable consideration, the Company hereby agrees to allow one person designated in writing by Institution (the "Institution Observer") to attend and observe all meetings of the Company's Board of Directors.

The Company will provide Institution Observer with written notice of all meetings of its Board of Directors at the same time it provides such notice to its directors and will provide Institution Observer with all materials and documents disseminated to its directors at the same time as such materials and documents are disseminated to its directors. Institution and Institution Observer hereby agree to keep all such materials and documents provided by the Company confidential in accordance with the same confidentiality obligations of the members of the Company's Board of Directors. Notwithstanding the foregoing, the Company reserves the right to exclude the Institution Observer from access to any material or meeting or portion thereof if the Company reasonably believes, upon advice of legal counsel, that such exclusion is reasonably necessary to preserve the attorney-client privilege or creates a conflict of interest with the Institution.

The agreements set forth hereinabove will terminate and be of no further force or effect upon the earliest to occur of:

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(a) the first date the Institution, along with the Equity Recipients (as defined in the License) and Institution affiliates, holds shares representing less than five percent[29] of the outstanding shares of the Company's common stock, assuming conversion of all preferred stock but not the exercise of any outstanding options, warrants or other securities;

(b) the consummation of a firmly underwritten public offering of the Company's capital stock at a price of at least $__ per share registered pursuant to the Securities Act of 1933 and the regulations thereunder with proceeds to the Company, after payment of underwriting discounts and commissions and offering expenses, of at least $__ million.[30]

We look forward to your acknowledgement of this understanding, selection of the Institution Observer, and Institution Observer's attendance at future Company Board of Directors meetings.

Sincerely,

_____
President

AGREED AND ACCEPTED:
RESEARCH INSTITUTION

By: _____
_____, President

APPOINTMENT OF DESIGNEE:
Institution hereby appoints _____, Vice President for New Ventures, as its initial Spin-Out, Inc. Board of Directors observer designee.

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Notes

1. It is most likely that the institution will be providing initial capital to an institution-organized new venture, however, depending upon the institution's availability of capital for new ventures, the institution could also provide capital to an entrepreneur-organized new venture or to early-stage new ventures that have need for capital in order to commercialize the institution's technology.
2. If the Next Equity Financing is a milestone in the license agreement that allows termination of the license if it is not met, then converting the bridge loan note into common stock will only have relevance if the new venture has assets and business other than the license or if the institution wants to dilute the founders and initial management and restart the new venture.
3. The stock purchase warrant provides additional equity to the institution for providing capital through the bridge loan note prior to the Series A financing. Because the bridge loan is even higher risk capital than the Series A financing, the bridge loan note provides for conversion of the amount of the loan into equity at the same valuation as the Series A financing, and the stock purchase warrant provides for additional equity without additional capital to compensate for the additional risk.
4. The term of the warrant will depend upon the business plan of the new venture. A five-year warrant would be appropriate for technology that can be quickly commercialized, but technology that requires regulatory approvals or some other lengthy commercialization process would justify up to ten years or even more. The goal is to allow the institution to exercise the warrant and sell the underlying shares in a liquidity event after the new venture has realized the potential of the technology.
5. Since the licensee's representations concerning its ownership and capitalization are as of the Effective Date, this date should be as close as possible to the date the license is signed and the date the institution's stock is to be issued to make sure that the institution's ownership percentage is what has been bargained for.
6. If the technology has been jointly developed with another research institution and if the inter-institutional agreement calls for the other institution to receive equity, then the other institution needs to be included in this definition.
7. Whether the inventors are to receive shares depends upon the policies of the institution. If an inventor is to be a founder of the new venture, provide services directly

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to the new venture, be an employee or director, or otherwise receive equity from the new venture, then provision for equity for these purposes should be separate from the license.

8. This amount will depend on the business plan of the new venture and should be sufficient for the new venture to attain the initial milestones set forth in its business plan.
9. When the only consideration coming to the institution under the license is royalty payments, it is acceptable to allow the licensee to extend the license to affiliates without requiring a sublicense. When equity is part of the institution's consideration, however, the license should be extended only to subsidiaries so that the value of the equity is preserved.
10. Obviously, the milestones will depend upon the business plan of the new venture.
11. There may be occasions, especially if the new venture already has preferred stock outstanding, that the license will call for preferred stock to be issued rather than common stock.
12. If there are commitments, such as shares set aside for management's incentive compensation, a convertible bridge loan, a stock purchase warrant, etc., then those commitments should be included in the representations and capitalization table and should be taken into account in the calculation of the number of shares to be issued to the equity recipients.
13. The concept of the "anti-dilution threshold" arises from the fact that, by definition, when licensing to a new venture the institution is licensing to an entity that does not have the capital, the management team, or other requirements to commercialize the technology. The percentage in this paragraph is based on the amount of equity the institution believes that it should receive from a fully capitalized new venture. If it turns out that the new venture has to issue more equity than its business plan called for to raise the amount of capital required, this provision will ensure that the founders and management team are diluted as a result of this miscalculation, but that the institution is not. This provision limits one of the risks of licensing to a new venture.
14. Both of these amounts should be the same as the amount that constitutes a Funding Event.
15. Both registration rights and tag-along rights are important to the institution's ability to participate in liquidity events.
16. Pre-emptive rights are only important if the institution has funds available (or plans to have funds available in the future) to invest in new ventures.

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17. Make sure that the new venture is obligated to reimburse the institution for expenses relating to organizing the new venture, negotiating the various stock ownership documents, and approving requests for consents and amendments in addition to reimbursement for patent-related expenses.
18. In the usual situation an institution wants to make sure that it knows who its licensee is and doesn't want to suddenly have the license assigned to an entity that it would not have licensed to in the first instance. In addition, when equity is involved, especially when the royalty has been reduced to increase the institution's equity, the institution does not want the new venture to prematurely sell out before the technology has been proven and the equity has attained a significant value.
19. A minority owner should only be required to participate in a sale by the controlling interest if it is a liquidity event for cash rather than a transaction involving stock or other consideration.
20 Any founders of the new venture who are crucial to the early success of the new venture should be included in this list so that their ability to liquidate is limited until the institution has an opportunity to liquidate its interest as well pursuant to the tag-along rights provisions.
21. If the institution expects to be one of the largest investors, then it may want a smaller number to trigger a liquidity event. If not, it is usually better to require a larger number, because even though the institution would like an early liquidity event, it does not want a premature sale of the new venture before the value of the institution's equity has had a large jump in value.
22. Although not unprecedented, it is not normal to have a voting provision in a shareholder agreement, and it is not recommended for the institution to have one unless the institution desires to have a strong role in management or the management of the new venture insists on having such a provision. For the institution, the decision to have a role in management of the new venture includes the media risk discussed in the next footnote.
23. If the institution has decided not to designate a director, it generally would also not want to be required to vote for the other designees. An institution that does not want to be accused in the media of being responsible for an unsuccessful new venture does not want to be in the position of having to explain why it voted for the directors of an

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unsuccessful new venture, especially if one of the directors is accused of inappropriate action. For that reason, the institution should not be required to vote for the management's slate of directors unless that obligation is in exchange for the other shareholders voting for the institution's designee(s).

24. This exception is important if the institution wants to be excluded from Section VIII and is to receive its shares after the original execution of the shareholder agreement. For example, the entrepreneur may negotiate an option for the license, sign the shareholder agreement upon organization of the new venture, and the institution becomes a party to the shareholder agreement after the option is exercised and the institution's shares are issued.
25. Note that the inventors and others receiving stock through the license are not included and, therefore, do not receive registration rights. On the one hand, the institution may want to ensure that everyone receiving stock through the license receives the same rights as does the institution, on the other hand, the new venture and Series A investors may not want small investors to have registration rights. The institution will have to decide its position on this issue.
26. Note that this document, which will generally be signed in advanced of the closing of the Series A financing, nonetheless is subordinate to the subsequent Series A investors. This subordination is usually the final result of any negotiation with the Series A investors, and often an experienced management team will raise this issue at the time this document is negotiated. In general, it is better to capitulate on this issue in advance than to create an issue with potential Series A investors.
27. In many states, the doctrine of sovereign immunity will apply to state institutions. It is best to include a reference to this issue, and many state institutions' legal departments have obligatory form language dealing with the issue.
28. Although the institution is generally more comfortable with the laws of its own state applying to the agreement, it is generally not a problem for the laws of the state of incorporation of the new venture to apply to corporate documents, especially if it is incorporated in Delaware.
29. There comes a point at which the institution's investment is too small to justify board observation rights, both from the standpoint of the institution and the new venture. Although this percentage will depend upon the specific business plan of the new venture, 5 percent is a good rule of thumb.

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30. Filling in these blanks will depend upon the specific business plan for the new venture. Often the investment documents will contain a definition of IPO, which the definition in the observation rights side letter should track.

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Funding for University Startups

David B. Lerner and Andres Soto

David B. Lerner is director and Andres Soto is assistant director of the Venture Lab for Columbia Technology Ventures in New York City.

Introduction

Obtaining funding for university spinoffs is generally quite difficult and requires a comprehensive approach on the part of the technology transfer office. It also requires understanding the marketplace and the realities of how the process works. This is very different from traditional and often exaggerated discussions regarding funding of university spinoffs. Each year at university and venture events held around the country a great deal of university technology transfer offices report an astoundingly high amount of venture-backed startups. Audiences there, often comprised of university personnel and entrepreneurs, emerge with a very unrealistic picture of the process.

The truth is university spinoffs rarely emerge from the academy with true venture backing—this is the exception rather than the rule. The overwhelming majority of university spinoffs emerge from the academy with angel and/or entrepreneur funding. The hope is that after a year or more of development some percentage of these spinoff companies will be ready for a traditional institutional venture financing.

Is it true that sometimes an appealing mix of an extraordinary technology and an experienced and committed team results in a university spinout with institutional venture financing? Yes, this does happen, but most of the heavy lifting at this nascent stage is done by angels and/or angel entrepreneurs.

The emphasis on venture financing thus misses this essential point and contributes to the fact that many technology transfer offices do not recognize the importance of angels and angel entrepreneurs to this ecosystem.

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Another major emphasis is on the resource requirements of technology transfer offices seeking to focus on spinouts. The technology transfer office needs to have a dedicated person or persons on staff in the form of a new ventures/venture lab type group to handle the startup and investment activity of the office.

Foundation: Cultivating and Supporting an Entrepreneurial Culture on Campus

Inventors

It may at first seem obvious, but while intellectual property may provide a commercial advantage, a key to success for a startup is transferring the actual know-how to the new venture. This know-how typically resides with the inventor and the people in his or her lab who, over the years, have developed intimate knowledge of the technology. A fundable startup will often require someone from the lab to eventually dedicate himself or herself full time to the venture. In most cases this key person is a member of the research team who is completing his or her studies or a postdoctorate student intent on a career in industry.

Institutional Commitment

Technology transfer as a profession is relatively young, and the practice of spinning off startups is even younger. To create successful startups, universities need to have policies and programs in place that give new ventures the best possible chance of securing funding. Policies in this area include allowing inventors to participate in early-stage companies provided there is no unreasonable conflict of interest, as well as allowing the technology transfer office to provide company formation advice. Universities also ought to have programs that foster entrepreneurship. Such programs can include business plan competitions, incubation space, validation funds, seed funds, mentorship programs, etc. The key is to provide an environment where there are a minimum of institutional barriers to startup formation.

Having the Right People and the Need for a New Ventures Office/Venture Lab

The foundation of a successful program begins with the experience and background of the people running it. We recommend having people on staff who are totally dedicated to spinning off companies and have strong entrepreneurial and investment backgrounds. These new

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ventures or venture lab people should come from the city's entrepreneurial/investment ecosystem and bring the requisite experience of having launched multiple companies and raised capital for these companies. They should be respected members of the early-stage community that investors and entrepreneurs trust and know well. They should then be the central contact for the technology transfer office for investors, entrepreneurs, and all startup activity. Essentially they act as entrepreneurs in residence and can cultivate a sophistication, vibrancy, and buzz around the program.

Entrepreneurship Office Hours: Outreach

The new ventures team should offer entrepreneur office hours to the university community. This is a terrific way of creating awareness on campus that the technology transfer office is a welcoming place that cultivates entrepreneurship on campus. Instead of a transactional atmosphere, a welcoming and startup-friendly atmosphere is created. This establishes an environment where anyone associated with the university—including adjunct faculty, undergraduate and graduate students, faculty, alumni, and the like—can share their startup ideas with the office and receive assistance, advice, and mentorship. Remarkably, it also has the benefit of getting faculty to emerge from the woodwork and helps cultivate deeper relationships with them over time.

Crosspollination across Schools and Campuses

It is also important for the new ventures/venture lab team to establish relationships with the various deans and department chairs around campus. By making occasional departmental visits, faculty members will be encouraged to keep their eyes open for startup opportunities and reinforce recognition of startup services available on campus.

Collaboration with Other Universities and Industry

Technology transfer is one of few industries in which competition does not play a dominant role. This is to say that value can often be increased by collaborating with other universities and, in many cases, is required when an inventor's work is done at more than one university. On the licensing side, this is commonly done, but in the startup arena this can be critical for success. Very rarely does an inventor discover a truly disruptive technology that will be sufficient on its own to form the basis of a company. Often there are other enabling discoveries in other fields or labs, and often there is more work to be done

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to establish proof of concept. Investigators are often well-connected with the thought leaders in their field both in industry and academia. It is important, therefore, to explore and identify other enabling technologies in other universities, companies, and industries that together can turn an interesting idea into a company with reasonable chances for success and, therefore, have a higher likelihood of being funded.

Incubation

More universities are taking a hands-on approach and provide additional support to start-ups after they begin operations. In many cases, this leads to the creation of an incubator or venture lab. While some universities take on a more virtual approach, others go so far as to provide funding, office space, and other resources such as mentorship and student involvement. An example of a best-in-class program is the Advanced Technology Development Center at Georgia Tech. This program attempts to be a focal point for entrepreneurship in the community. It does this by identifying promising technologies and joining them with talented entrepreneurs, student teams, development grants, and other resources.

Presence in the Entrepreneurial, Angel, and Venture Capital Community

The Importance of Venture Mentors

The venture lab/new ventures group should also cultivate relationships venture advisers/mentors with domain expertise and who are willing to assist with positioning emerging pipeline opportunities. It's important to have these go-to people as advisers/mentors as they offer real-life market-savvy insights about the value of technologies and help position them properly. Most mentors are happy to do this for free as it brings them close to the program and provides them with a first look at projects emerging from the university.

Stable of Talented People with Applicable Skills

There is no such thing as a permanent stable of talented entrepreneurs as there is rapid changeover in this community. Nevertheless it is very useful to maintain a flexible list of talented entrepreneurs who have an appetite for spinning companies out of a university.

Events and Resources

The venture lab/new ventures staff should always attend local startup events in the town or city where the university is located. Being a regular, steady presence at these events is

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important as it raises the profile of the venture lab program and its pipeline opportunities in the early-stage community. This will also lead to many opportunities to work with talented entrepreneurs and investors—all of whom are the lifeblood of a successful program. In many cases the university is a central part of the community. In such circumstances, the venture lab can serve as a focal point for entrepreneurship and startup activity.

Identifying Legitimate Startup Opportunities: It Starts Early

Many factors determine whether an opportunity is suitable for a startup.

Solving a Significant Problem

The technology should be addressing a real problem in the industry, as opposed to being a solution looking for a problem.

Market Size

Niche markets typically don't attract investors or talented entrepreneurs who are typically looking for an addressable market of $1 billion plus.

Competitive Advantage

The technology should ideally provide what is colloquially termed an unfair competitive advantage rather than some kind of incremental advantage over an existing product.

No Logical Licensee

If the technology has a logical licensee in industry, there is no logic behind trying to create a startup. Just license it.

People/Teams and Investors for New Ventures

If much of the above criteria are in place, you should be relatively confident that you can find a talented entrepreneur and investors to launch a new venture. However, finding the right team with suitable experience and industry background is critical. Even the most promising breakthrough technology is unable to overcome the handicap of an inexperienced management team.

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Funding Scenarios

University Sources

Many universities have formed seed or validation funds over the last few years. Although there are many variations on how these funds operate, their stated missions are to bridge the gap for promising technologies. That is, provide funding for proof-of-concept studies to make the technology more commercializable. What is relatively uniform, however, is that these funds are not intended to replace grant funding—they are intended to bridge extremely promising technology from out of the lab and into a viable commercial market.

If you are a member of a university faculty with this kind of work going on in your lab, it is a good idea to inquire what the possibilities are with your technology transfer office.

Nondilutive Sources

Of course the best form of early funding for a university startup are Small Business Innovation Research (SBIR) or Small Business Technology Transfer funds in that they are nondilutive government funding. If you can get through Phase I (which involves a grant of $150,000) and get accepted into Phase II, then your company will typically receive $1 million and the government will eventually be a customer. This is ideal, and you should always check if your work fits in any of the SBIR categories put forth each year.

The Entrepreneur

Entrepreneurs and angels are the most important part of the university spinoff ecosystem. Often, they are one and the same, but angel investors are covered separately in the next section. In short, the venture lab folks should always be networking and on the lookout for talented entrepreneurs looking for their next company.

As the professor/inventor is often best-suited to remain at the university and serve as a chief scientific officer to a new venture, to have a chance for success, a university spinoff must at some point have a dedicated, talented entrepreneur to lead the company. This will be essential for both funding and eventual success as investors only back talented, experienced teams.

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Angel Investors (Individuals and Syndicates)

Angel investors are the absolute lifeblood of startups and early-stage investing in this country. Angels are the ones who get involved with entrepreneurs at the earliest, highest-risk stages of a venture, bringing that essential capital, as well as a high degree of support and enthusiasm.

It is a common misconception that university spinoffs *emerge* from the academy with venture backing. Despite an enormous amount of promotion of this in the technology transfer industry, this is the exception rather than the rule. The overwhelming majority of university spinoffs emerge from the academy with angel funding. The hope is that after a year or more of development, some percentage of such companies will be ready for a traditional institutional venture round of financing.

Is it true that sometimes an extraordinary technology and a committed team will spinout a company from the academy with institutional venture financing? Yes, it does happen and that's terrific. But again, most of this heavy lifting is done by angels and/or angel entrepreneurs at this nascent stage.

This is why it is key for the venture lab staff to come from the investment community and always be in touch with angels and entrepreneurs at local events in the city where the particular university in question is located.

It bears mentioning that in addition to independent angels, a great number of angel groups have also sprung up in cities around the country. Most of these are excellent resources, especially in areas where there is not a developed early-stage ecosystem. So long as they are not charging entrepreneurs to present, these are usually excellent forums to attend.

Venture Capital Funds

Despite the fact that very few university spinoffs get funded ab-initio by venture capital funds, it is nevertheless very important for the venture lab people to constantly be engaging with the venture community for a number of reasons. First, they develop an awareness of what the sweet spot of these funds happens to be and on occasion they will indeed have a

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hit resulting in a new venture getting funded out of the box. Second, it is likely that some of the better companies they have previously spun out have been able to generate traction in the marketplace and they can now introduce them to interested venture funds for Series A funding. This is incredibly valuable to the university's portfolio companies. Lastly, the office should always be learning from venture funds and cultivating venture mentors from that community as they can help the venture lab folks package the most promising technology in an intelligent way. Insights from venture capitalists (VCs) are incredibly valuable to the technology transfer office, and they are a vital part of the early-stage ecosystem.

When it comes to understanding what venture funds are looking for at universities, it is best to hear it from the proverbial horses' mouth so to speak.

Last year's annual University Startups Conference organized by the National Council of Entrepreneurial Tech Transfer (NCET2) was well-attended by investors and university personnel alike. Through the course of multiple panels and discussions, a good cross-section of venture investors from very reputable firms weighed in candidly on both what they like to see and what they don't like to see when they try to spinout companies from university technology transfer offices. Many colorful stories were exchanged to say the least.

Here are some highlights from that conference:

VCs like to see:

- platform technologies
- great faculty stars, great scientists, great science
- rich entrepreneurial culture and community throughout the university
- a go-to person at the technology transfer office with entrepreneurial experience
- a technology transfer office that's all about throughput and getting deals done quickly
- Deal terms that are flexible because business models change over time

VCs do not like to see:

- slow-moving offices that take too long to get a deal done
- mismatches in terms of respective legal counsel (turnaround time, skill, expertise)
- greedy technology transfer offices with onerous deal terms
- big egos at the technology transfer office that get in the way of deals
- no business plans (VCs prefer to have a short summary and decide for themselves)

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Deal Terms: Business Friendly

The reality is that *every deal is different,* and it's difficult to generate a one-size-fits-all template for deal terms. Also, the criteria for a business-friendly deal is different from industry to industry and can change with time. Be mindful that university technology transfer offices across the country vary greatly in their approach to startups: Some pursue a one-size-fits-all approach and seek to rapidly execute licenses that are the same across all industries, while others take a more tailored approach specific to each licensee.

Here are some very general guidelines to a business-friendly deal:

- In most cases a startup will seek an exclusive license to the technology for the fields in which it intends to operate. The intention is to provide an early competitive advantage to gain market share as well as make the company more fundable to later-stage and venture investors.
- In most cases you should seek to back end the economics of the deal and stay away from high upfront license fees. Startup companies are often cash poor, and aggressive fee payments can drown the company before it is able to gain traction in the marketplace.
- The entrepreneur should be prepared to partner with the university and let it have an equity stake in the company. The equity stake varies from situation to situation.
- The parties should mutually agree to some diligence milestones that specify timelines for items like first product sale and, in some cases, capital raised or revenue targets. As is often the case, the marketplace and the business plan can change. Therefore, the agreement should have built-in flexibility and not be unduly burdensome on the company.
- Royalties depend a great deal on the industry in which the company will be operating but should never be a yoke around its neck, allow it to operate with a comfortable margin.

More and more offices understand the challenges of launching a startup and, when a talented entrepreneur is at the table, increasingly have the right approach.

Royalties/Fees/Milestone Payments

Almost all startups are severely cash constrained. As such, they do not have the resources to pay upfront fees typical to a license to industry. To accommodate this fact, a university

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should seek to back end milestone payments and fees in exchange for equity. Depending on the underlying economic environment it can take from months to years for a startup to develop a viable product, and the university should structure payments to allow for product development.

On the other hand, if the startup is unable to meet these milestones, sufficient protections should be in place to recover the intellectual property (see the "Bayh-Dole Compliance: Development Milestones" section). Of course every transaction is different but payments should be structured in a way suitable to the industry. For example, royalty rates for a drug therapy will be much different from those related to software. Similarly, milestones across industries will also vary. In general, these milestones should be tied to concrete developments in the company's life and should be justified as a way for the university to participate the company's success. Examples of suitable milestone payment events are: sale of first product, investigational new drug application, 510k filing, etc.

Equity

As mentioned above, equity consideration in lieu of a substantial license fee is critical to the viability of a startup. The amount of equity that the university takes will vary according to: how essential the intellectual property is to the company's product, the relative importance of the technology to the company as a whole, and the company's stage of development.

On the other hand, in cases where the startup is already a going concern and needs a license to complement a larger intellectual property portfolio, then a very small equity stake is more suitable. In all cases, negotiating the right amount of equity is an art rather than a science and depends greatly on the underlying marketplace and the specifics to each transaction. Some offices negotiate equity stakes on a case-by-case basis while others, in order to expedite the licensing process, take a one-size-fits-all approach and take a predetermined equity stake for all transactions. I favor a case-by-case process if you are working with a broad range of technologies that touch a broad range of industries as the deal terms across industries are bound to vary greatly.

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Diligence Milestones

While all companies are formed with the most optimistic of intentions, it is well-known that most new ventures fail within a short time of being formed. The purpose of diligence milestones is to ensure that the company continues to be a going concern despite the ability to maintain payments under the license agreement. Failure to do so may result in valuable intellectual property being tied to a company that is not sound enough to commercialize it. As is the case with all licenses, these milestones need to be suitable to the industry and technology in question. Examples of diligence milestones may include: completion of a business plan, successfully raising financing across different time periods and in different amounts, successfully securing paying customers within a certain timeframe, etc.

Patent Reimbursement

Patent fees can be a significant source of anxiety for a startup company. Management often underestimates the costs related to a patent portfolio, and this can result in friction between the company and the university if the university seeks to be remunerated for patent prosecution costs. In this situation, patent prosecution remains with the university, and the company is invoiced at a later date for this activity. To avoid surprises and put undue financial strain on the startup, it is best for the university and the company to work together to determine a patent strategy that is both suitable for a competitive business as well as economically viable for the licensee.

Participation in Liquidity Events

When a university takes equity as partial compensation for a license, it becomes a shareholder in a startup. As is the case with any shareholder, it is prudent to secure rights allowing participation in liquidity events. Often the license is executed at the beginning of the company's life, and the university may or may not participate in follow-on investment rounds. Either way, as the company grows and develops into a more complicated capital structure, it is, therefore, important to think through a comprehensive list of shareholders rights. With regard to participating in the upside the following are common provisions:

Piggyback Rights

Piggyback registration rights ensures that you as an equity shareholder will be able to register your shares of common stock when the company conducts a public offering. This

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is typically not disruptive and does not require a special effort. By obtaining this right you ensure that your shares are not excluded from an initial public offering, which may be one of the few orderly ways to sell your shares.

Tag-Along Rights

Similar to piggyback rights, tag-along rights seek to ensure that a liquidity preference is not given to other shareholders ahead of yours. Most privately held companies are controlled by a single shareholder. By securing tag-along rights you ensure that if the majority shareholder sells his stake, the university will have the right to join the deal and sell its stake at the same terms and conditions. This is also a fairly standard term in a shareholder agreement.

Antidilution

The whole topic of antidilution is highly charged. In our experience, it makes sense for universities to ask for antidilution through a certain threshold of institutional funding (so long as there are no institutional investors involved ab initio).

The threshold can be through a Series A round, for example. This removes any opportunity for artful manipulation of valuations prior to professional investors arriving.

If at the time of a professional Series A the investors wish to tweak the antidilution provisions, the university should, in most cases, be willing to do so as the "goal" of avoiding mischief earlier on in the company's lifecycle has been achieved.

Speed

Probably the most important factor to being business friendly is speed. Entrepreneurs are doers more so than planners meaning they are quick to make decisions with the goal of moving their business forward a few inches every day. It is important to appreciate the potential opportunity cost of having a license negotiation drag on for six months or more. The entrepreneur community is very tight-knit and one bad experience can create a reputation that cuts off a vital ingredient for creating a viable startup program. Conversely, a reputation for speed could be the factor that converts your technology transfer office into a focal point for new ideas and venture creation.

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Protecting Your Institution

Shareholder protections should not focus solely on preserving the economic interest of the university. Once a company begins operations it becomes one of your institution's portfolio companies and may carry with it some reputational risk. The vast majority of companies are run by well-intentioned professionals. Nevertheless it important to consider the following provisions.

Adverse Effect

Licensing university technology can be valuable asset to a fledgling startup. In fact, in addition to providing a competitive advantage it can be a valuable marketing tool. While this should be encouraged, steps should be taken to protect against improper use of the university name or any other activity or association that might adversely affect the reputation of your institution.

Bayh-Dole Compliance: Development Milestones

As with any licensee, care should be given to Bayh-Dole compliance. This can be addressed in development milestones in that the company agrees to develop the technology for commercial purposes. In the case where the company goes in a different direction or simply does not require the technology, then the license should terminate and revert to the university.

Keep Your Intellectual Property out of Bankruptcy or a Company in Limbo

In the long term there are three possible outcomes for a startup: It is (1) successful and either becomes a going concern or is acquired by another company, or (2) after a heroic effort it runs out of money and enters bankruptcy, or 3) it is just successful enough to avoid bankruptcy but not enough to do much else. Careful consideration should be taken to avoid your institution's intellectual property being tied up in the latter two cases. In order to avoid intellectual limbo any license to a startup should contain provisions that terminate the license in the event of bankruptcy or in the case of business development milestones not being met (see the "Diligence Milestones" section). Failure to do so could result in possibly valuable intellectual property being wasted on a company that cannot execute or worse, being tied up for years in bankruptcy court. In the case where a company is clearly headed toward bankruptcy, it is best to exercise a breach of the license based on diligence milestones well ahead of any bankruptcy proceedings.

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Have a Board Observer

Universities rarely have an in interest in actively participating in the management of a company; however, remaining current with company events can both alert you to potential problems as well as help cultivate future opportunities in the form of follow-on licenses or relationships with venture capital firms. Asking for a board observer provision is rarely disruptive and can be a way to foster a more cooperative environment between the university and the startup.

Conclusion

Securing seed and venture financing for a university startup has never been easy, and the recent economic turmoil ensures that only the most promising ventures will secure early-stage funding. This is not necessarily a bad thing as it forces the current generation of scientists, engineers, and entrepreneurs to develop economically sustainable ventures that will comprise the next generation of technology-based companies. In the face of this higher standard it is up to the technology transfer profession to rise to the challenge and enable this next generation of companies to have every possible chance of success.

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Building a Successful Trademark Licensing Program

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Introduction

Universities and other institutions of higher learning are facing increasing revenue pressures. Rising tuitions are putting greater pressure on students and their families. The average cost in tuition and fees for private colleges in 2010 was $27,293, while the average cost for four-year public colleges during the same time was $7,605, with two-year colleges costing $2,713.[1] President Obama's proposed budget for higher education over the next ten years reduces support for higher education by $89 billion over the next ten years.[2] In the face of cuts, universities are searching for other sources of revenue.

One source of revenue is the development of an intellectual property portfolio, including trademark licensing. Implementing a successful trademark-licensing program includes (1) understanding what a trademark is, (2) obtaining and protecting trademarks, (3) implementing a licensing program to generate revenue from the trademarks, and (4) using licensing as an enforcement tool to prevent and minimize potential losses.

Building a Trademark Licensing Program

The first step in building a trademark-licensing program is for a university to identify its existing trademarks and build on those marks by recognizing and exploiting other potential marks.

What Is a Trademark?

Generally, a trademark is an identification of the commercial origin of a product or service; in other words, a source indicator for goods or services. Essentially, a trademark is a manifestation of a brand, such as the identification of the university as a source for goods and services. For example, the university name, the university seal, and the university mas-

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cot, as well as any nicknames. From a technology transfer perspective, this would include university-developed programs, joint ventures, and research groups.

Trademarks are important because they identify the source or origin for products and services and provide notice to others of where those goods and services originate. This encourages product quality and ultimately provides consumer protection. Consumers are given certainty of the source of products or services. Another way of looking at this is that a trademark embodies the good will of its owner, and consumers often make purchasing decisions based on that good will. It is that good will associated with a trademark that the licensee is willing to pay for when it licenses a trademark.

What Are the Different Types of Trademarks?

A trademark is any word, name, symbol, or device, or any combination thereof that serves as an identification of the origin of a product or service.[3] Service marks are used to identify and distinguish the services of one entity, including a unique service, from the services of others and to indicate the source of the services even if that source is unknown.[4] For the purposes of this discussion, the term *trademark* will be used interchangeably for a trademark or a service mark.

The traditional use of trademarks by universities is the licensing of marks, logos, and designs for use with merchandise related to the university and its sports teams. University technology departments can also build trademark portfolios and license those trademarks.

How Are Trademark Rights Obtained?

Essentially, the underlying concept to all trademark rights in the United States is that all rights are derived from use. First in time, first in rights; whoever uses a mark first has the superior rights. These rights, known as common law rights, establish the trademark owner's rights in the United States and certain other countries. Under common law rights, a trademark owner has rights based on its use of a mark for particular goods, in a specific geographic area, where it has made actual use of the mark for those goods. This use may be made through a licensee, even if that is the only use of the mark.[5]

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In the United States there are also rights based on registration, both state and federal. In order to obtain federal registration rights, however, the owner must still use the mark, and that use must be in commerce.[6] This is in contrast to much of the rest of the world, where rights may be acquired simply through a trademark registration.[7]

What Are the Benefits of a Federally Registered Trademark?

The registration and enforcement of trademarks in the United States are governed by the Trademark Act of 1946, 15 U.S.C. §§ 1051, et seq., also known as the Lanham Act. Trademarks are registered with the U.S. Patent and Trademark Office (USPTO). There are two types of federal registration: (1) registration on the Principal Register, providing maximum benefits, and (2) registration on the Supplemental Register, providing limited benefits.

Registration on the Principal Register

Fanciful, arbitrary, and suggestive marks, which are inherently distinctive, are all registrable with the USPTO on the Principal Register. Descriptive marks, surnames, and other noninherently distinctive marks are also registrable on the Principal Register if the owner can prove secondary meaning or acquired distinctiveness.

The most interesting and essential feature of a federal registration is that a trademark owner is able to establish trademark rights by simply filing a federal trademark application with a bona fide intent to use the mark.[8] Essentially, this allows the trademark owner to establish constructive use by merely filing a U.S. trademark application. The filing date will be considered the owner's use date once use in commerce commences and the mark is allowed to register.[9] This use may not commence until some time (even years) after the trademark application was filed.

For a potential licensee these registration rights are very important. The licensee is purchasing the right to use the trademark. He or she wants certainty that the rights being acquired are valuable and valid. A federal registration gives the licensee a great deal of reassurance that the rights he or she is purchasing are valuable based on these enumerated rights.

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Benefits of federal registration from a licensing perspective are:

(a) constructive notice to the public of the registrant's claim of ownership of the mark,[10]

(b) a legal presumption of the registrant's ownership of the mark and his or her exclusive right to use the mark nationwide on or in connection with the goods and/or services listed in the registration,[11]

(c) the ability to bring legal action concerning the mark in federal court,[12]

(d) the ability to record the registration with the U.S. Customs Service to prevent importation of infringing foreign goods,[13]

(e) the registrant's exclusive right to use a mark in commerce on or in connection with the goods and/or services covered by the registration can, after five years, become incontestable and can only be cancelled or revoked under limited circumstances,[14] and

(f) a registrant can use a U.S. registration as a basis to obtain a registration in a foreign jurisdiction.[15]

Other benefits of a U.S. trademark registration are (a) that the owner has an exclusive right to use the mark for the goods and services or any similar goods and services within a reasonable zone of expansion and (b) the ability to prevent the use of any confusingly similar marks or names in conjunction with identical or related goods and services.[16]

Another key benefit of federal registration is that the rights will continue for as long as use continues. The term for a registration in the U.S. is ten years, but it can be renewed for like terms indefinitely as long as use continues. Rights may be lost, however, where there is nonuse without an intent to resume use for three years[17] or if the mark becomes generic.[18]

Finally, the owner of a federal registration is entitled to use the registration symbol,®, to denote that its mark is registered.[19] Prior to registration, a trademark owner can use the trademark (TM or SM) symbols to designate its claims of trademark rights.

Registration on the Supplemental Register

Marks that are descriptive, surnames, or other marks not inherently distinctive are not eligible for registration on the Principal Register. If, however, these marks are capable of distinguishing a trademark owner's goods or services they may be registered on the Sup-

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plemental Register.[20] Generic marks are not eligible for registration on the Principal Register or the Supplemental Register.

Registrations on the Supplemental Register do not have many of the benefits of a registration on the Principal Register. The primary benefits of a registration on the Supplemental Register are that:

(a) it will be cited by the USPTO to prevent registration of an identical mark for identical goods or services,
(b) the owner of a registration on the Supplemental Register has the ability to bring legal action concerning the mark in federal court,[21] and
(c) the right to use the ® federal registration symbol.[22]

A registration on the Supplemental Register can be used as evidence to establish acquired distinctiveness or secondary meaning to allow registration on the Principal Register.[23] As a general rule, a university should avoid selecting noninherently distinctive marks and registrations on the Supplemental Register if it hopes to build a strong trademark portfolio.

State Trademark Registration Rights

These rights are in contrast to federal trademark registration rights. Although a state registration is inexpensive and supports the owner's common law rights, its scope is very narrow, usually limited to the state where the mark is registered. State registrations are not recommended unless a university does not intend to use its mark in commerce or license it for goods sold outside the state. In most instances that is not the case and it makes sense for a university to go forward with a federal trademark registration.

Standard for Trademark Infringement

Trademark infringement is defined as whether or not a mark creates a likelihood of confusion when used on or in connection with the goods and services of another similar, competing mark to cause confusion, mistake, or to deceive.[24] At its core, the basic principle for determining confusion between marks requires that the marks be compared in their entireties and must be considered in connection with the particular goods and services for which the marks are used.[25] There is no mechanical test for determining a likelihood of confusion between marks.

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The issue is not whether the actual goods and services are likely to be confused, but rather whether there is a likelihood of confusion as to the source of those goods and services.[26] Determining likelihood of confusion is, therefore, very subjective and fact specific. The issue is not whether the goods and services will be confused with each other, but rather whether the public will be confused about their source. It is not necessary to show actual confusion to establish a likelihood of confusion.[27] Generally, a university, in selecting a mark, will seek to avoid a likelihood of confusion with a prior mark. At the same time, a university will enforce its marks and will seek to stop others from using a mark that creates a likelihood of confusion with its own prior marks.

Maximizing Trademark Assets

To maximize trademark assets, a university must develop an effective trademark strategy, including a licensing program. This means identifying core marks, and then ranking your other marks on the basis of importance. For example, the university's name, seal, and mascot are likely to be core marks. Other marks of importance include the key nicknames and logos and other strong brands that consumers associate with the university. The next step is identifying the university's key goods and services. Education and sports entertainment immediately come to mind, as do clothing, toys, bags, jewelry, glassware, and other accessories.

Another way to maximize a trademark portfolio is to register trademarks for institutions and organizations within the university. This may include university-developed software, telecommunications services by way of cable television programming, and various schools within the university, for example, a school of business or a school of law. All this will create an ever-widening pool of trademarks that can then be licensed or used by the university for a wide variety of goods and services that will all result in further growing revenues to the university.

For a university to maximize its trademark assets, it is imperative that its trademarks be inherently distinctive and that they are registered on the Principal Register. What are other factors that a university should consider in establishing a successful trademark-licensing program?

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General Considerations

One area that is often overlooked is the importance of doing a clearance search. It is important that a university should adequately screen its marks prior to selecting a mark for use and registration. The search will help the trademark owner determine whether the mark is available or give a risk assessment of possible trademark infringement.

Building a trademark portfolio can be very expensive, both domestic and foreign. There are costs associated with searches, the preparation and filing of trademark applications, the prosecution or process for obtaining those trademark registrations, and the maintenance of the resulting registrations. A university would do well to carefully balance the cost of developing and registering a trademark against the revenues to be derived from that trademark. Not every mark needs to be registered for every product or service that the university would like to protect with a trademark registration and ultimately license to others.

Licensing Trademarks

Why should a university license its trademarks? First, there are marketing motivations to consider. It allows an expansion of the awareness of the university and its products without incurring the cost. The licensee will do the advertising for the licensed mark and products. Along those same lines, the university will expand beyond its core business without a significant capital investment. This expansion allows the university to update its image and reach out to new customers with new products, which has the overall effect of enhancing the university's image and commercial appeal and ultimately raising revenues.

The traditional avenue for a university to maximize revenue for its trademarks is by licensing their use to third parties. This licensing right could include the right to use the university's name, official seal, or other logos, sports mascots, or any of its other exclusive brands. The licensees who use the mark will assist the university in generating revenue because the licensee has a greater expertise or ability to sell university-branded products to the purchasing public. The licensee enters into the licensing agreement because he or she realizes that there is greater revenue potential selling the product or services with the university trademark than without it.

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In return for this, the licensee agrees to pay the university a licensing fee or royalty payments that generate a revenue source without requiring the university to manufacture or market those same products. By licensing and merchandising products bearing the university trademarks, both parties enjoy a mutually beneficial relationship.[28] For example, for the year 2005-2006, the University of Texas led the nation in licensing revenue and set a record with $8.2 million in royalties.[29]

Why should a university not grant a license? When it does not make sense from a financial and marketing perspective. Granting a license should not create a competitor. There are costs associated with any warranties or guarantees made, as well as with the license administration. Care must be taken to ensure that the value of the licensed trademark is not underestimated.

What Is a Trademark License and How Does It Work?

A trademark license is an agreement between the owner of a trademark (the licensor) and a third party (licensee) to allow the licensee to use the licensor's trademark. Remember, trademark rights are based on use. Use by a licensee will inure to the benefit of the licensor. The university as the licensor will often apply to register its mark for a wide variety of goods and services, but that use and registration is supported by the licensee's use and not the university's use.

Generally, a license is nonexclusive; the university will license its trademark to a wide variety of licensees. In a typical trademark-licensing arrangement, the university will grant a nonexclusive license to third-party licensees, which grants the right to use one or more of its trademarks. These licensees are manufacturers, retailers, vendors, and others who wish to apply the university's trademarks to products or use the university's trademarks in advertising and promoting services. There is also the option of an exclusive license. An exclusive licensee has the right to enforce the mark without the consent or joining with the licensor.

The agreement sets forth the terms by which the licensee is allowed to use the mark. Generally, the licensee will be required to submit certain background and financial information concerning its company and the products for which it intends to use the mark. The university should be careful to ensure that it picks quality licensees who will produce quality products bearing the university trademarks.

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Basic Requirement: Quality Control by the Licensor

As the owner of a trademark, the licensor must control the use of its mark by the licensee. The key to a proper license is for the licensor to maintain quality controls for the products sold by the licensee and require that they meet certain standards for use. Because, from a legal standpoint, all use by the licensee inures to the benefit of the licensor, the licensee's use must be controlled by the licensor. Failure by the licensor to control the licensee's use may result in a finding that the licensor has abandoned its rights.[30] This also has practical applications.

From a practical standpoint, if the university's mark is going to be appearing on products produced by a third party, and its good name and the associated good will of its mark appears on that product, it is in the university's interest to make sure that the products are of a certain quality so as not to reflect poorly upon the institution, its good name, and its mark.[31] A university will require product samples to be submitted for prior approval to ensure that the licensee's products fulfill certain quality criteria.

The university should also set forth for its licensees certain standards for use. Failure to maintain this control will result in the mark becoming diluted and in those exclusive rights that are claimed by the owner becoming eroded. Standards for use would include the size, shape, color, or context in which a university trademark may be used. The university must strictly control the goods and services associated with its marks. For example, there should be prohibitions against use with alcohol, tobacco, weapons, sexually explicit activities, or other goods and services that would reflect poorly upon the university and its reputation.

Licensing Fees and Royalties

The university will receive an income stream from licensing fees and royalties associated with the license. These can be structured in many different ways, including a fee to the university for entry into the license with a third party and/or in combination with a royalty. Royalties are generally computed based on a percentage of net sales and generally range from 8 percent to as high as 12 percent.

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Key Points for Trademark License

The following are some of the key points for inclusion in a trademark license.

1. *Clear identification of the parties as the licensor and the licensee:* The names and addresses of the parties should be listed together with their states of incorporation. It is important that the parties are adequately identified so that there is no ambiguity as to who is licensing the trademarks to whom.
2. *Clear background information:* For example, identity of the licensor and licensee, their business, and their reasons for entering into the license. There should be an acknowledgement of licensor as owner of trademarks and licensee's desire to use the trademarks that are the property of the licensor.
3. *The license should define key terms:* For example, the trademarks and the particular goods associated with each mark.
4. *Express grant of license:* This sets forth whether the license is exclusive, nonexclusive, or semiexclusive; perpetual or limited in its duration; the scope; whether it is worldwide or geographic in limitation; and whether it includes the right or authority to sublicense. All of this sets forth the conditions upon which the licensee and licensor agree that the mark or marks shall be used.
5. *Representations and warranties:* These are typically made by the licensor and include ownership of the mark and the power to grant a license, as well as a warranty that the licensor is the owner of the mark, and that the marks do not infringe third-party marks. The licensor will also usually represent that it has the right and authority to enter into the agreement without violating any right or obligation to a third party.
6. *Restrictions:* These are typically borne by the licensee and govern the licensee's ability to use the mark. This would include an agreement that the licensee will manufacture or arrange for manufacture of the goods in accordance with standards and specifications approved by the licensor, and the licensee will agree to permit the licensor or its authorized representative to inspect the goods and methods of manufacture at a reasonable time and place. The licensee will usually agree to allow the licensor to review advertising copy for goods with which trademarks are used and will agree to incorporate or make any suggestions or changes the licensor may require with regard to the advertising. This includes an agreement to properly mark the goods with the appropriate registration symbol, whether it be the ® or TM or another designation. The licensee recognizes the licensor's right, title, and interest in the trademarks and the

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good will associated therewith, and that as a condition of the license, the licensee will not contest the validity of any registration or application to register the trademarks. The licensee will agree not to register the trademarks. This is especially important in a foreign jurisdiction where trademark rights are based on the registration of the mark. The licensor may license the right to use the mark to the licensee, but without the registration, licensee has no legally recognized ownership in the mark. In connection with this, the licensee acknowledges that the license granted is not intended to be construed as an assignment of any rights in the trademarks owned by the licensor.

7. *Payment of royalties:* This should be set forth very carefully and includes whether royalties will be calculated based on a formula as a percent of net sales, volume of sales, value of sales, and when those sales will be calculated. There is also the issue of a cash down payment and whether that payment is applied to the subsequent royalties or is considered an upfront licensing fee. Other factors for consideration include a guaranteed minimum payment and agreed to or stipulated maximum amount, as well as any suspension or adjustment of payment in the event of third-party competition, inability to sell the product due to acts of God or other incidents outside the control of the licensee, as well as a payment schedule, penalty rates of interest for late payment, currency method and place of payment, and any other matters concerning payment.
8. *Recordkeeping:* If the license has a schedule of royalties, then it should also set forth the terms for the licensee to provide records and reports to the licensor. This includes a reporting schedule, maintaining records for a stipulated purpose for a stipulated period, availability of those records to acceptable auditors at licensor's expense, maintaining confidentiality of those records, and defining the specific accounting periods.
9. *Trademark infringement and enforcement:* In the event of trademark infringement, the agreement should set forth the duties and the obligations of the parties. These include the licensor's right to sue the infringer, the licensor's obligation to sue the infringer, the licensee's right to sue the infringer if the licensor fails to do so, and the licensor's cooperation or enjoinder in the licensee's infringement suit; in the event that the licensor takes no action or is not obligated to do so, allotment of payment of attorney's fees and expenses, division of recovery in excess of fees and expenses, and whether there is an abatement of royalties due to the licensor during a lawsuit or a period of infringement.

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10. *Termination and renewal:* Unless the license is for an indefinite period, the license should set forth the stated termination date and whether or not there is a right of renewal. It should also state the terms upon which the agreement may be terminated upon written notice of breach or default and any other issues related to termination.
11. *Notices:* Where and to whom notice will be sent, including address of licensor and counsel and address of licensee and counsel, and the effect of notice upon mailing receipt or other method of communication.
12. *Other issues for consideration:* Finally, an agreement should include such language governing the binding effect on successors, the license being the entire agreement, any and all amendments are to be written, severability with regard to any provisions that may be invalid, and the governing law, as well as the jurisdiction.

This list is by no means exhaustive, nor are all of those elements required. Boilerplate or form agreements should be used judiciously. An agreement should reflect the intent of the parties and be tailor-made for the licensing relationship.

Establishing a Successful Trademark Licensing Program

Establishing a successful trademark-licensing program involves registering marks for a wide variety of goods and services, having a fairly sizable portfolio of different and recognizable university trademarks, and finding appropriate third-party licensees who will use these marks for various goods and services. It is important that universities diversify their goods and services beyond what may be seen as the traditional uses.

For example, university trademarks for clothing have gone beyond jackets, hats, and sweatshirts to include children's clothing. Most universities have licensed their marks or registered them for entertainment services related to sporting events and other athletics. Universities sell branded food items including coffee and other soft drinks. All of these are potential revenue sources.

Trademark licensing programs must be properly administered in order to be effective. To achieve this, many universities have created offices or departments solely dedicated to trademark protection and licensing. These departments assist in handling and assessing various trademark licensees, computation of royalties, and other details. This allows the university to license and control its marks directly to third-party licensees.

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For example, Harvard University has an independent trademark licensing office.[32] The advantages of an independent trademark licensing office include greater control over third-party use of marks as well as maximizing revenues from licensing arrangements.

There are also outside companies that will handle the licensing of a trademark for a university. Universities can often benefit from the experience and resources a licensing company can provide, especially when negotiating agreements with multiple licensees, and in handling and coordinating all of the various agreements. In a survey of major U.S. universities, both public and private, thirty-eight schools used a licensing agency, while twelve schools managed their programs internally.[33]

The most well-known of these licensing agencies include the Collegiate Licensing Co. and the Licensing Resource Group.[34] Based on the client lists available from both of these companies, the trend appears to be for universities to employ these services to increase revenue while simplifying the process by not having to devote university resources to maintain an independent licensing office.

Enforcement of Trademark Rights

As a trademark owner, the university has a duty, like every other trademark owner, to enforce its trademark rights. Failure to enforce a trademark will result in that mark becoming diluted. As the owner of a trademark, a university wants to protect the good will of the organization for its students, faculty, alumni, and the general public and maintain its status as the source indicator and the party with exclusive rights to use the mark. Remember, one of the goals is to prevent consumer confusion. In order to do this, a university must be in a position to enforce its trademark rights.

A licensing agreement should set forth which party will be responsible for enforcement. Generally, the licensor will have the duty to enforce, unless the license is exclusive. In that case, the licensee may have the duty to enforce the mark. In either case, the parties will cooperate to assist in the enforcement. Related to this is indemnification, and similarly, the license agreement should set forth which party will indemnify the other or whether the cost of enforcement will be shared equally.

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Generally, a trademark owner or licensee should be willing to employ an attorney or other trademark professional to assist in establishing an effective enforcement program. One object is to establish a trademark-watching program through a commercially available watch service. This involves checking the trademark applications being filed and published to watch for potentially infringing marks. Other sources for identifying and reporting unauthorized uses are employees, faculty, students, and alumni.

How It All Comes Together

An example of how a university can generate and protect revenue from a trademark-licensing program is as follows:

A university decides to choose an inherently distinctive new design for a mascot. This is a core mark so the decision is made to seek registration protection. University staff members perform a search to be sure that there are no other similar marks already in the marketplace. The search comes back clear. The university files an application to register the mark for a variety of goods and services. The mark is allowed to register for some of the goods, but the university is not yet using all of the goods or services, so it begins a licensing program so that use by the licensees will be to the benefit of the university, and the mark will be allowed to register for the remainder of the goods.

The university does not have a very large trademark program, so it hires a trademark licensing organization to administer the trademark-licensing program. The use of the mark is strictly controlled, and the licensees are required to submit product samples as part of the license. The licensees pay a licensing fee, and the products begin to generate profits based on the royalties.

The university has developed an online service for communication and transmission of information between institutions that have sought to register the mark in the United States and abroad. In connection with this service, they have developed a proprietary software and will license that software together with the corresponding trademark to the participating institutions in a royalty-free arrangement to encourage its use and growth of participation in the education community.

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These are just examples, but one can begin to see how a successful trademark program can be built and implemented.

Conclusion

Universities can reap significant benefits through increased recognition of their brands by implementing a trademark-licensing program. Establishing such a program is not difficult. It requires identifying the universities' distinct brands, registering them as trademarks, and implementing an effective licensing program to put those trademarks on a variety of products and services for sale to the public. This, coupled with a rigorous enforcement program, should result in increased revenue to those universities.

For more information about trademarks, see the "Trademark Primer" chapter in Volume 1 of the 3rd Edition of the Association of University Technology Managers Technology Transfer Practice Manual.

Notes

1. "What it Costs to Go to College," www.collegeboard.com/student/pay/add-it-up/4494.html; See also, William Trombley, "The Rising Price of Higher Education," www.highereducation.org/reports/affordability_supplement/affordability_1.html.
2. John Lauerman, "Higher Education Funding Cut by $89 Billion Over 10 Years in Obama Budget." *Bloomberg*, February 14, 2011, http://www.bloomberg.com/news/2011-02-14/higher-education-funding-cut-by-89-billion-over-10-years-in-obama-budget.html.
3. 15 U.S.C. §§ 1051 and 1052.
4. 15 U.S.C. § 1127.
5. *Central Fidelity Banks, Inc. v. First Bankers Corp. of Florida,* 225 U.S.P.Q. 438 (T.T.A.B. 1984).
6. Use lawfully regulated by the United States Congress. 15 U.S.C. §§ 1051(a)-(b); see 37 C.F.R. §§ 2.34(a)(1)(i), 2.76(b)(1)(ii) and 2.88(b)(1)(ii).
7. However, many foreign jurisdictions may require use in order to maintain that registration, which may become vulnerable to cancellation for nonuse after a certain period of time.
8. 15 U.S.C. § 1051(b).
9. 15 U.S.C. §§ 1057(c) and 1141(f).

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10. 15 U.S.C. §1072.
11. 15 U.S.C. §§ 1057 (b) and 1115(a).
12. 15 U.S.C. § 1121.
13. 15 U.S.C. § 1124.
14. 15 U.S.C. §§ 1065 and 1115(b).
15. 15 U.S.C. § 1126(e).
16. *In re General Motors Corp.*, 196 U.S.P.Q. 574 (T.T.A.B. 1997).
17. 15 U.S.C. § 1127.
18. *H. Marvin Ginn Corp. v. International Association of Fire Chiefs, Inc.,* 228 U.S.P.Q. 528 (Fed. Cir. 1986).
19. 15 U.S.C. § 1111.
20. 15 U.S.C. §§ 1091-1096.
21. 15 U.S.C. § 1121.
22. 15 U.S.C. § 1111.
23. 15 U.S.C. § 1052(f).
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26. *In re Shell Oil Co.,* 26 U.S.P.Q.2d 1687 (Fed. Cir. 1993).
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34. For general information see, www.clc.com for the Collegiate Licensing Co. and www.lrgusa.com for the Licensing Resource Group Inc. The author does not endorse either of these companies.

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Venture Funding for the University Startup

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Universities have long-served as the breeding ground for innovative technology and research. For that reason, university-developed technology has often been an attractive target for venture capital funding. Such venture funding has aided in the successful commercialization of select intellectual property developed by entrepreneurial-minded university faculty and students. Without this financial assistance, the technology may still be considered a great academic accomplishment for the university but may never develop into a successful business for its inventors.

This chapter is aimed at helping technology transfer offices (TTOs) and entrepreneurial faculty and students understand the role of venture funding for university startups. It will first explain the sources, stages, and strategies for venture funding. It is also designed to provide insight into how to attract investors and how to manage investors' expectations. Finally, this chapter will provide guidance on how your university can support entrepreneurship and foster an innovative culture that attracts venture funding for its startups.

Startup or License?

Not all technologies coming out of universities are appropriate to spin off into startup companies. It is important for TTOs to recognize which technologies should seek venture funding and which are more appropriate for licensing transactions. Technology that results in a range of products for a variety of new markets are the most suitable for venture backing. Technology that simply builds on existing products, markets, or customers is often more suitable for licensing.

In addition, if the startup costs are high, and the founders have insufficient resources and experience to see their idea to market, licensing to a well-established and integrated com-

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pany may be a more practical approach. Therefore, you should first analyze whether your technology is suitable for a startup before seeking venture capital. This will save both you and your prospective investors time and effort and will add credibility to your TTO.

What Is Venture Capital?

Venture capital is a type of private equity investment. Private equity investments are, as the name indicates, investments in private companies and are generally not available to the public. These investments are made with the expectation of a high rate of return for its investors through a realization event such as an initial public offering (IPO) or the sale of the company.

Venture capital is generally provided to early-stage companies with a high potential for growth. Most venture capital investments are made in high-technology sectors, such as bioscience and software development. Since these investments are made in the early stages of a company's lifecycle, they can be risky investments. For that reason, venture capital investors demand higher rates of return for their investment. The goal of a venture capital investment is to identify unique technologies at an early stage that have the potential to generate high investment returns quickly.

Sources of Venture Capital Funding

There are several sources of venture capital funding. When seeking funding from these different sources, you should understand the investor's investment objectives, as well as the advantages and disadvantages of seeking capital from a particular source.

Friends and Family

Friends and family may be your only viable source of funding in the early-development stages of your technology. Investments from friends and family are also the easiest to secure. You already have a personal relationship with these sources, and their objective (at least initially) is more aligned with helping their friend or family member rather than seeking a rapid and significant return on investment. When friends or family members invest, they are usually not thinking about their exit strategy and they are less concerned about the valuation of the startup. The pre-money valuation of a startup (the valuation of the company prior to the investment) is more important to venture capital (VC) funds because

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it correlates directly to the amount of equity an investor may receive in the startup. Although friends and family may seem like the easiest source of funding, it probably is the source with the most disadvantages. Everyone has been advised at some point that it is not good to mix personal matters with business. This certainly holds true when it comes to seeking funding for a startup. In addition, friends and family will generally not be able to provide the same business advice and managerial experience that you usually are able to obtain from other sources of funding such as VC funds. Finally, friends and family may not qualify as accredited investors. To be classified as an accredited investor, a person's assets or salary must exceed a certain threshold. If the friend or family member does not qualify as an accredited investor, an investment from such friend or family member may result in a violation of state or federal securities laws.

Angel Investors (Individuals and Syndicates)

Angel investors are wealthy individuals (that qualify as accredited investors) who are looking to invest in startup companies. These investments often range from $100,000 to $1 million early in a startup's lifecycle (although the investment can be less or more depending on the particular technology and capital needs of the startup) and can often serve as bridge funding until the startup company is at a stage where it may seek funding from a VC fund. A startup may seek capital from individual angel investors or may approach an angel syndicate. An angel syndicate is a network of angel investors within a particular community.

Angel investors can be a great source of contacts and advice since they are usually very connected within the business community and generally have been successful with their own business ventures. However, be aware that angel investors are more concerned with an exit strategy than a typical friend or family member. This exit strategy is a mechanism for liquidating their investment quickly and with a substantial return. They will also be more sensitive to valuation issues than friends and family. Deal terms with angel investors vary from angel to angel depending on the angel's comfort level with the deal and his or her risk tolerance. There are not as many standard requirements from angel investors as you may see from VC funds.

Seed Financing Companies

Seed financing companies are similar to angel investors, however, they approach the in-

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vestment process like a business. Like angels, their investments are generally smaller and during the very early stage of a company's lifecycle. In addition, they can serve as bridge funding until the startup is ready to seek funding from VC funds. For that reason, seed financing companies will usually offer advice on how to market your startup to VC funds.

Venture Capital Funds

It is critical to understand what a VC fund is so you understand its goals and objectives. A VC fund is a pool of private equity used to grow new businesses. A fund is generally comprised of a general partner and limited partners. The general partner makes all the decisions about where to invest this pool of capital and owes a fiduciary duty to its limited partners. The limited partners are the individuals or entities making the contributions of capital to the fund. VC funds have a fixed lifespan and are generally seeking an above-market return on their investments.

A startup should consider a VC fund's three main investment criteria when marketing its business to such fund. These are survivability, profitability, and growth. First, the startup must have a product or service idea that can survive competition. As a result, VC funds generally want to invest in startups that have patent or patent-pending technology. This will prevent other more established companies with more resources from competing with the startup (and possibly stealing all of the startup's potential customers).

Second, the startup must show profitability. Before a VC fund will invest, it generally likes to see that a startup has achieved breakeven cash flow on a sustainable level. Ultimately, VC funds want to be assured that they are investing in a company that will provide an above-rate return on its investment. Finally, VC funds are looking for investment opportunities that are high growth. Startups that tap into a large and rapidly growing market are ideal investments for VC funds. VC funds want to invest in companies where they can see a clear and identifiable exit strategy in sight (approximately two to five years). High-growth markets provide for this clear exit strategy.

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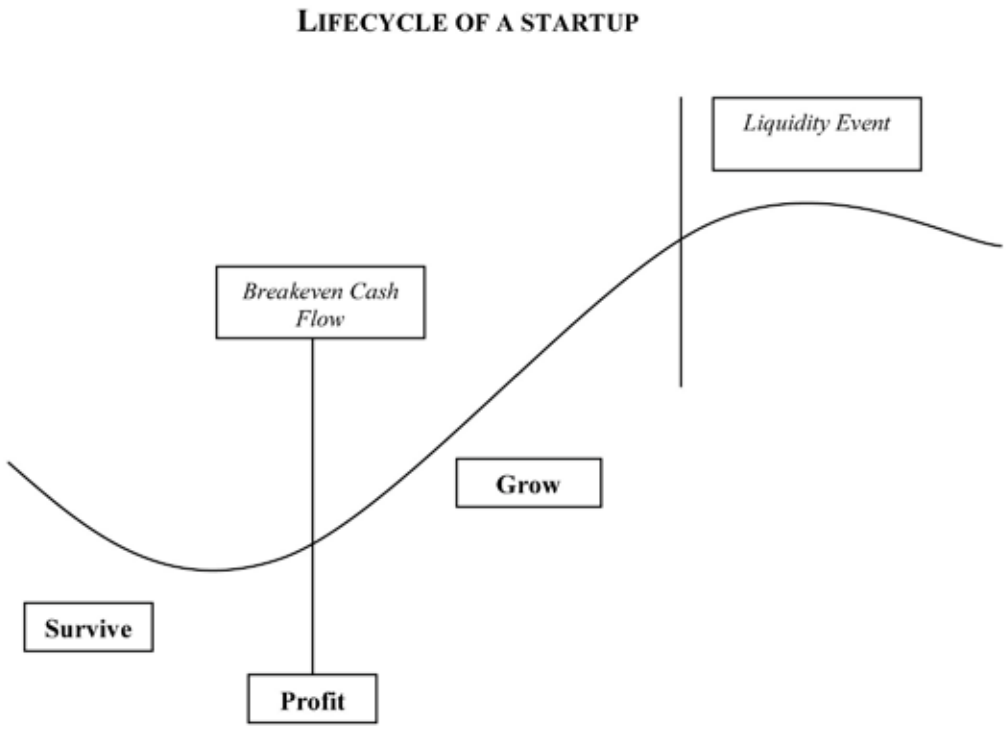

Investment from a VC fund can instantly add credibility to a startup company. In addition, it can offer professional management services and business advice that can help a startup achieve a liquidity event. This advice can be critical to the success of a startup. However, you should be aware that you may get this advice whether you want it or not. An investment by a VC fund is usually conditioned on the startup relinquishing certain control of the company to the fund. This is justified because the VC fund is generally willing to make a larger investment in the company than some other sources of funding. Lower tier firms may provide better terms because they need more companies in their portfolio, but they will not offer as much credibility as some of the more successful funds. In general, however, most VC funds are much more sensitive to valuation issues than friends, family, and angel investors.

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Stages of Funding

At the beginning of a startup's lifecycle, the founders may need capital to develop the business, but the company might not be at the stage yet where it can successfully solicit funding from a VC fund. During this initial or seed round, startups may turn to friends and family for funding. At this stage, the startup has just enough money to survive until it can get funding from an angel investor or seed financing company.

By the angel round, the startup has developed a business plan and may be able to demonstrate its product, rather than just describe an idea. During this round, the startup focuses on developing its business so that it can get to a stage to seek additional funding from a VC fund. These early-stage investments can be critical for sustaining a startup until it is ready to seek funding from a VC fund. Between the angel round and the venture round, there is generally a funding gap. The startup can spend this time to work on its image and other intangibles that require minimal capital expenditures.

During the venture round, it is not unusual for the startup to receive funding in several different series. Many funds are wary of giving all of their investment at once due to the risky nature of the investment. Therefore, they may give funding in various series after certain milestones are met by the startup.

It should be noted that a startup does not necessarily have to go through all of these stages of funding, but may actually skip a round depending on the technology and the product market. Additionally, government grants and funding can also serve as an important source of initial funding and may replace one or more of the rounds discussed above. Grants are a welcomed source of capital by any investor because there is no expectation from the government to receive any equity in the company and, thus, this funding does not dilute any previous investments.

Exit Strategy

A VC investor's primary concern at the time of investment is how and when it will receive a return on its investment. At the moment the initial investment is made, the VC is already thinking about an exit strategy or liquidity event. The goal is to receive its investment back with the highest rate of return and in the shortest amount of time possible.

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There are four main types of exit strategies discussed below, each offering different advantages and levels of risk for the investors and the startup.

Industry Collaboration

Universities have become a critical source of research and development for many innovative industries. More and more large companies are building strategic alliances with universities to help develop and deliver products to market faster. These strategic relationships include licensing arrangements, corporate-sponsored research or grants, and VC investments. Although industry collaborations are becoming more and more popular, they are not seen as frequently in some areas, such as the biotechnology sector.

Industry collaborations provide significant opportunities for university-developed technology. First, the corporate partner is making more than an investment, it is developing a strategic partnership. In addition to funding, the industry partner can also provide the startup access to its own research and development (R&D) as well as product and market knowledge. Since industry investors have a direct interest in the technology being developed, they often times can serve as the best avenue for commercializing university-based technology. This benefits industry investors as well because it can provide them with early access to new technologies and lowers their R&D costs.

Licensing Agreement

A licensing agreement serves as a partial exit strategy. It is an agreement between the startup and an interested strategic partner, whereby the strategic partner licenses the startup's technology from the startup for a certain period of time in exchange for a royalty payment. Generally this includes a substantial initial licensing fee, as well as ongoing royalty payments.

With a licensing agreement, the startup will continue to own the technology (although it may have licensed away its right to use the technology temporarily). It allows a startup to ensure a long-term source of revenue, but it does not necessarily create an opportunity for the equity owners to completely cash out their investment. Note, however, that in some instances, the initial license fee is enough to allow certain investors to exit the ven-

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ture. As discussed earlier in this chapter, some technology is more suitable for licensing rather than an IPO or acquisition.

Acquisition

Often times VC firms invest in university startups with the thought that they will be able to make a return on their investment when the startup is in a position to sell or merge with another company. As opposed to a licensing arrangement where the startup (and investors) will receive royalty payments over a long period of time, an acquisition results in a lump sum payment to the founders and investors. Larger companies looking for a new product usually are the most interested in acquiring a startup company, although private equity funds looking for portfolio companies for their fund may also be potential purchasers.

Finding a strategic buyer is usually the best exit strategy. A strategic buyer is purchasing a startup for the purpose of adding a new product or building on existing products, rather that buying for investment purposes. For that reason, strategic buyers generally provide the best valuation for the company because they are willing to pay more for the good will they will be receiving from the startup's business.

One of the most important factors that helps drive up the valuation of a company is the company's current accomplishments. Has it developed a product yet, and if so, how far along is it in its progress? Are there paying customers? If so, what are the company's revenues? Another valuation driver is the long-term potential of the business. If there is a large market for the startup's product and the intellectual property can be protected to prevent others from easily entering the market, the valuation of the company will increase. In addition to the factors above, a strong management team will also contribute as a valuation driver.

IPO

An initial public offering, more commonly known as an IPO, is the most glamorous of the exit strategies, but it is the strategy with the largest amount of risk, particularly in a depressed economic climate. An IPO is when a company issues common stock or shares in its company to the public. IPOs have the potential of bringing the highest return to inves-

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tors, but can be risky because of the difficulty of predicting the valuation of the shares on the initial trading day and other external uncontrollable factors (e.g., terrorist attack or natural disaster). Additionally, in a declining economy, it can be difficult to find a buyer or underwriter for these shares. An IPO can offer the most liquidity for investors, however, because the shares can be easily resold on the open market.

Finding Venture Funding

There is plenty of venture funding available to university entrepreneurs. The key is knowing where to look and to know what VC investors are looking for. Below are some tips for attracting VC funding for your university.

Be Visible

Before a TTO can assist its university entrepreneurs in finding funding for their startups, the TTO must make itself visible in the VC community. It is critical that individuals within the TTO develop personal relationships with angels and VC fims. These investors are more likely to fund companies that have been introduced to them through a personal contact, rather than to a startup that has sent its business plan out blindly to all potential investors within a 300-mile radius.

One of the easiest ways to become visible within the venture community is to attend venture forums and participate in community venture clubs. Local, regional, and national venture forums provide a platform for early-stage companies to gather and showcase their business to various angel investors, seed financing companies, and VC funds. This also provides an opportunity for TTO personnel to develop relationships with these potential investors. Additionally, many cities have venture clubs comprised of business professionals who share a common goal of increasing the amount of venture-backed activity within their community. These venture clubs provide various opportunities for TTO personnel to interact with the key players in the local VC community.

TTOs should also encourage their university entrepreneurs to become active in the local venture community. Many communities sponsor business-plan competitions that provide a platform for early-stage companies to compete for a cash prize that can serve as an initial

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source of funding. These competitions are often attended or even judged by local angels and VC investors and provide great exposure for aspiring university entrepreneurs. Additionally, it is not unusual for the winner of the competition to receive additional funding from a VC fund in attendance. Therefore, it definitely pays (literally) to participate in these competitions. Some universities may choose to go one step further and actually sponsor or serve as a host for a competition.

Know What Your Investors Want (Survivability, Profitability, Growth)

In addition to becoming visible within the venture community, it is essential that a TTO understands what prospective investors expect in a startup investment. In general, investors are looking for companies that can show a clear and quick path to commercialization in a high-growth market. They want a higher than average return on their investment, and they want to invest in a company that is sustainable with protectable intellectual property.

Biotechnology and other high-technology businesses, such as software, generally are the most attractive to VC investors because they have high-growth markets. Software and technology usually require smaller investments and are fairly fast to market. Startups in the life sciences and biotech industry generally take longer to mature due to higher degrees of regulatory scrutiny and, therefore, go through several rounds of financing.

In addition to looking for technology with high-growth potential and the ability to move to market quickly, investors are generally looking for unique innovations that do not require extensive capital. A strong management team is preferred. VCs are also looking for a strong intellectual property position that can serve as a barrier to other potential competitors entering the market.

All of these features must be conveyed clearly and concisely by the startup in a realistic business plan. The business plan should explain the need for the startup's product as well as identify a clear path for establishing market share. The plan should also be drafted and packaged in a VC-friendly manner, with less scientific and more business terms. If an investor cannot understand the business from reading the business plan, it certainly will not take the investment risk.

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Selecting the Right Venture Fund

In some instances, a startup will have the fortunate opportunity of choosing among several potential VC investors. Even if your startup has only one suitor, it is essential that you select the right fund to work with your business. A VC fund is more than an investor; it is your business partner. Therefore, the following factors should be considered when selecting a fund:

1. What stage in a product's lifecycle does the VC fund generally choose for investment? Is your business in that stage?
2. Does the fund have expertise in your industry? VC funds can often provide technical and business advice that can be extremely useful to a startup. As a result, expertise in the industry can be critical.
3. What is your position in the fund's portfolio? Are you a small investment, or do you make up a large portion of the fund's portfolio? Funds that invest in your startup's competitors should be avoided. Ultimately, you want your startup to be the most important investment in a fund's portfolio, but at the very least, you do not want to have to compete with a competitor for your VC fund's attention. Competition should be left to the marketplace.
4. Does the VC fund have strong financials and industry contacts? An investment from a credible and financially stable VC fund is an automatic stamp of approval and will assist the startup in seeking additional funding and securing its exit strategy.
5. How much control does the VC fund want over your company? As discussed more in the next section, VC firms will rarely invest without receiving certain management rights in return. Entrepreneurs should consider how much control they are willing to relinquish when choosing a VC fund.
6. Will this VC fund make a good business partner? A VC investor is more than a source of funds; that investor is your business partner. Therefore, entrepreneurs should consider whether they are comfortable with a long-term business relationship with this investor. If you do not trust the VC investor, it will not make a good business partner.

The Deal

Investor Expectations

Once a startup has located a VC partner, it will need to negotiate the terms of the investment with that partner. Founders should have a general understanding of investor expectations before they begin this negotiation process.

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Company Management

Often times founders are eagerly willing to accept funding for their startup, but are not so eager to relinquish control of their company. VC funds rarely contribute capital without receiving certain management rights in the company in return. Generally, the VC fund will want the founders to continue working for the company, but it is not unusual for the investor to want to bring in some of its own management team. The VC fund may even demand to fill the chief executive officer position with someone other than a founder.

Losing control over their creation is often difficult for many founders to handle. The founders must realize, however, that a VC fund will be unwilling to provide funding and then watch its investment dwindle away due to poor management. VC funds believe that the founders' strength rests mainly with the product technology, whereas the VC fund has the business experience to manage the company and bring the product to market.

The expectations of both the VC investors and the founders should be addressed upfront. The founders should expect to give up some control of their company. In most cases this is beneficial to the startup because of the business and management skills that the VC firms can offer to an early-stage company. The founders should also recognize their threshold for relinquishing control. If the VC funder wants more than it is willing to give, it might be time to search for another investor. TTOs should help educate their entrepreneurs on investors' expectations as they relate to control so that they are prepared to address this issue when it arises.

Preferred Stock

In almost every transaction, the VC firm asks for certain rights and preferences over the other stockholders in the company. It primarily wants to ensure that it can recoup its investment (and any premium) before the other stockholders. Therefore, VC investors generally ask for preferred stock in the startup. Some rights that preferred stockholders have over common stockholders include liquidation preferences (if the company is liquidated, the VC investor gets paid first and will receive a preferred return before the other stockholders), preferred distributions (the VC funder might receive dividends at a higher rate and before common stockholders), and antidilution rights (if additional shares are

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issued, the preferred stockholder will automatically be issued new shares so its ownership is not diluted). The preferred stockholders may also have voting rights that are superior to the rights of the common stockholders.

Preferred stock may be convertible as well. At the option of the holders, they may convert the preferred stock to common stock at any time. However, generally the preferred stockholders will have no incentive to give up preferred rights and convert the stock until an IPO. When the company consummates an IPO that meets certain minimum size and share price requirements, the preferred stock will then automatically convert to common stock.

Board of Directors

In conjunction with the VC funder's desire to maintain some control over the startup, it will often secure a seat (or a few seats) on the board of directors of the company. The number of seats granted to the VC firm is generally commensurate with the VC investor's ownership percentage in the startup. This is usually accomplished through a stockholders' agreement whereby the stockholders agree to vote a certain way to secure the VC firm's board positions. It varies among investors whether they want actual control over the board.

Vesting Shares for Founders

In some instances, the VC firm may want to impose vesting requirements on the founders' shares. This means that the founders' ownership in the company will vest over a certain period of time. For example, the VC investor might implement a vesting schedule whereby 25 percent of the founders' shares vest each year over a four-year period, at which point they will be fully vested. These shares often automatically vest upon a certain trigger event, such as the closing of the sale of the company.

Vesting shares demonstrate to the VC funders that the founders are committed to the company. It also ensures that co-founders that leave the business early do not receive the same rewards as the founders who stay with the company. Some VC firms will ask the founders to trade in their current shares for vesting shares. This is a negotiable item. A compromise would be to give the founder vested shares for time already served to the company and create a vesting schedule for its shares going forward.

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Closing the Deal Quickly

Time kills deals. This is a familiar saying in the business world and certainly holds true for university startups seeking venture funding. The longer a transaction takes to close, the more opportunity a VC firm has to back out of the deal. However, the TTO should still do everything it can to help its startup get the best deal possible while at the same time protecting the university's interest in the technology. This should be balanced with the ultimate goal of getting the deal closed in a smooth and efficient manner that benefits all parties involved.

Supporting Entrepreneurship

In addition to establishing relationships with VC investors in your community, there are many things that can be done to support the spirit of entrepreneurship at your university.

Educate Your Entrepreneurs on What to Expect

Educating your university entrepreneurs about what to expect from VC investors will be extremely beneficial in expediting the transaction. Most importantly, startups should realize that VC firms will not write a blank check for their business. VC funders will first conduct due diligence on the company and technology to get a better understanding of whether this company will fit within their fund portfolio. This usually involves a lot of questions, and the founders should be prepared to answer these questions. This also includes a review of any contracts and financial statements of the company. Therefore, it pays to have accountants and lawyers assist you in the preparation of these financials and business contracts to the extent the startup can afford it. If the VC funder finds a contract that did not properly protect the startup's intellectual property or inaccurate financial statements, it will be less likely to invest.

In addition, as discussed previously in this chapter, VC firms are not going to invest in your startup and then sit back patiently and wait to see what happens to their investment. They will want to be involved, and they will be aggressive in making sure they are granted certain controls. This is often times shocking to the entrepreneur who has invested a great deal of time and effort in his or her technology and is unwilling to relinquish any control. Therefore, it is imperative that your entrepreneurs realize the VC firm's expectations up-front and that concessions will need to be made from both sides of the transaction.

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Resolving the Internal Struggle Between Academics and Entrepreneurship

One of the primary goals for a research university is to promote research and innovation among its faculty. The purpose behind this is to create and disseminate knowledge for the public good. On the other hand, the goal of business is to provide a financial return to its founders, investors, and employees using this knowledge. This causes an internal struggle between university academia and the entrepreneur. Therefore, if universities are going to embrace the entrepreneurial spirit on their campus, they must recognize how their culture may need adjusting.

One primary conflict among academia and business involves the university's faculty. If universities are going to make the decision to serve as an incubator for venture-based portfolio companies, they must also be prepared for their talented researchers to leave the university to work full-time on their new business venture. Ultimately, universities must create a balance of supporting their faculty and students in commercializing their discoveries through new businesses and serving society's need of developing solutions to society's problems.

Eliminate Red Tape

One of the biggest complaints heard from investors about technology coming out of universities is that it often takes longer to market than other startups, thereby making the investment riskier and less attractive. Therefore, it is critical that TTOs assist productively in the marketing of their entrepreneurs' technology, rather than serving as an additional obstacle to commercialization. Although TTOs should be focused on protecting the university technology, they should also help to ensure that the investment process is streamlined. Ultimately, the TTO should help package the startup's technology to interested VC firms and serve as an intermediary between the VC funder and the startup. They should be helping their startups find funding, not serving as an obstacle to closing the transaction.

Look for Alternative Funding Sources

There is nothing a VC investor likes more than to know that a startup is receiving additional funding from alternative funding sources, such as university or government grants.

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First, this adds some additional credibility to the startup's technology. Additionally, a VC firm may find comfort in knowing that it is not responsible for fulfilling all of the startup's capital needs. Government grants are particularly favored because they serve as a source of capital that does not dilute any existing owners' equity interest in the company. University entrepreneurs should be encouraged to look for these alternative funding sources before or as they are seeking venture funding. In fact, VC funders often consider whether a faculty member has a good track record of receiving grants as part of their investment decision-making process.

One primary source of additional funding can be from the university itself. Many research universities offer grants to faculty for various research projects. This is often a good source of initial funding to help jumpstart technology research. There are numerous grants offered by the federal government as well, including grants from the U.S. Department of Commerce for SBIR (Small Business Innovation Research set-aside program for small business concerns to engage in federal R&D with potential for commercialization) and STTR (Small Business Technology Transfer set-aside program to facilitate cooperative R&D between small-business concerns and U.S. research institutions with potential for commercialization).

Additionally, state and local governments may provide grants for certain technologies that have the potential of stimulating economic development in the community. A startup with an additional source of funding is certainly more attractive to a VC firm than a startup that must rely entirely on VC funding. Universities should therefore help educate their faculty on the grant-writing process and provide assistance where they can.

Support a Culture of Innovation

Once a university has chosen to support the spinoff and commercialization of technology developed by its faculty and students, there should be a systemwide movement to support innovation on the campus. This promotion of a culture of innovation may start with the TTO, but should cross over through all aspects of the university. Certainly any success a TTO has in spinning out technology can be used to support other segments of the university, such as fundraising or faculty recruitment.

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One way a university can help support an innovative culture is by providing free resources to its aspiring faculty entrepreneurs. These resources can range from classes on business management skills for the university's doctoral candidates to providing free access to certain facility space. Some universities may serve as incubators for certain startups that show high potential for fast growth. These incubators often provide facility space for their university entrepreneurs to utilize during the early stage of their business development, as well as legal, management, and technical advice from other university researchers and outside partners.

Conclusion

University-developed technology has long been an attractive target for VC investors. However, for various reasons, universities have not always been successful in finding venture backing for their startups. One way to improve this success rate is to first recognize which technologies are suitable for venture funding and which are not. Once a technology has been identified as suitable for a startup, the TTO should help to educate the founders on the process and the investors' expectations. Additionally, there are many things the TTO and university can do to develop relationships with potential investors and encourage a spirit of entrepreneurship on its campus. Venture funding is available for your university entrepreneurs. The TTO simply needs to serve as an intermediary between the startup and the investors to facilitate the investment process.

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