Volume 1, Number 1

Winter 2009

TOMORROW'S Technology Transfer

The Journal of the Association of University Technology Managers™

Highlights:

Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned

A Long, Hard Journey: From Bayh-Dole to the Federal Technology Transfer Act

U.S. Government Use of Patented Technology

Royalty Monetization: A Post-License Value-Creation Strategy

And more...

AUTM®

Volume 1, Number 1
Winter 2009

TOMORROW'S Technology Transfer

The Journal of the Association of University Technology Managers™

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The Association of University Technology Managers

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Foreword

Dear Reader:
Welcome to the updated and improved journal put together by AUTM!

You will have noticed the new name *Tomorrow's Technology Transfer: The Journal of the Association of University Technology Managers.* Yatin Karpe of Lehigh University suggested this forward-viewing name that the editorial board members felt captured much of the spirit of this publication—timely articles about the cutting edge of technology transfer, building on the base of experience of AUTM members to help you in your job of transferring the technologies that will be products tomorrow.

The entries for the new name were very creative, and a few evoked some chuckles. Some of the suggestions included:

- AUTM Leaves
- The Non-prophet
- Germinate
- Know How: The Journal for Technology Transfer Professionals
- NUTS (So we could use the tagline, "From SUPA to NUTS.")
- AUTMatic Transmissions
- The AUTM Scribe
- AUTM Impact

Thank you to everyone who took the time and contributed suggestions.

As you leaf through *Tomorrow's Technology Transfer,* you will see two distinct sections: Features and Research.

The new Features section is meant to serve you in two ways. First, the Features broaden the content of *Tomorrow's Technology Transfer* beyond traditional research articles with shorter pieces of interest and use. In this issue, you'll see a calendar of conferences, a Legal Tips column of current intellectual property considerations, a book review, a chapter from the recently launched Volume 3 of the 3rd Edition of the *AUTM Technology Transfer Practice Manual™,* and a Hot Topic that we hope will spark an online discussion among members. We want these Features to complement both the research articles and other AUTM publications to expose you to all that AUTM has to offer.

Which brings up the second point: the Features section provides another way for you to share information with your colleagues. Anyone can submit content to this section, and we are counting on you! Please forward us your book reviews, your topics for Legal Tips, your additions to the calendar, and any other ideas or articles you have. We truly envision this publication as a two-way communication and educational tool.

Yatin Karpe of Lehigh University suggested this forward-viewing name that the editorial board members felt captured much of the spirit of this publication.

Note that the book review in this edition of *Tomorrow's Technology Transfer* is about Henry Chesbrough's *Open Business Models.* Chesbrough, a professor at the University of California, Berkeley, will be one of the keynote speakers at the 2009 AUTM Annual Meeting℠, to be held Feb. 12–14, at the Marriott Orlando World Center Resort in Orlando, Florida.

The Research section continues with the tradition of providing in-depth articles regarding all aspects of technology transfer. This issue begins with "Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned," by John Fraser, an article about how to effectively communicate the benefits of technology transfer—an important topic for any professional in the field who has to teach legislators and administrators about the public benefits of technology transfer.

However, to effectively communicate the benefits of technology transfer, it is important to understand the events leading up to the passage of the current U.S. federal technology transfer laws. In the second article, "A Long, Hard Journey: From Bayh-Dole to the Federal Technology Transfer Act," Consultant Joe Allen, a key player in the successful passage of the Bayh-Dole

Act, provides insights into the history of these landmark acts.

In addition to Bayh-Dole, technology transfer professionals should also be aware of Title 28, Section 1498, of the United States Code. The third research article, "U.S. Government Use of Patented Technology," by Beth Bornick, discusses how this section of law gives the U.S. government the right to take compulsory, nonexclusive licenses to use any U.S. patent without the owner's consent. All technology transfer professionals should understand how this provision can affect their institutions' patent rights and how to obtain compensation when the government does take this unilateral compulsory license.

With *Tomorrow's Technology Transfer* now up and running, submit articles early and often. Details are available on the AUTM Web site.

Finally, the last article, "Royalty Monetization: A Post-License Value-Creation Strategy," by Lou Berneman, addresses the more advanced topic of royalty monetization techniques that can be used by a patent holder to generate financial value and reduce risk early in the life of a license.

Overall, we hope that the longer, peer-reviewed articles that appear in the research section continue to benefit you by providing new insights and ideas concerning the profession. But we need your help! We encourage you to submit new research articles and suggest new topics of interest. After all, it is you, the practitioner, whose expertise and experience are needed to advance the profession so that technology transfer can continue to benefit the public by moving tomorrow's technology into the public domain.

With *Tomorrow's Technology Transfer* now up and running, submit articles early and often. Details are available on the AUTM Web site. The journal will publish twice a year, bringing you the most current articles affecting the field. Welcome and enjoy!

Kirsten Leute
AUTM Vice President for Communications
Stanford University

Jennifer Gottwald
Features Editor
Wisconsin Alumni Research Foundation

David Grossman
Research Articles Editor
George Mason University

Wanted: real-life photos that represent AUTM

We need your help! In addition to articles, *Tomorrow's Technology Transfer: The Journal of the Association of University Technology Managers* is looking for photos for the cover. Sure, we could use stock photos of outdated technologies or generic business people posed around a conference table, but that doesn't represent what AUTM is about – its members and the amazing technologies that they manage.

So consider submitting a cover photo to TTT. We'd like to see photos of your colleagues in action. (OK, so they are probably still posed around a conference table, but at least we know who they are.) Or submit a photo of a technology out of your university or research institution.

Photos should be digital, at least 300 dpi, and four color. In addition, photos must have permission from the picture subjects as well as the photographer. Please include two to four sentences explaining your photo. E-mail photos for consideration to Jennifer Gottwald at Jennifer@warf.org.

Tell us what you think!
Join an interactive discussion on these topics by visiting the *Tomorrow's Technology Transfer* page on the AUTM Web site.

U.S. Provisional Patent Applications: Pro or Con?

Kurt Ehresman, JD, and Mark Simpson, JD

In this issue, Legal Tips provides brief suggestions and considerations to help you best obtain patent rights.

Technology transfer professionals report a wide disparity in the advice they receive from patent attorneys concerning the wisdom of filing U.S. provisional patent applications. Some patent attorneys swear by them, others don't. However, because you must ultimately make a choice, here are some issues to consider.

Obtaining the Earliest Priority Date Possible

While the United States remains a first-to-invent country, the rest of the world grants patent rights to the first inventor who *files* a patent application.

Pro: Filing a U.S. provisional application results in an early priority filing date that carries through to a later-filed U.S. nonprovisional application, PCT (Patent Cooperation Treaty), and/or foreign filing. The filing date of the provisional does *not* count against the patent term of a U.S. patent that claims the priority date of the provisional.

Con: Because the priority date will apply only to the invention features that are fully disclosed and enabled, additional provisional or nonprovisional applications may be required for later-developed features.

U.S. Provisional Patent Applications Are not Examined

Claims are not required in a provisional application.

Pro: Because provisional patent applications are not examined, there is no requirement for a claim, and an applicant can continue to improve the application for up to one year before filing any nonprovisional patent applications.

Con: Provisional applications do not enter the examination queue, which currently includes a large backlog of unexamined patent applications. Therefore, if the goal is to obtain a patent as soon as possible, you might consider filing a nonprovisional application.

Initial Cost

Weigh the short-term and long-term costs and benefits.

Pro: Provisional applications can be prepared and filed for a fraction of the cost of a nonprovisional application. The minimum filing requirements are a United States Patent and Trademark Office cover sheet (an application data sheet or cover letter identifying the application as a pro-

Saving Money and Improving Performance for PCT Applications

A new option for PCT (Patent Cooperation Treaty) patent applicants involves selection of South Korea as the PCT searching and examining authority. This option was the culmination of a cooperative effort between the United States Patent and Trademark Office (USPTO) and the Korean Intellectual Property Office (KIPO), wherein KIPO patent examiners were trained by the USPTO in the searching and examination of patent applications. Our experience has been favorable involving several PCT applications filed in the USPTO and designating the KIPO as the searching authority. The average PCT fee was about $1,000 less than if the USPTO had been selected. Additionally, the KIPO has consistently produced high-quality international search reports within the 18-month period specified by the PCT.

Legal Tips

visional application), a specification that fully discloses and enables the invention (in any form), a drawing (in most cases), and a $110 filing fee. Such "cover sheet provisionals" often include an inventor's prepublication article as the specification.

Cons: Because of their informal format, cover sheet provisionals can be more expensive to convert into nonprovisional applications. Additionally, because provisionals become part of the public file history of any patent that may be issued, provisionals should be reviewed carefully before filing to redact any dates that are not required to be in them and confusing inventorship statements (such as gratuitous attributions by author to students and other non-inventors) and to redact any trade secret or proprietary information.

Kurt Ehresman, JD, and Mark Simpson, JD, are partners at Saul Ewing LLP in Philadelphia, Pennsylvania.

If you have a timely topic you would like to see addressed or a tip you would like to share, contact Emily Bauer at emily@warf.org.

Opinions expressed are those of the authors and not of AUTM.

Hot Topic

We want to know!

Do you file patent applications in other countries? If so, under what conditions?

Share your thoughts, opinions, and experience by posting to the interactive discussion board on the AUTM Web site.

Find out how by visiting the *Tomorrow's Technology Transfer* page on the AUTM Web site.

If you have a topic you'd like to discuss, contact Emily Bauer at emily@warf.org.

AUTM

Advancing Discoveries for a Better World

AUTM offers year-round learning opportunities—at least one educational opportunity every month—online and/or in person. AUTM members receive deep discounts on registration.

Don't miss these upcoming learning opportunities:

AUTM ANNUAL MEETING

The AUTM 2009 Annual Meeting, *Defining Our Profession,* Feb. 12–14

Orlando World Center Marriott Resort & Convention Center
Orlando, FL USA

The AUTM 2009 Annual Meeting offers more networking opportunities than ever before, along with a new online partnering system that provides greater access and control over meetings with industry colleagues.

AUTM ONLINE PROFESSIONAL DEVELOPMENT COURSES

Startups, Equity, and Company Formation: Online, noon–1:30 p.m., EST, March 10

These 90-minute courses are designed to offer cost-effective training that you can participate in from the comfort of your own office. All you need is a computer and a phone line. In addition, your office pays one low registration fee regardless of how many of your colleagues take advantage of the presentation.

REGIONAL MEETINGS

AUTM Eastern Region Meeting, June 15–17
San Juan, Puerto Rico

AUTM Central Region Meeting, July 27–29
Madison, WI USA

AUTM Western Region Meeting, Sept. 13–15
Vancouver, BC Canada

AUTM regional meetings offer targeted learning in an intimate setting along with many opportunities to network with industry colleagues in your area.

Visit the AUTM Web site for more information about these and other programs.

Inventor Relations Are Complicated! Developing and Maintaining Good Inventor Relationships Is Key

Katharine Ku, MS

This article is reprinted from the recently released Volume 3 of the AUTM Technology Transfer Practice Manual™, *3rd Edition. Volume 3 of the* TTP Manual *is available free to AUTM members on the AUTM Web site.*

Know Your Inventor

In the Office of Technology Licensing (OTL) at Stanford, we believe that the inventors are the most important clients, our customers. They are the source of our raw material, the people who give us inventions to find homes for. Therefore, we need to establish good relationships with inventors who sometimes don't really understand the commercialization process. Other inventors do not want to be bothered or educated with the legal and commercial details—especially prior to having inventions; some want to be very closely involved. Still other inventions are, frankly, not of commercial interest, but the inventors, as the creators with little objective perspective, often have unrealistic expectations.

The ideal inventor is someone who is involved and interested in giving input but is willing to rely on, and learn from, the experienced judgment of the licensing professional. On the other hand, sometimes the inventor has important insights that can help the licensing office make a better decision. The inventor, understandably, wants the technology developed and usually wants the licensing office to "get the best deal possible." Inventors often think we undervalue their technology.

Inventors come in all flavors! They do not always speak with one voice. Inventors are faculty, staff scientists, graduate students, post-docs, or undergraduate students. Sometimes, one inventor wants the technology to be licensed nonexclusively but his or her joint inventor wants to start a company. Sometimes inventors don't get along with their co-inventors. Sometimes student inventors are afraid to speak their mind. Sometimes an "inventor" is not really an inventor in the patent sense and appears on invention disclosures because he or she is the principal investigator (or worse, a chairperson). Sometimes inventors are at different institutions. The licensing office must be aware and sensitive to all these relationships to make reasonable decisions for all the affected parties.

The biggest challenge, but the greatest requirement for good inventor relationships, is to keep *all* inventors informed, not just the faculty inventor. This can be very difficult when the number of inventors is high and their status is different. We try to meet with all inventors for the initial meeting to explain the process and set realistic time, patenting and/or licensing, and monetary expectations (another important aspect to maintaining good inventor relationships). Although often one inventor is more interested than the others, or speaks for the others, we try to keep all inventors informed on general patenting and marketing correspondence so that they each have the opportunity to have input.

Lastly, sometimes inventors actually do know best. We have had inventions that we clearly thought were unpatentable and unenforceable but around which a company was created. We have wanted to drop inventions for good reasons, but inventors have persuaded us to continue with patent applications that eventually led to licensing activity. So, inventors' opinions should always be given serious consideration. We get their input on licensing strategies (nonexclusive/exclusive, startup/existing company) and their perspective on pricing (so as to see if our expectations are similar to theirs). Inventors do not dictate licensing to the licensing office, but we are very generous with asking for their input and reactions.

Lastly, sometimes inventors actually do know best. We have had inventions that we clearly thought were unpatentable and unenforceable but around which a company was created

In general, our licensing teams work very closely with inventors—students and faculty alike—and are in regular communication with them. Working well with inventors ensures that the office will have repeaters whose second and third inventions may end up to be more valuable than the first. If a first-time inventor has a bad experience, the office may not get the opportunity to work on those second and third valuable ideas.

Outreach to New Inventors

Like other university inventors, Stanford researchers vary tremendously with regard to commercialization of their inventions—from disinterested inventors to very interested researchers, from experienced inventors to inexperienced. We have various informal activities to reach out to new inventors: taking faculty to lunch; participation in new faculty orientation; attending speaking engagements at the laboratory or departmental level; hosting seminars for students, grad students, and post-docs as well as for faculty only; and exploiting speaking opportunities at Stanford entrepreneurial organizations. We have had barbeques and box-lunch occasions to attract student interest in the licensing office. But the OTL has been in business for more than 37 years, and we are fairly confident that a new inventor will be encouraged by colleagues to contact us if there is a discovery that has commercial potential.

For universities that are trying to build their technology transfer program, we believe that inviting successful inventors who can share their stories with colleagues is a good way to generate positive publicity. Often university researchers are more interested in hearing from external "experts," such as patent attorneys, venture capitalists, and well-known entrepreneurs, about the their roles in the commercialization process. Any kind of interesting seminar on aspects of technology transfer is a chance to educate the community about the opportunities and challenges of university licensing.

We also caution, however, against overselling technology transfer because disillusioned inventors can be a very negative influence on colleagues. The best way to encourage disclosures is to have a good reputation among researchers.

We believe in providing abundant information via many sources: the Internet, brochures, pamphlets, annual reports, a newsletter, and an *Inventors' Handbook.* We are willing to meet with new inventors (or potentially new recruits to Stanford) whenever they call so that we can establish a relationship early on. We find that it helps to calibrate future inventions if we can start to understand an area of research before inventions are disclosed to the office, when at all possible. If the OTL is aware of large research grants that may produce inventions, licensing staff can easily meet with faculty and staff to encourage disclosures.

However, if an office is swamped, getting new disclosures/the best disclosures may not be a priority. You have to prove yourself with what you get, not what you don't get.

Outreach to Current Inventors

As mentioned in the first section on our philosophy, we try to maintain regular communication with our inventors. We have an Inventor Portal, which is one of the most effective ways to allow the inventor to keep abreast of his or her invention activity without having to call/write the office all the time. The Inventor Portal, a Web-based, confidential system, provides a real-time, continuous status report on all invention disclosures, all patents filed, expenses associated with the filings, all licenses, and all royalty income past and current.

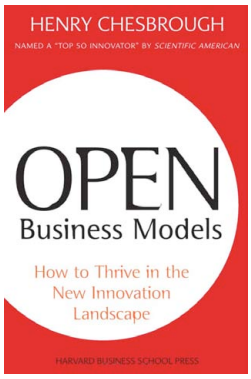
We also survey our inventors, six months and one year after the disclosure is submitted. The questions, about 8 to 10, are specific to the events related to the timing of the survey. For a new disclosure, we ask the inventor if he or she has met with the licensing staff and understands the process. For an older disclosure, we ask if he or she has been kept informed. If the customer survey indicates that there is an issue or unanswered questions, we respond right away to the inventor. The customer survey is a great way to keep in touch with inventors and resolve issues as soon as possible. The most common complaint, if there is one, is that an inventor is not kept as informed as he or she would like to be, so it is very important to keep inventors informed. If we discover this, we call him or her right away.

We assign inventors to various licensing professionals based mostly on technical area of the invention. For repeat inventors, we try to keep the same licensing representative to enable people to establish a relationship, but there are times when the invention involves a different discipline or there are several inventors who have worked with different licensing staff so it's not a hard-and-fast rule. Very rarely, an inventor does not get along with a licensing person and we will change assignments, but inventors do not generally get to choose the licensing person.

Summary

The ability of office staff to manage inventor relationships well is one of the most important keys to success. Regular communication with and respect for the inventor will go a long way to contributing to good inventor relationships, some of which may last for years and many inventions and licenses.

Former AUTM President and Bayh-Dole Award Winner Katharine Ku, MS, is director of the Office of Technology Licensing at Stanford University.



Open Business Models: How to Thrive in the New Innovation Landscape

by Henry Chesbrough, MBA, PhD, University of California, Berkeley

Reviewed by Leona C. Fitzmaurice, PhD

Open innovation is a concept that most technology transfer professionals welcome with enthusiasm. Wouldn't the world be nearly perfect if companies large and small opened their doors to an influx of technological innovations and did not brand them "not invented here"? And what would happen if companies chose not to hoard technological innovations that were not of use to them but could be critical to the growth and development of other companies?

Henry Chesbrough's first book about this concept, *Open Innovation,* was published in 2003 and became a nonfiction bestseller that paved the way for him to become an acknowledged expert and public speaker in this arena. Chesbrough's second book, *Open Business Models,* was published in 2006. This latter book addresses not only the reasons that a company should embrace the concept of open innovation but also begins a discussion of how this can be accomplished.

If you have not read *Open Innovation,* you may want to do so before reading *Open Business Models.* On the other hand, Chesbrough does a very nice job of describing the concept of open innovation in the first few pages of his second book and links it to his definition of an open business model.

Open Innovation demonstrates that companies can gain a competitive advantage in today's marketplace by licensing their underutilized intellectual property to third parties while seeking new ideas and inventions from external sources. A company that practices this concept most likely will have developed what Chesbrough defines as an open business model.

According to Chesbrough, "A business model performs two functions: It creates value and it captures a portion of that value. It creates value by defining a series of activities from raw materials through to the final consumer that will yield a new product or service with value being added throughout the various activities. The business model captures value by establishing a unique resource, asset, or position within that series of activities, where the firm enjoys a competitive advantage.

"An open business model uses this new division of innovation labor—both in the creation of value and in the capture of a portion of that value. Open models create value by leveraging many more ideas, due to their inclusion of a variety of external concepts. Open models can also enable greater value capture, by using a key asset, resource, or position not only in the company's own business model but also in other companies' businesses."

Perhaps the greatest strength of *Open Business Models* is found in Chesbrough's descriptions of companies that have developed such models, for example, Procter & Gamble (P&G), Air Products, and IBM. In the case of IBM, the continued existence of the company is linked to its redefining itself as a company that embraces open innovation.

Similarly, P&G began to embrace an open innovation business model in the early 2000s when new Chief Executive Officer Alan G. Lafley challenged his company to find "…50 percent of its innovations from outside the company." At that time, approximately 20 percent of P&G's new ideas, technologies, and innovations were derived from external sources. Within three years, that percentage had increased to 35 percent, and today the

company is nearing its goal of 50 percent as it implements its leading-edge Connect and Develop strategy (see, for example, P&G's Web site). P&G continues to explore and improve its open innovation business model as it accumulates tangible evidence of its successful implementation. Lafley states, "Our vision is simple. We want P&G to be known as the company that collaborates—inside and out—better than any other company in the world." Simply put, Lafley believes in the open innovation business model and wants to implement the model so well that P&G becomes the first choice for those seeking to place or obtain new technologies.

Chesbrough's review of what he terms *innovation intermediaries* is a bit disappointing, however. Innovation intermediaries are sometimes termed *innovation brokers* or *technology brokers.* Typically they are entities that help to move innovations from the creators to the seekers of innovation as well as to investors and policy-makers. Typically an innovation intermediary will seek to identify opportunities for a non- or underutilized innovation and broker the relationship between the creator and potential user of the innovation. Chesbrough is critical of the processes that these third parties have used to make innovations available to companies, but his suggestions regarding how these processes should be changed or improved are not compelling. Then again, perhaps it is not Chesbrough's responsibility to even suggest changes and improvements.

Members of the AUTM community continually strive to improve their ability to market and commercialize their innovations, and *Open Business Models* provides an insight into a changing marketplace for new discoveries and ideas. As more companies embrace the concept of open innovation and create open business models aimed toward enhancing their competitive advantage, universities and other nonprofit entities are likely to find new and increased markets for their innovations. The challenge continues to be how to best interact with this emerging customer base and ensure that universities and other nonprofit entities become desirable sources for innovations. The opportunity exists for universities and nonprofit entities to chart new paths as innovation intermediaries in the emerging innovation economy.

Reviewer's note: Henry Chesbrough, MBA, PhD, currently conducts research and teaches at the University of California, Berkeley, where he was named executive director, Center for Open Innovation, Institute of Management, Innovation, and Organization, Haas School of Business, in 2003.

Leona C. Fitzmaurice, PhD, is director, technology transfer, at The UAB Research Foundation in Birmingham, Alabama.

If you have a book you'd like to see reviewed or would like to review a book, contact Emily Bauer at emily@warf.org.

Calendar

Check out these events, there might be one just right for you. Or, if you'd like to add your event to the *Tomorrow's Technology Transfer* Calendar, contact Emily Bauer at emily@warf.org.

Notation of these events does not imply AUTM endorsement.

JANUARY 2009

Jan. 28–31
AIPLA Mid-Winter Institute
Miami, FL

FEBRUARY 2009

Feb. 12–14
AUTM Annual Meeting
Orlando, FL

Feb. 25–27
LES 2009 Winter Meeting
San Antonio, Texas

MARCH 2009

March 10
AUTM Online Course: Startups, Equity and Company Formation
Online Distance Learning

APRIL 2009

April 1–4
ABA Annual Intellectual Property Law Conference
Arlington, VA

MAY 2009

May 4–7
Federal Laboratory Consortium for Technology Transfer National Meeting
Charlotte, NC

May 6–8
LES Spring Meeting*
Montreal, QC, Canada

May 13–15
AIPLA Spring Meeting
San Diego, CA

May 16–20
INTA Annual Meeting
Seattle, WA

May 18–21
BIO International Convention
Atlanta, GA

JUNE 2009

June 15–17
AUTM Eastern Region Meeting
San Juan, Puerto Rico

JULY 2009

July 27–29
AUTM Central Region Meeting
Madison, WI

July 30–Aug. 4
ABA Annual Meeting*
Chicago, IL

SEPTEMBER 2009

Sept. 13–15
IPO Annual Meeting
Chicago, IL

Sept. 13–15
AUTM Western Region Meeting
Vancouver, BC, Canada

OCTOBER 2009

Oct. 15–17
AIPLA Annual Meeting
Washington DC

Oct. 18–22
LES Annual Meeting*
San Francisco, CA

JANUARY 2010

Jan. 27–30
AIPLA Mid-Winter Institute
La Quinta, CA

MARCH 2010

March 18–20
2010 AUTM Annual Meeting*
New Orleans, LA

**As of press time, links do not provide specific meeting information.*

Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned

John Fraser

The following article is derived from "Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned," originally published in the January 2008 edition of the Licensing Journal *and based on a presentation in January 2007 in Tokyo, Japan.*

Since the 1980 passage of the Bayh-Dole Act, academic technology transfer has gained profile, globally, as a key component of knowledge-driven economic development. The following article provides information on this phenomenon in the U.S. and summarizes some of the lessons I've learned.

Lesson 1: Clearly Written Policies Accelerate the Activity: Purpose of the Bayh-Dole Act

Academic technology transfer received a major boost in 1980 with the passage of the Bayh-Dole Act by Congress.[1] Essentially, by pre-assigning the option to acquire ownership of intellectual property (IP) created using federal grants, universities and small U.S. businesses would have certainty of ownership. Senator Birch Bayh (D-IN), co-sponsor of the act, believed that such certainty would increase the commercialization of academic and small-business discoveries into products that would improve the U.S. economy and U.S. competitiveness. At the time of passage of the act in 1980, the U.S. auto and steel industries were reeling under foreign competition. As Bayh said, "We had lost our no. 1 competitive position in steel and auto production. In a number of industries we weren't even no. 2."[2]

A number of universities in the U.S. enthusiastically supported this law and in 1980 took up the challenge of technology transfer. Interest expanded until, in 2006, AUTM's *Licensing Survey™* identified technology transfer activities in 189 universities, hospitals, and research institutes.

With the passage of Bayh-Dole, many universities adopted written policies to clarify the conduct of commercial activities on their campuses. Specifically, these addressed disclosure mechanisms, intel-

Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned

John Fraser

lectual property protection, commercialization responsibilities, and, in the case of success, profit distribution from successful technology transfer. Such policies established technology transfer as an acceptable academic pursuit and a creative vehicle for the benefit of society, in line with the Bayh-Dole Act. (See Figure 1.)

Lesson 2: Academic Technology Transfer Works!

Yes, it does. In fact, it is quite amazing to consider the far-reaching advances developed through this process and their profound impact, both on the economy as well as society. Some of the older, better-known products include:

- Taxol, an anticancer drug made by a process invented at Florida State University;
- Gatorade, a sports drink, developed at the University of Florida;
- Pablum, a baby food from the University of Toronto;
- Vitamin-enriched milk, created from research at the University of Wisconsin;
- Stannous fluoride, used in some brands of Crest toothpaste, first combined at Indiana University;
- Bufferin, the buffers in buffered aspirin, from the University of Iowa; and
- Mosaic, browser software prior to the Netscape browser, both from people from the University of Illinois.

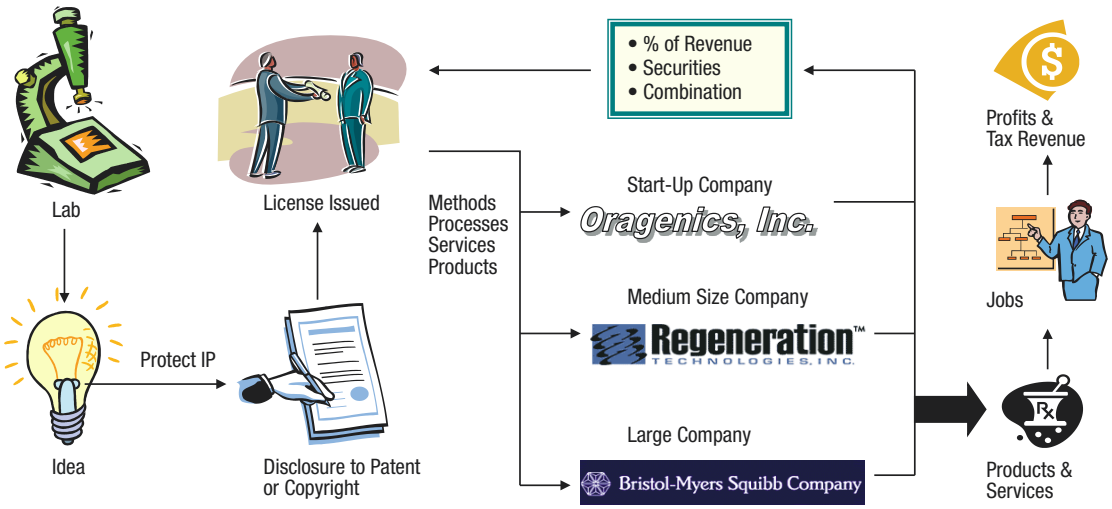
More recent products, highlighted in the Better World Project, published by AUTM, include:[3]

- Farecast, a Web site that helps travelers save money by forecasting the best time to buy airline tickets, designed at the University of Washington;
- ALEKS, intelligent student tutoring software from the University of California;
- ADEPT, a diagnostic system to detect early-stage Alzheimer's disease, credited to the University of Glasgow; and
- Levulan, a light-based therapy for skin conditions, including some cancers, invented at Queens University.

Invention disclosures, patents, and licenses, etc., are all parts of the process, but the ultimate goal is to help create products that benefit people.

The aforementioned innovations are only examples. AUTM reports in its FY2006 *Licensing Survey* that 697 new products were introduced into the market in 2006 for a total of 4,359 introduced from FY1998 through FY2006.[4] These well-known products all have at least one thing in common: Each and every one of them originated from discovery and invention at an academic institution. Some of them were patented, some of them are protected by copyright. All were licensed to a company as an idea/prototype that the

Figure 1: Lab to Market: A Chain of Value



Source: Florida Research Consortium

Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned

John Fraser

company then commercialized and brought into the marketplace.

The stories in the Better World Project illustrate the impact of the thousands of such products on society and the economy and show, without question, that academic technology transfer really works.

Lesson 3: The Impact of Technology (How to Measure Success)

For a number of years, observers of the field generally assumed that the best way to measure the impact of technology transfer was through the licensing income received each year. This approach bred an assumption that the most successful technology transfer offices were those that pushed for the highest payment and made the most money on deals. This may make sense in a commercial setting, but it overlooks key concerns in an academic setting, where the core mission of the institution is education, research, and community service. As Kevin Cullen elegantly points out in his article in the December 2006 issue of *Milken Institute Review,* universities will continue with an activity even if it generates a financial loss, as long as it has positive impacts in the local and larger community.[5]

Current thinking supports that the impact of technology transfer should be measured more comprehensively by taking into account a number of different factors. These include: increased financial support of the academic research activity, the number of licensing deals concluded, the number of products and services introduced to the marketplace, the number of companies and jobs created as a result of a license (spinout companies), as well as induced financial investment for product development, etc. Other measures include the impact of testing facilities, research parks, and incubators in the area around the academic center.

From the academic perspective, licensing income represents an isolated indicator of overall success; important, to be sure, but not the sole end of a licensing office. Frankly, the amount of licensing income generated is not under the control of the university at all. Rather, it is entirely dictated by market pressures, the usefulness of the actual product, and how adeptly the company brings the two together. Because the inherent risks and monetary costs of developing basic research into a marketable product are so high, a school's technology transfer office generally considers the commitment and capabilities exhibited by a commercial company, first and foremost, not how much they are willing to pay.

Lesson 4: Inputs, Outputs, Outcomes, and Impacts

Increasingly in America, the success of academic technology transfer is not registered through *inputs*—the number of disclosures or patents realized. Nor is it measured by *outputs,* the number of licensing agreements signed. Instead, considered more significant are the *outcomes*—reflected in the benefits of products brought to the marketplace—and the *impacts* that these products have on society, in terms of increased productivity and competitiveness, lives saved, and improved quality of life. This recognition is occurring despite the fact that universities exercise no influence over the *outcomes* and *impacts,* but only the *inputs* and *outputs.*

Personal experience has also shown that the metrics of an academic technology transfer program depend upon the age of that program. For example, an office that is less than five years old should measure progress by the number of disclosures, patents filed, confidentiality agreements signed, and licensing or research contracts signed. An office between five and ten years old should place less emphasis on these variables *(inputs)* and begin to look at the *outputs,* such as deals signed, increased funding to the research base of the university, and licensing income. After ten years, more emphasis should be placed on measuring the *outcomes* of the

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activity, such as the number of products in the marketplace. The previous *inputs* and *outputs* are still relevant measures, but of importance to managing the office, not measuring success. After ten years, the *impacts* of the activity can be meaningfully measured through the number of lives saved, improvements to the lives of patients, and also increased competitiveness and productivity as a result of the products introduced to the marketplace.

In summary, early in the life of a technology transfer office, measuring *inputs* provides a valid testament to the relative success of that program. Later, *outputs* receive more consideration (assuming the university has dedicated enough resources to allow this to happen). As the office and its relationship with faculty and corporate partners mature, *outcomes* produced by the licensed companies become increasingly important. Ultimately, once a number of products have been in the market for some time, *impacts* represents the truest barometer of success.

Lesson 5: Return on Investment (ROI)

I am often asked: What is the return on investment in technology transfer? Before answering, I stop and remind myself that the person is really asking about the *financial* return on *financial* investment. I usually start my answer by pointing out that my ROI calculation always begins by recognizing that the financial aspect is only one element (and usually not the most revealing) of a determination of ROI. Other elements include: the enhanced reputation of the university in the local economy, student enrichment through association with the activity in research labs and the licensing offices, and, not least of all, the national and international credibility gained by the institution.

The financial return depends on the financial investment. Many observers look at the major investment of public funds in research and look to the academic technology transfer for a return, as its purpose is to move research discoveries into products. The financial ROI depends as well on the investment in the office of technology transfer and whether or not there are sufficient resources to affect the outcome of commercialization. Calculations using a decade of AUTM *Licensing Surveys* show that, for all the reporting university programs, the average annual licensing income amounts to 3.2 percent of the annual reported research expenditures.[6] By any measure, this is a modest financial return, based on licensing deals done years before. The full impact and ROI are only truly understood once all other elements are taken into account.

Lesson 6: How Academic Discoveries Develop into Products that Benefit People

Universities do not undertake product development or product sales. Commercialization, therefore, occurs through licensing commercial rights to a company for development, or, in 15 percent of all yearly licenses, by creating a new company and basing its product development on a license from the university.

The process of developing a product in a corporation is complicated and extensive. Over the last several decades, the basic research and proof-of-concept activities (steps 1 and 2 in Figure 2) can occur in a university setting and are licensed into a company for further evaluation, then development and distribution of a product. Technology transfer offices act as conduits between the companies and the universities.

Lesson 7: Academic Technology Transfer Is an Enormous Activity in the United States

This is an enormous activity, fuelled by annual U.S. university research expenditures in the billions ($45 billion in U.S. research and development expenditures [FY2006]).[8] U.S.-based *AUTM Licensing Survey* respondents signed 4,963 new licenses, transfer-

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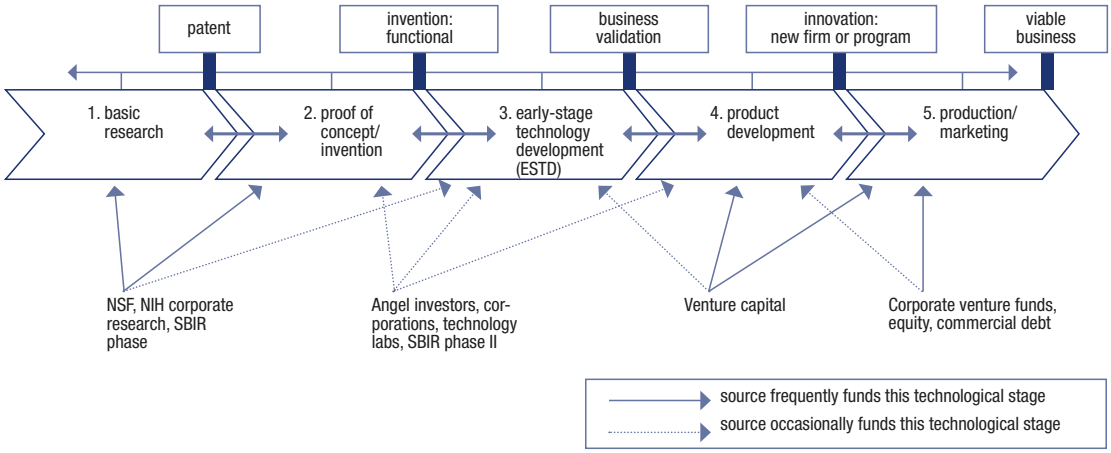
Figure 2: Sequential Model of Development and Funding

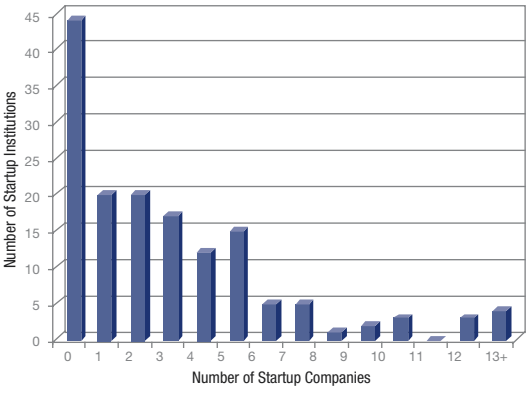


Source: National Institute of Standards and Technology[7]

ring commercialization rights to companies in FY2006. At any one time, respondents report there are more than 12,600 active U.S. licenses yielding income, each representing a one-on-one relationship between a university and a company.[9] Such arrangements exist in every state and every part of the country.

Of the 4,963 licenses above, 553 were used to create a newly incorporated spinout company. Survey respondents reported 5,724 new spinouts since 1980. Six hundred ninety-seven new products were introduced into the market in 2006, bringing the total entering the market to 4,350 from FY1998 through FY2006 alone.[10]

Figure 3: Startup Companies Formed By U.S. Universities, 2006



Source: AUTM Licensing Survey Summary™, FY2006[11]

Lesson 8: Startup Companies: One Aspect of Economic Impact

Figure 3 shows that many institutions are assisting their faculties in this activity, and the number of startups, per institution, is very diverse. For FY 2006, 17 universities created three startup companies each, and four universities each created more than 13 startups. Naturally, the universities with the largest research expenditures are clustered on the right side of the chart. Clearly, not every university functions at the same level of technology transfer activity. There were 44 universities that reported no startups that year.

While slightly dated, Table 1 shows another fascinating aspect of academic startups: Individuals represent almost half of the initial investors. Professional, institutional investors, whether venture capital groups, government, or corporate investors, do not dominate the initial investor groups. The largest fraction of reported funding came from neighbors, friends, and family.

Lesson 9: New Metrics

Academic technology transfer has gained profile through the publishing of the *AUTM Licensing Survey.* This gold standard report has provided consistent definitions and reports on the U.S. and Canadian activity for the past 15 years. The number

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Table 1: US-18 Sources of Funding for New Startups Formed by U.S. Respondents in 2004

Individuals	Number	%
Friends and Family	94	20.5%
No External Funding	57	12.4%
Individual Angel(s)	49	10.7%
Angel Network	26	5.7%
Institutional Sources		
Venture Capital	85	18.6%
State Funding	36	7.9%
SBIR/STTR	32	7.0%
Corporate Partner	25	5.5%
Institutional Funding	26	5.7%
Other	28	6.1%
Total	**458**	**100.1%***
Number of U.S. Respondents	155	

**Because of rounding, total does not equal 100%.*

Source: AUTM Licensing Survey Summary, FY2004[12]

of disclosures, the number of patents, the number of licenses, and the gross licensing income are presented. The easiest measure to track in the survey is the gross licensing income total across the United States. Over time, readership expanded while the notion of universities as local engines of economic development gained momentum. Academic technology transfer was one interface of the university and the local economy. Given the data presented and the emphasis, readers assumed that the purpose of technology transfer was simply lucrative licenses–income. Overlooked and underemphasized were the economic benefits attributable to startup companies, research parks, bolstering the research base, and new products entering the marketplace—or what I would call the *impacts.*

AUTM is moving beyond its traditional metrics to create additional measures of success and provide a broader understanding of the process, as well as the impact. AUTM is undertaking a pilot experiment[13] with counterpart organizations in the United Kingdom (UNICO) and in Canada (Alliance for Commercialization of Canadian Technology [ACCT]). In all three countries, there has been coordinated consultation with senior academic leadership, policy-makers, politicians, and grant providers to help identify new metrics, collect the data, and publish it.

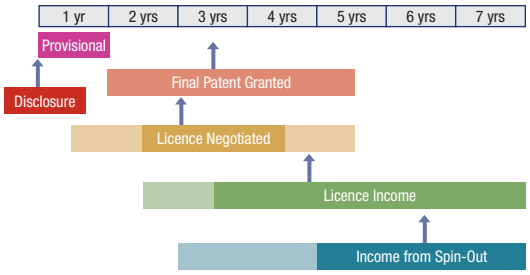
The traditional approach to quantifying this activity no longer provides as complete a picture as the public requires. Table 2 lists some of the additional metrics that AUTM, UNICO, and ACCT might implement to measure the impact of technology transfer. While incomplete, the table provides some sense of the direction.

Table 2: Potential Metrics

Internal to the Institution	Measured by
Research partnerships	Numbers and $$ size
Products in market	Case studies
External to the Institution/ Impact in the Community	
Research park, incubators	Local licenses, interactions with university
Local startup companies • With technology licenses • Without technology licenses	Jobs created and sustained Investments in product development Stories and case studies

Lesson 10: Time Is a Major Factor in the Technology Transfer Process

Figure 4: The Phasing of the Value Chain



Difficult to generalize. Averages hide wide variation in individual transactions

Source: Southern African Research and Innovation Management Association[14]

The chart in Figure 4, created by Southern African Research and Innovation Management Association (SARIMA) researchers in 2005, represents a study of data from many countries including South Africa, the United Kingdom, the United States, and Canada. As illustrated, the interval separating disclosure by the university and introduction of the eventu-

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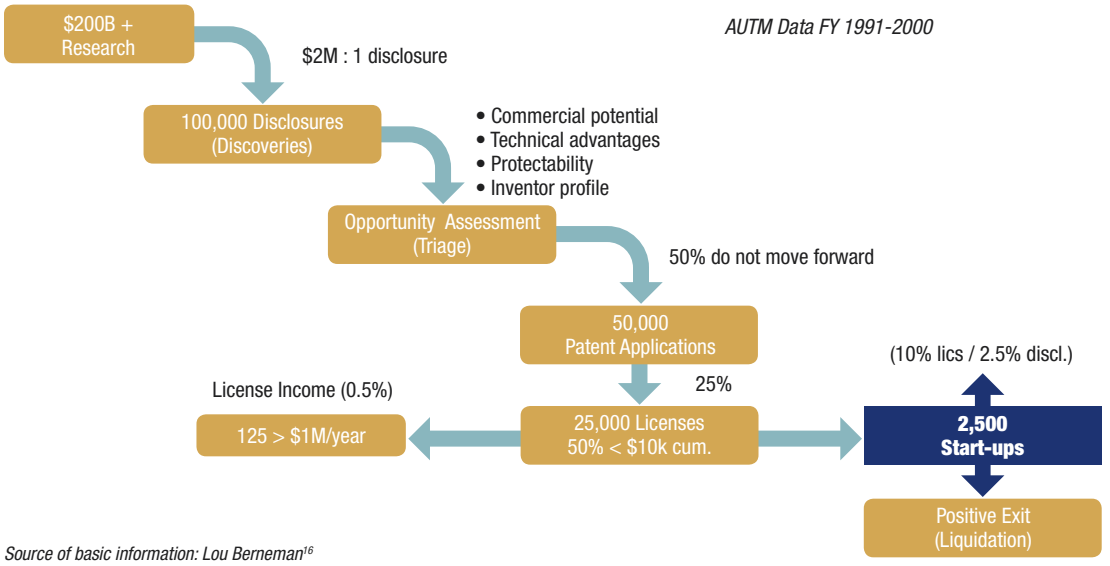
al product into the marketplace by the corporation is measured in many years. The color bars indicate the spread of the data for any measurement. The SARIMA study found that, from the point of disclosure, granting a company a license took well over three years on average in the United Kingdom, the United States, and Canada. Notice the difference between licensing income from licenses granted to existing companies versus successful product introduction by spinout companies; a significant number of years after founding of the spinout. University of British Columbia's Caroline Bruce pointed out that a pharmaceutical product takes much, much longer than indicated in the above chart (personal communication). (As an aside, a necessary characteristic of people active in academic technology transfer is patience and wanting to create a portfolio of licenses.)

A fascinating study is under way, led by Ashley Stevens, Boston University, and Mark Rohrbach, National Institutes of Health, that emphasizes impact and time. Preliminary results were displayed as a poster at the 2007 AUTM Annual Meeting[SM]. Of the small molecule drugs, vaccines, biologic drugs, and in vivo diagnostics approved by the U.S. Food and Drug Administration (FDA) since 1980, more than 131 are based on a key patented invention from an academic institution.[15] According to Stevens (personal communication), preliminary data showed that, on average, a period of 5.6 years elapsed between receipt of an external grant to perform research, the disclosure of the invention, and filing the key patent. On average, a further 12 years passed until the patented invention was developed into a drug and received approval from the FDA.

Lesson 11: Failure Is a Key Characteristic of Academic Technology Transfer

Failure is much too drastic a term, but I use it to make a point. Not everything the technology transfer office handles turns into gold. The flow diagram in Figure 5 was created by Lou Berneman from the *AUTM Licensing Surveys* conducted during the 1990s. He found that, of the reported disclosures that resulted from the $200 billion in funded research and development, 50 percent of them led to patents and 50 percent did not. Only 50 percent of the filed patents were licensed. The other 50 percent stayed in the filing cabinet. Of the signed licenses, 10 percent went to startup companies (15 percent in 2006). Of the 25,000 licenses in place in FY1999, only 125 had royalties

Figure 5: From Disclosure to Patent Royalties



Source of basic information: Lou Berneman[16]

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of more than $1 million that year. Small numbers! This reflects a great deal of work and expenditure, which for the most part, generate only modest financial returns (if that is all you measure).

Over 99.5 percent of the licenses in place generated a yearly amount less than $1 million each (*AUTM Licensing Survey,* and above). It was reported recently that, in the enormous University of California system, only slightly more than 4 percent of all licenses earned more than $100,000 per year.[17] Therefore, universities engaging in technology transfer for the sole purpose of making money, or to replace declining state or federal financing, are in for a major disappointment, based on the statistics.

Lesson 12: The External Environment Is Changing

Recently, a significant number of recent U.S. Supreme Court cases have changed the landscape of academic technology transfer. R. Polk Wagner commented on the following cases:[18]

- ***MedImmune v. Genentech:*** Companies can obtain a license and later sue to have the licensed patent invalidated or declared non-infringing. This ruling represents "a big shift of power to licensees and away from patentees."
- ***e-Bay v. MercExchange:*** "This is a big loss for patentees because injunctions are no longer almost automatic, so patents are naturally weaker and enforcement is much more costly," says Wagner.
- ***KSR v. Teleflex:*** Wagner continues, "The fact that KSR is out there gives challengers another crack at the patent." People will "need to think through very carefully in terms of patenting strategy whether [a potential patented technology] is indeed something that no one had thought of before, and that nobody could have thought of before even though all elements of it were preexisting. That's the key argument you're going to have to make—the same argument as before *KSR,* but I think it will be a little bit harder to win those cases today, particularly with simplistic technologies." His advice is to keep papers or other documents from people, who at the time of the invention, did not think what was being proposed as an invention would work.
- **Patent Reform Act 2007:** Wagner noted many elements, but pointed to the "establishment of postgrant opposition procedures, which will create a system of 'mini-trials' at the U.S. Patent and Trademark Office that would attempt to resolve patent disputes before going to the expense of full-scale litigation." Major players in the professional venture-capital community have written Congress and pointed out that the open-endedness of this element will greatly add to the risk of an early-stage startup based on recently patented technology, in that a challenger has a relatively inexpensive way to call the validity of the patent into question. (In my opinion, this Patent Reform Act element, if passed as is, will have a devastating effect on the willingness of seed-stage investors to invest in university startup companies.)
- **U.S. Patent and Trademark Office rule changes:** While an injunction has delayed implementation, Wagner states that the changes will "radically alter the way people do patent prosecution; change the nature of examination; and make [patenting] harder, more costly, and more risky."

Overall, the presumption of patent validity that strengthened significantly starting during the term of President Reagan seems to be significantly weakening during the term of President Bush, 25 years later.

Lesson 13: After 25 Years, Big Players Are not the Only Players

As seen in Table 3, the distribution of deals with different-sized companies has

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remained relatively steady in the last eight years. Note particularly the drop in licenses with large companies (more than 500 employees) and the significant number of licenses to startup companies (defined as companies founded on the license). But the bulk of the action remains with small companies (under 500 employees).

Table 3: Where the Action Is

FY	Total Licenses/ Options	To Startups	To Small Companies	To Large Companies
1999	3,792	12%	50%	38%
2006	4,963	15%	49%	33%

Source: AUTM Licensing Survey Summary, FY 1999, FY 2006[19]

Lesson 14: Having a Large Institutional Research Base Matters

Table 4 includes the top U.S. research universities, reporting to AUTM by yearly research expenditure, and separates those reporting the most research expenditures (the Top 20); the 10 next largest (for the Top 30); then all the 141 universities that reported in FY 2005.

In Table 4 the Top 20 line of the table reads: The Top 20 universities (representing 14 percent of the 141 institutions) employed 35 percent of the licensing professionals (full-time employees), generated 77 percent of the three-year royalty averages, and were older than the other 86 percent of the reporting universities. This table shows that it takes time to build up a significant royalty cash flow (no surprise), that a large research base is important, and that the royalty cash flow is highly concentrated in the very large schools with the oldest programs.

Lesson 15: Know Your Commercial Partner

Jack Sams has worked with me at FSU for the past decade. While an IBM employee, he licensed the DOS operating system from Bill Gates at Microsoft for IBM to power the early IBM PC in 1980. He has pointed out that, while there are different approaches to academic licensing to the information technology community compared to the pharma/biotechnology sector, the more important cultural differences exist between the academic sector and the private sector, not within the industry sectors. In a 2007 workshop he pointed out several differences in perspective.

PRIVATE SECTOR PERSPECTIVE

Everyone is an employee, thus,

- Each employee works on assigned portions of a problem.
- Research results belong outright to employer.
- Royalty payments to employees are rare to nonexistent.
- Results are kept secret.
- Attribution of the research is largely anonymous.
- Management controls use of research.
- And, the above statements are the assumed starting point for collaborations with universities.

UNIVERSITY PERSPECTIVE

Employees are primarily teachers and/or professors, thus,

- Research is self-directed, not assigned.
- Research funds are personally solicited.
- Results are the property of the researcher.

Table 4: Size Matters*

Universities FY2005	Percent	FTEs	Percent	3-Year Royalty Totals (B $$)	Percent	Median Age
Top 20	14	234	35	2,357	77	1983
Top 30	21	322	48	2,597	85	1983
All 141	100	667	100	3,064	100	1989

Source: AUTM Licensing Survey FY2005[20]

*See text for further explanation.

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- Academic publication and personal attribution are the primary goals.
- Researchers are required to assign rights to university.
- Researchers are entitled to share in revenue thus obtained.

▸ Researchers may retain control of use/revision of works.[21]

The key point is that corporate attitudes in negotiating an academic license are based on the above common practices (usually unstated) inside the company. The successful academic technology transfer officer will recognize this and clarify the differences for all parties.

Lesson 16: Expect Problems

In an enterprise as vast as U.S. academic technology transfer, with 12,000 active relationships between one university and one company (all involving cultural differences, egos, time zones, and generational differences), expect problems. Recently, Congressional hearings and articles have purported to show that not all is well with regard to Bayh-Dole. There have been articles stating that the system does not work, that a major overhaul of academic technology transfer is required, and the Bayh-Dole Act needs to be changed and "improved." These authors point to a number of stories and presume to project anecdotal instances into a general condemnation of the entire system. Mark Crowell, a former AUTM president, reminded the audience in a 2006 Council on Governmental Relations workshop that "the plural of anecdote is not data"[22] on which to make solid decisions.

It would be a real surprise if there were not problems in a system this large and complex with so many different players. This is a human interaction activity, with many people involved. Change is constantly occurring; sometimes internally driven, other times in response to external pressures. Problems are an unavoidable part of this activity.

Lesson 17: Communicating the Value of Public Sector Technology Transfer

AUTM's *Better World Reports*[23] are a new tool for communicating the value of academic technology transfer. Combined, the reports contain hundred of stories of products in the marketplace, all based on academic inventions. Behind it is a database of almost 500 stories from the U.S., the UK, Canada, and, increasingly, other countries. Collectively, these stories supplement the data in the *Annual Licensing Survey.*[24]

Lesson 18: The Nine Points to Consider—Neglected Diseases

In the summer of 2006, representatives from twelve of the leading U.S. universities wrote a document entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology"[25] that identified certain shared perspectives emerging within the U.S. academic community. In it, they stated:

> Recognizing that each license is subject to unique influences that render 'cookie-cutter' solutions insufficient, it is our aim in releasing this paper to encourage our colleagues in the academic technology transfer profession to analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated herein when crafting agreements with industry. We recognize that many of these points are already being practiced. In the end, we hope to foster thoughtful approaches and encourage creative solutions to complex problems that may arise when universities license technologies in the public interest and for society's benefit.

The ninth point, in particular, illustrates one of the new currents shaping activities in the community:

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Consider including provisions that 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.

Summarized from the nine points text: Universities share a social compact with society. As educational and research institutions, they share a vested responsibility to generate and transmit knowledge, both to students and society at large. Centers of higher learning assume a specific and central role in helping to advance knowledge in many fields and to manage the deployment of resulting innovations for the public benefit. In no field is the importance of doing so clearer than it is in medicine.

Around the world, millions of people suffer and die from preventable or curable diseases. The failure to address this serious problem has many causes. However, there is an increased awareness that responsible licensing demands consideration of human needs in developing countries and underserved populations. This includes a responsibility, on behalf of both academia and industry, for finding a way to share the fruits of what we learn globally at sustainable and affordable prices, for the benefit of the world's poor.

The details involved in any agreement attempting to address this issue are complex, requiring expert planning and careful negotiation. The application will vary in different contexts. The principle however is simple. Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of essential medical innovations.

Conclusion

Today, academic technology transfer licensing is recognized as successful and a key component of knowledge-driven economic development. It is having a substantial economic and social impact in our society, as measured by products that save lives, improve the quality of life, and increase the competitiveness and productivity of the licensed corporations. Just what the Bayh-Dole Act wanted.

Former AUTM President John Fraser is the assistant vice president for research and economic development and executive director of the Office of Intellectual Property Development and Commercialization at Florida State University. He can be reached via e-mail at jfraser@research.fsu.edu.

Notes

[1] Birch Bayh, "Don't Turn Back the Clock," *les Nouvelles* (December 2006). In this article, the former senator reminisces about the purpose of the bill and the cut and thrust around its passage. It can be downloaded at http://www.lesi.org/BirchBayh/Bayh.pdf.

[2] Ibid.

[3] AUTM publishes the *Better World Report* series, which lists modern products based on discoveries at academic centers and commercialized by companies around the world. They can be downloaded at http://www.betterworldproject.net/. Like many universities, Florida State University has a Product Showcase page of discoveries that led to products. It can be found at http://www.techtransfer.fsu.edu/.

[4] The *AUTM Licensing Survey* can be found at http://www.autm.net/about/dsp.Detail.cfm?pid=214.

[5] Kevin Cullen, "Big Ideas: The Squeeze on Universities," *Milken Institute Review* (December 2006): 215–218.

[6] This information is harvested from 10-year data (FY1997–FY2006, *AUTM Licensing Survey*), available online from STATT, a data warehouse created under the leadership of Dana Bostrom during her tenure as AUTM's vice president for metrics and surveys. It is available at http://www.autm.net/directory/index.cfm.

[7] Lewis M. Branscomb and Philip E. Auerswald, "Between Invention and Innovation: An Analysis of Funding for Early-Stage Technology Development," http://www.atp.nist.gov/eao/gcr02-841/contents.htm.

[8] The *AUTM Licensing Survey,* FY2006, located at http://www.autm.net/about/dsp.Detail.cfm?pid=214.

[9] Ibid, 5.

[10] Ibid, 5.

[11] Ibid, 38.

[12] The *AUTM Licensing Survey,* FY2004 located at http://www.autm.net/about/dsp.pubDetail2.cfm?pid=28.

[13] *AUTM Licensing Survey,* FY2006, 9.

[14] This information was developed by the Southern African Research and Innovation Management Association and presented at the 2005 AUTM Annual Meeting in Phoenix, Arizona.

[15] Ashley Stevens and April Effort, "Using Academic License Agreements to Promote Global Social Responsibility," *les Nouvelles* (June 2008): 1.

[16] Lou Berneman presented at a National Council of University Research Administrators Summer Workshop, Colorado, 2002. "Academic Technology Transfer." Bottom three boxes modified by author, 2005.

[17] *Chronicle of Higher Education* (November 23, 2007): A21. G Blumenstyk

[18] R. Polk Wagner, "The Rapidly Evolving Patent Law Landscape: Practical Impact for Tech Transfer Professionals," *Technology Transfer Tactics,* August 2007.

[19] As per Table US-6, *AUTM Licensing Survey,* FY2006, 31. Note rounding error.

[20] From *AUTM Licensing Survey* FY2005 data, at the

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suggestion of Ashley Stevens.

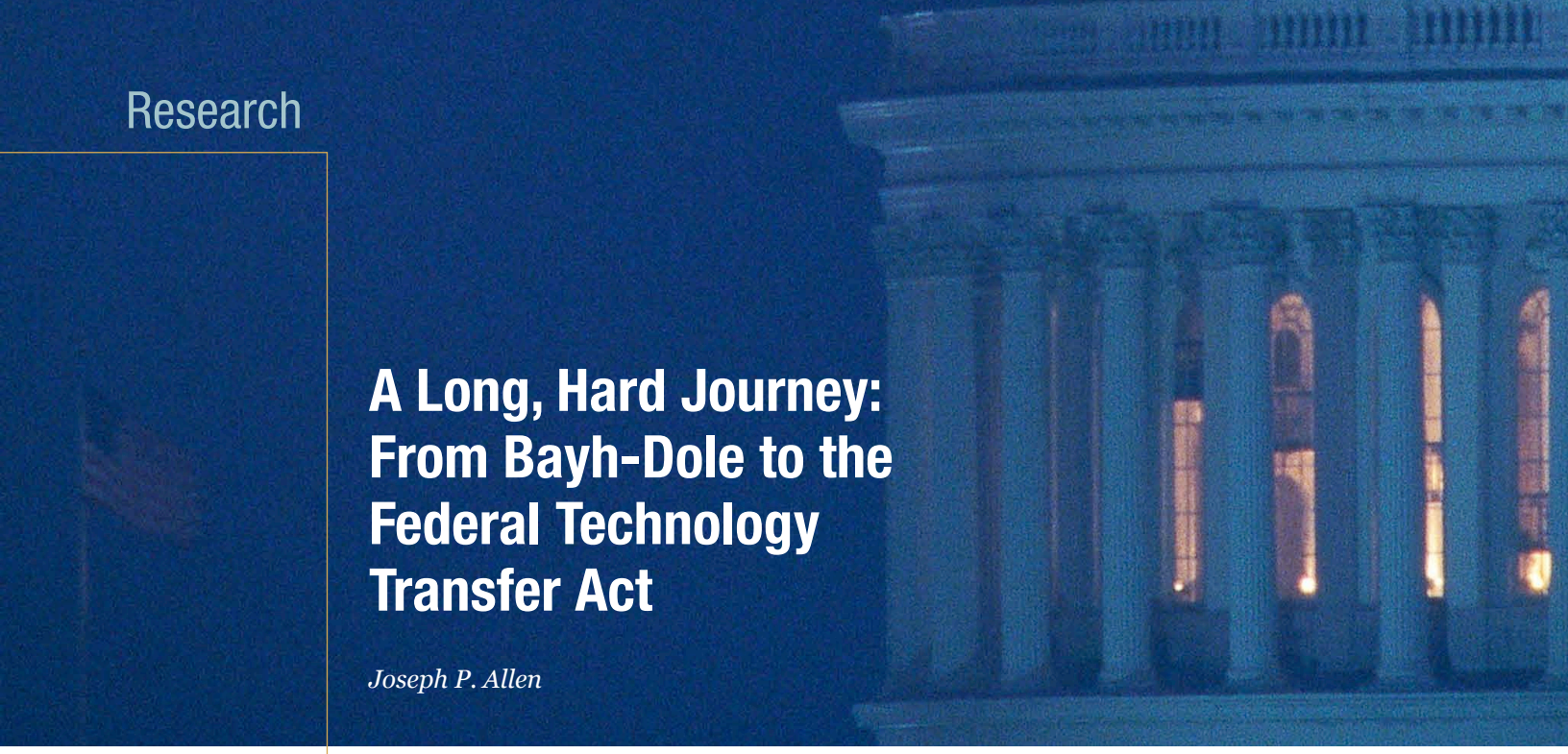
[21] Jack Sams, Florida State University, CREATE presentation, 2007.

[22] Found at http://www.sysprog.net/quotdata.html.

[23] Found at http://www.betterworldproject.net/.

[24] A favorite story of mine involves an antistuttering device, invented at East Carolina University, brought to market by a startup company. Search at http://www.betterworldproject.net/.

[25] Found at http://www.autm.net.



A Long, Hard Journey: From Bayh-Dole to the Federal Technology Transfer Act

Joseph P. Allen

A constant series of Congressional actions between 1980 and 2000 directly link the evolution of federal patent policies from universities straight to the federal laboratory system. Congress consciously modeled federal laboratory policies on the 1980 Bayh-Dole Act.[1] Senator Robert Dole even tried expanding Bayh-Dole to cover the federal laboratory system in 1984.

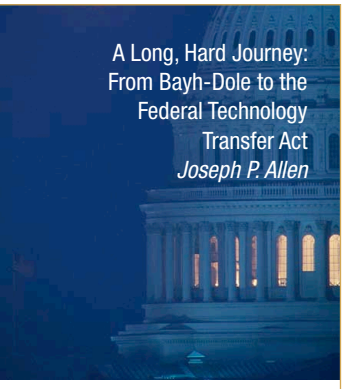
That this did not happen and there are now separate statutes for universities and most federal laboratories was an accident of political history. Because this history is largely lost, many practitioners see the university technology transfer system and the federal laboratory system as similar but unrelated.

This article demonstrates that the Federal Technology Transfer[2] Act truly is the son of Bayh-Dole in the fullest sense.

It also demonstrates that a key driver in the development and implementation of a comprehensive patent policy was the existence of an effective executive branch oversight office. That this oversight function is now absent raises serious questions about the future of the U.S. technology transfer system that has done so much to restore American competitiveness by linking the best research minds in universities, federal laboratories, and industry.

Prior to 1980, management of federally funded inventions was covered under a mish mash of conflicting statutes, agency policies, and presidential directives. Normally the federal government took ownership of inventions created under its funding, making them available to all nonexclusively. Because creators and potential developers of these inventions lacked the authorities and incentives of patent ownership, most such discoveries languished on the shelves of government agencies. This lack of return on taxpayer investment, coupled with a serious decline in U.S. competitiveness, led Senators Birch Bayh (D-IN) and Robert Dole (R-KS) to introduce legislation in 1978 to begin the overhaul of federal patent policies.

Hearings on the bill revealed that at least twenty different patent policies existed across the government, with some federal agencies having conflicting policies in various programs. Normally, universities and contractors whose inventions were taken by their funding agencies could petition to have patent ownership rights restored to them. Such actions frequently took between eighteen to twenty-four months to process. This did not imply that the result was necessarily



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favorable to the inventor. Obviously, such uncertain ownership coupled with serious delays in decision making made commercialization difficult.

A very successful administrative policy of the National Institutes of Health (NIH) granting patent rights to universities with technology transfer offices was weakened by the Carter administration. NIH appeared to be considering reverting back to the federal ownership model then prevalent.

This action led several universities to approach Bayh and Dole separately asking them for a legislative solution establishing for the first time a uniform patent policy to encourage the commercialization of billions of dollars of federally funded research and development (R&D).

The result was the introduction of the University and Small Business Patent Procedures Act seeking to "cut through this sea of red tape," in the words of Bayh. Because the unusual partnership of a liberal Democrat and a conservative Republican addressing what was becoming a pressing competitiveness issue made such a strong political impression, the bill was quickly nicknamed "Bayh-Dole."

While the initial debate on the Bayh-Dole bill focused on patent ownership by universities and small businesses, Congress was also developing a framework for more effective management of federally funded R&D in general. The key principles were the decentralized management of inventions by their creators, rewards for public-sector inventors, along with funding more research in their facilities, and the utilization of the incentives of the patent system to encourage industry to assume the risks of subsequent commercial development.

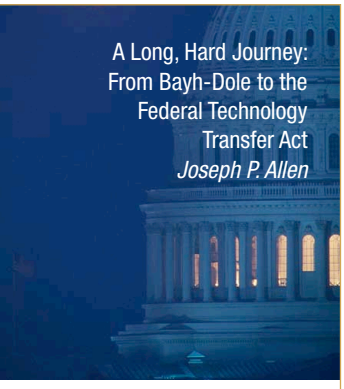
Because of the unique role that universities and small businesses have in fostering innovation, the Bayh-Dole legislation focused on this element. However, it also provided authority for licensing all government-owned inventions. The fact that the government rarely found licensees for more than 28,000 patents "gathering dust on the shelves" was a rallying cry for Bayh-Dole supporters.

Many of these inventions came from federal laboratories either operated by the government or its contractors. To address this problem, Sections 207–210 of the bill authorized the federal agencies to apply for patents and license them non-exclusively or exclusively as necessary for commercial development. These provisions were the genesis for the subsequent overhaul of patent policies for the federal laboratory system.

Obviously, such uncertain ownership coupled with serious delays in decision making made commercialization difficult.

During the Senate Judiciary Committee's deliberations, the legislation's scope began to broaden in other ways as well. Early on Senator Howard Metzenbaum (D-OH) asked Bayh to expand coverage of the bill to nonprofit research organizations like the Battelle Memorial Institute. Bayh was happy to make this change as it comported with the intent of the bill and Metzenbaum was thought to be one of the most likely opponents of changing the old patent policies of putting inventions freely into the public domain. Subsequently, Metzenbaum joined as a co-sponsor of the bill.

Large companies were also closely following the Senate Judiciary Committee debate. Because many big defense contractors were allowed to own resulting inventions under Department of Defense (DOD) administrative polices, General Electric (GE) requested that Bayh insert a provision stating that passage of Bayh-Dole was not intended to undercut DOD practices. If such language was accepted, GE pledged that it would not block passage of Bayh-Dole even though competing legislation by the Carter administration and Senator Adlai Stevenson (D-IL) was pending focusing on big business while



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also providing coverage to universities.

Given such an offer from GE, Bayh inserted the following provision into the bill:

> Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on August 23, 1971.

Thus, even in its original pure form, Bayh-Dole expanded the definition of nonprofit organizations beyond universities, assured large companies that they would not lose existing protections under agency administrative policies, and created statutory guidelines for the management of inventions made by federal laboratories.

The Bayh-Dole Act also provided flexibility to agencies such as the Department of Energy (DOE) to extend the provisions of the law to its laboratories managed by nonprofit organizations. Thus, Section 202, Disposition of Rights, states that patent rights will be left with nonprofit organizations, but that "a funding agreement *may* provide otherwise when the funding agreement is for the operation of a government-owned research or production facility."

Note that the language leaves the door open for an agency to grant such rights if it is disposed to do so. This provision set the stage for the next Congressional action expanding patent policies to federal laboratories.

There were three basic schools of thought opposing Bayh-Dole:

1. One was the public interest philosophy that government-funded technologies should be put in the public domain, freely available to all.
2. Another was a belief that large companies were more important than universities or small companies in driving the economy and should be the real focus of any new policy.
3. There was opposition to the decentralization of technology management out of Washington, DC. This belief was particularly strong at the DOE.

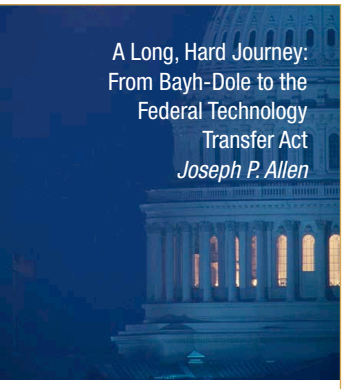
To understand the motivation of DOE, it is important to review its nature. Despite the name, the agency is home to the laboratory system that developed the atomic bomb in World War II and devotes a large percentage of its R&D to weapons-related research. The resulting culture emphasized protecting national security through close control of its technology. Thus, it is easy to see why some in DOE viewed the decentralized approach of Bayh-Dole as a serious threat to its established culture.

Like most agencies, DOE had a policy of requiring case-by-case petitions for ownership of inventions made by its contractors or grantees. The comptroller general of the United States, Elmer Staats, testified that it could easily take from eighteen to twenty-four months for such requests to be decided. Such delays were, of course, normally fatal to commercialization efforts.

While muted at the hearings on Bayh-Dole, as the bill gained momentum in Congress, DOE became more active behind the scenes opposing it. Eventually the resistance at DOE became a serious threat to the bill.

When the Bayh-Dole Act was finally enacted in a lame duck session of Congress, it was widely rumored that DOE was working behind the scenes urging President Carter not to sign it. Since Congress had adjourned its session, by simply not signing the law, it was effectively pocket vetoed. Frantic efforts were launched by the Small Business Administration to the White House urging the president to sign Bayh-Dole. Finally, on the last day before it would expire, the bill was signed into law.

At the same time it was approving Bayh-Dole, Congress also passed additional legislation encouraging the commercialization of federally funded R&D. The Bayh-Dole Act falls under the legisla-



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tive jurisdiction of the Senate and House Judiciary Committees. The Senate Commerce Committee and the House Science and Technology Committee authored the Stevenson-Wydler Act.[3] This legislation also passed in the closing days of the 96th Congress.

This bill sought to establish cooperative research centers to encourage university-industry collaborations, required federal laboratories to establish an Office of Research and Technology Applications to promote technology transfer, and gave Congressional recognition to the Federal Laboratory Consortium for Technology Transfer, which had been established informally to help trade best practices among the agencies.

However, the Stevenson-Wydler Act did not remove many of the legal barriers preventing federal laboratory technologies from being commercialized. The incoming Reagan administration declined to fund the cooperative research centers authorized in the bill, preferring the Bayh-Dole decentralized technology management approach empowering universities to commercialize their own inventions.

Fighting to Implement Bayh-Dole

However, this did not mean that the fledgling Bayh-Dole Act was out of the woods by any means. Just because a law is enacted does not necessarily mean it will be implemented as Congress intended. Creating the necessary regulations instructing the federal agencies how to apply the various provisions of Bayh-Dole were critical to its uniform application. If undermined by the bureaucracy, the regulations could provide sufficient loopholes to undo its intent.

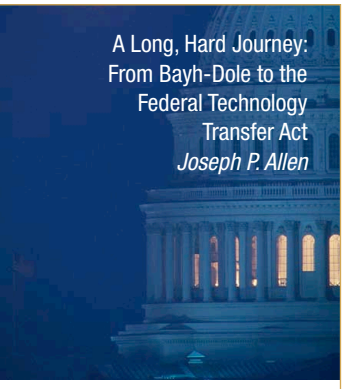
With Bayh defeated in the 1980 election, the Senate going from Democratic to Republican control, the defeat of an incumbent president, and the incoming president's team not firmly in place, there was plenty of opportunity for mischief. What next ensued was a two-year battle over the initial regulations and with continuous bureaucratic skirmishing over the next five years.

That the original intent of the law was preserved in the regulations was only because there was a strong oversight entity ensuring that the intent of Congress was met. This operation was headed by Norman Latker, former patent attorney for the NIH. Latker was intimately familiar with the problems in the old government patent policies having seen firsthand at NIH that, unless universities were allowed to manage their inventions, taxpayers were not likely to see research turn into products improving public health and well-being.

The impetus of the Bayh-Dole Act was the administrative program Latker established allowing universities to retain patent ownership of NIH-funded inventions. Not only did the Carter administration overturn this policy, it also sought to fire Latker. Latker only remained a federal employee due to the strong intervention of Bayh and Dole. Subsequently, Latker moved to the Office of Federal Procurement Policy (OFPP). Because of his presence there, Bayh and Dole placed the regulatory authority for the new law at OFPP. That this confidence was well-placed was soon borne out.

Because he understood both the language and intent of Bayh-Dole and the ins and outs of bureaucratic infighting, Latker was able to go toe to toe with DOE over the implementing regulations. Without this strong policy oversight, Bayh-Dole would have been smothered at birth under the very red tape it was designed to remove.

One significant fight was over DOE's attempt to use the exceptional circumstances provisions of the law (exempting title to universities in extraordinary circumstances) to exclude any technologies listed under export control regulations from the law. Since the list of such technologies is very large, this would have seriously



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eroded the impact of Bayh-Dole, creating a dangerous precedent for other agencies to follow. Latker was able to fight off DOE with assistance from Dole's office, which closely followed the implementation fight.

In addition to fighting the regulations, DOE made it clear that it had no intention of using the discretion under the law to allow its university-operated federal laboratories to manage their inventions. Thus, the discretionary nature of the original statute was an insufficient carrot for change. Policy-makers reached for the stick.

In the first term of President Reagan, it became apparent that something significant was occurring under the Bayh-Dole Act helping the U.S. to restore its competitiveness. In 1983, the president asked David Packard (U.S. deputy secretary of defense in the Nixon administration) to report how to get similar results from the federal laboratories. The report said:[4]

> The ultimate purpose of federal support for R&D is to develop the science and technology base needed for a strong national defense, for the health and well-being of U.S. citizens, and for a healthy U.S. economy. Federal laboratories should recognize that they are an important part of the partnership with universities and industry in meeting this goal. A strong cooperative relationship must exist between federal laboratories, universities, industry, and others of the laboratories' research results.
>
> Federal laboratories have traditionally felt that they are part of the government, committed to its highest service, and totally dependent on it for support. They perceive industry as an awkward partner with a different value system. Although the degree of interaction with universities and industry varied among the laboratories visited, the panel feels that this interaction could be increased at all federal laboratories.

President Reagan accepted the panel's recommendation and issued a patent policy memorandum to all federal agencies instructing that, to the extent permitted by law, policies regarding the ownership of all federally funded research should be treated under the principles of the Bayh-Dole Act. It was felt that such language would spur DOE to overhaul its centralized management practices.

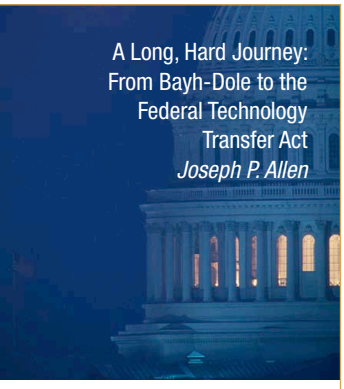
This was not the case.

Expanding Bayh-Dole to Cover University-Operated Federal Labs

Dole was growing increasingly frustrated by continued resistance at DOE. As it became apparent that legislation would be needed to compel change, Dole introduced a bill specifically including federal laboratories within the coverage of Bayh-Dole. This time DOE was openly opposing these efforts.

Finally fed up with an agency defying administration policy, on August 24, 1984, Dole wrote a letter to the Office of Management and Budget with a copy to Vice President Bush. It said:[5]

> I write to call your attention to the existence of continuing opposition within the Department of Energy to the implementation of the president's new policies regarding contractor ownership of inventions developed under federal research and development contracts...
>
> The administration and I have been seeking to establish the concept of contractor ownership of all federally funded inventions by law. Legislation proposing contractor ownership and repealing DOE's authority, which has been used by the agency to generally retain ownership, has been endorsed in a Cabinet Council Resolution, three letters from the president's science advisor to congressional committee chairmen, and OMB-approved testimony before House and Senate committees during the current and



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previous session. In spite of this clear position, DOE staff have recently been trying to influence Congress to exclude DOE from… the current bills providing for changes in the law needed to implement an agencywide contractor ownership policy.

The 1984 Dole bill amended the Bayh-Dole Act to give federal laboratories the authorities to manage their inventions on the same basis as the original law provided for universities and small businesses.

The bill was approved by the Senate Judiciary Committee with little debate. The night before full Senate passage, DOE sent an assistant secretary to try to dissuade Dole from proceeding to passage. Summoning Department of Commerce representatives to a late-night showdown with DOE, Dole's staff made clear they had no intent of backing off.

The bill was passed unanimously the next day and sent to the House of Representatives.

However, since the House companion bill was more limited, a compromise was reached as the Congressional session ground to an end. The final law extended the provisions of the Bayh-Dole Act to university-operated federal labs with exceptions for DOE "naval nuclear propulsion or weapons related programs." The other provisions of the Dole bill covering the remaining federal laboratories were dropped, leaving resolution of this issue to the future.

Another important part of the Dole bill was maintaining a strong executive branch oversight function for the expanded Bayh-Dole Act. The Department of Commerce in the Reagan administration had formed a new technology policy office recruiting Latker as the patent-policy expert. Ironically, the department strongly opposed Bayh-Dole in the Carter administration, but the new organization under the leadership of Assistant Secretary Bruce Merrifield warmly embraced the law and its philosophy. Thus, Dole moved oversight authorities for the law from the Office of Federal Procurement Policies to the Commerce Department.

Commerce was given statutory authority to notify the head of any federal agency if it believes "that any pattern of determinations is contrary to the policies and objectives of this chapter." If agencies still did not comply, Congress authorized the issuance of additional regulations bringing them into line.

This meant that the Department of Commerce was charged with ensuring that all federal agencies applied the law uniformly as Congress intended.

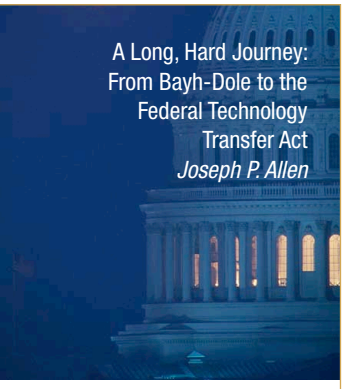
Son of Bayh-Dole, the Federal Technology Transfer Act

It quickly became apparent that, without specific authorization, federally owned and operated laboratories were not going to be able to implement Bayh-Dole type systems.

As we have seen, the Bayh-Dole Act allowed the federal government to license its inventions on a more effective basis. Government inventors were also receiving a percentage of resulting royalties under administrative policies. However, the Office of Personnel Management ruled that such royalty sharing for federal inventors would no longer be permitted since there was no specific legislative authority for them.

When the new Congress reconvened in 1985, Dole left the Senate Judiciary Committee to become Senate majority leader. The Senate Judiciary Committee had oversight for the Bayh-Dole Act.

Senator Slade Gorton (R-WA) picked up the mantel for a uniform technology transfer policy in the Senate. However, Gorton was not on the Senate Judiciary Committee. His staff re-worked the provisions of the old Dole bill covering federally owned and operated laboratories as an amendment to the Stevenson-Wydler Act. That law fell under the jurisdiction of the Senate Commerce Committee where Gorton served.



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Since Stevenson-Wydler also dealt with federal technology management, it was a good fit for expanding technology transfer policies to the remaining federal laboratory system. However, the political reason for this tactical decision was not widely appreciated. To the casual observer it appeared that Congress was creating a new system for federal laboratories separate from Bayh-Dole. Thus, the common heritage of the two systems in the Bayh-Dole Act was eclipsed.

Summoning Department of Commerce representatives to a late-night showdown with DOE, Dole's staff made clear they had no intent of backing off.

A fortuitous event paralleled the introduction of the Gorton bill. The success of the Bayh-Dole Act interested regional leaders in aggressively incorporating their publicly funded research institutions as drivers for local economic development. In what was being called the Rust Belt of America, the economy was in particularly bad shape.

Peoria, Illinois, is the home of Caterpillar tractor that, due to stiff foreign competition, was laying off workers. Community leaders identified complementary university-federal laboratory biotechnology research that could be the basis for forming an important new research consortium. The problem was that the local federal laboratory lacked the legal authorities to participate.

This led Peoria city leaders to visit the Department of Commerce to discuss the situation. Informed that the discarded provisions of the 1984 Dole bill were required to achieve their goal, the delegation next met with its Congressman, Bob Michel (R-IL).

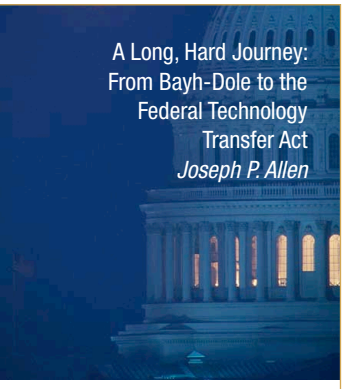
Michel was the House minority leader and was well-respected on both sides of the aisle. Michel pledged to help secure passage of new legislation. This interest brought an important new ally into the fight to extend the missing legislative authorities to federally owned and operated laboratories.

Soon legislation titled the Federal Technology Transfer Act was pending in the House and Senate allowing federally owned and operated laboratories to license their inventions and conduct cooperative R&D with industry. Since the legislation was originally intended to fall under the Bayh-Dole Act, it incorporated decentralized technology management with the local federal laboratory director as the key decision maker. The law also stipulated that royalties to the lab should be used to defray technology transfer costs, fund new research, and reward federal inventors. It also gave a preference to partnering with small companies and those who would manufacture resulting products in the U.S. as is the case under Bayh-Dole.

With the impact of university technology transfer growing before its eyes, Congress did not have the same philosophical debate over whether or not public-private technology partnerships were good policy or not. That they were essential to the nation's future prosperity was now a given. Instead, a small group of large companies was concerned that sharing royalties with government inventors represented a dangerous precedent that might be extended to their own employees. Countries like Germany had laws controlling how industrial inventors must be rewarded. Some companies feared that the pending bill was a dangerous precedent for rewarding employed inventors that must be neutered.

These companies succeeded initially in removing the royalty-sharing provisions from the House bill. They also tried to persuade Department of Commerce Secretary Malcolm Baldrige to reign in his staff from supporting the Senate bill. Baldrige rejected these overtures.

The Senate and House staff eventually resolved the differences in the bills restoring royalty sharing for government inventors. A provision was included requiring the comptroller general to report back to



Congress on the royalty-sharing programs of the various agencies along with recommendations for improving them.

The new bill became the Federal Technology Transfer Act of 1986 (FTTA). The FTTA is essentially Bayh-Dole for federally owned and operated laboratories.

The 1986 law says that agencies *may* permit directors of government-owned and -operated labs to enter into cooperative research and development agreements and negotiate licenses for inventions made in their facilities. The overall authority was made permissive because of opposition from NASA that it did not want to operate under the new statute, preferring its existing authorities of the 1958 Space Act.

The FTTA requires that agencies share royalties with their inventors and allows them to pay administrative costs associated with technology transfer. The majority of remaining dollars goes back to the individual laboratory to fund more research or to reward other employees associated with the project.

With the impact of university technology transfer growing before its eyes, Congress did not have the same philosophical debate over whether or not public-private technology partnerships were good policy or not.

Preferences are given to small businesses and to companies manufacturing resulting inventions in the U.S., as is the case under Bayh-Dole.

Agency headquarters have thirty days to approve or modify an agreement but must give a written explanation for any changes.

To track agency use of the new law, Congress charged the Department of Commerce with assisting other agencies to develop and share models and to report to the president and Congress every two years on how the act is being utilized.

President Reagan made the new law the centerpiece of Executive Order 12591[6] (which remains the guiding document on federal technology transfer policies) making clear that he expected all agencies to use these new authorities. Thus, the president said that the heads of federal agencies, to the extent permitted by law, *shall* delegate the authorities of the Federal Technology Transfer Act to the directors of its government-owned and -operated laboratories.

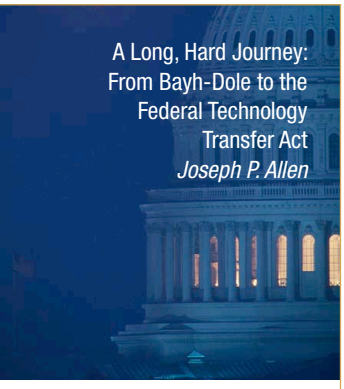
Covering All Federal Labs, Providing New Tools for Partnerships

DOE continued to insist that it still lacked clear legislative authority to implement the president's executive order to many of its contractor-operated laboratories. Because of the importance of DOE laboratories such as Sandia and Los Alamos to New Mexico, Senator Pete Domenici (R-NM) decided to intervene. He pushed through Congress an amendment to the Federal Technology Transfer Act in 1989.

Domenici included government-owned, contractor-operated laboratories under the FTTA. He also added language permitting laboratories to keep information "that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party" that is generated under a cooperative R&D agreement (Cooperative Research and Development Agreement [CRADA]) exempt from release under the Freedom of Information Act for up to five years. This provision underscored how far Congress had come from the old policies essentially putting federally funded R&D into the public domain without regard to impact on subsequent commercialization.

The law also signaled a shift in Congressional attention. The emphasis was moving from providing authorities to partner with U.S. industry to an insistence that federal laboratories effectively use the technology transfer tools Congress had provided.

This is illustrated in the next step in our journey. Vocal companies began complaining of the difficulty in completing agreements with the laboratories in a



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timely manner to Congress. These concerns led Senator Jay Rockefeller (D-WV) to introduce legislation amending the Federal Technology Transfer Act to assign *title* to any resulting inventions under a CRADA to the industry partner because:

> I believe that this ability by the federal government to claim a right of ownership to intellectual property developed jointly with American companies has inhibited the establishment of cooperative R&D agreements and has retarded the commercialization of federally supported technology developments. This view is shared by the many research-intensive U.S. companies we contacted.

Rockefeller added:

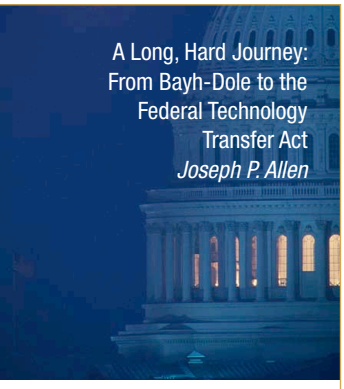
> The bill we are introducing today eliminates this option by directing Federal laboratories to ensure that the private sector is assigned title to any intellectual property arising from a CRADA…
>
> This provision, in addition to putting technology in the commercial sector where it can be commercialized, will greatly speed up the negotiations of CRADAs. Under current law, the most time-consuming, and often deal-breaking, part of the negotiation between federal laboratories and the potential research partners is over the ownership, assignment, licensing, restriction, etc., of the intellectual property rights. Our bill eliminates this obstacle.[7]

In the House, Representative Connie Morella (R-MD) had the NIH and the National Institute for Standards and Technology as major drivers of the economy of her district. She also wanted the laboratories to be more aggressive in developing cooperative R&D agreements with industry, but felt that wholesale assignment of title went too far. She was concerned that a company might not be interested in—or even capable of—commercializing an invention in all its possible fields that could span many markets. Because of the early-stage nature of federal R&D, unexpected applications for a technology could easily arise that might be neglected by a one-size-fits-all approach. Morella felt that improving licensing was a better approach.

The result was an amendment requiring the laboratory to ensure "that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement…" This approach was acceptable to the Senate and enacted into law.[8]

Continuing her interest in spurring on federal laboratories to maximize the commercialization of their research, Morella authored the Technology Transfer Commercialization Act of 2000.[9] The intent of new legislation is laid out in the Findings section of the bill. In passing this legislation, Congress again recognized the link of Bayh-Dole to the FTTA, with clear guidance on how the tools should be applied:

> The Congress finds that-
>
> 1. the importance of linking our unparalleled network of over 700 Federal laboratories and our nation's universities with United States industry continues to hold great promise for our future prosperity;
> 2. the enactment of the Bayh-Dole Act of 1980 was a landmark change in United States technology policy, and its success provides a framework for removing bureaucratic barriers and for simplifying the granting of licensees for inventions that are now in the federal government's patent portfolio;
> 3. Congress has demonstrated a commitment over the past two decades to fostering technology transfer from our federal laboratories and to promoting public/private sector partnerships to enhance our international competitiveness;
> 4. federal technology transfer activities have strengthened the ability of United States industry to compete in the global marketplace; developed a new



paradigm for greater collaboration among the scientific enterprises that conduct our nation's research and development- government, industry, and universities; and improved the quality of life for the American people, from medicine to materials;

5. the technology transfer process must be made "industry friendly" for companies to be willing to invest the significant times and resources needed to develop new products, processes, and jobs using federally funded inventions; and
6. federal technology licensing procedures should balance the public policy needs of adequately protecting the rights of the public, encouraging companies to develop existing government inventions, and making the entire system of licensing government technologies more consistent and simple.

Demonstrating her concern that it was simply taking too long to license federal patents, Morella cut through a Gordian knot of required public notices. The Bayh-Dole Act requires federal agencies to place notices in the Federal Register whenever they want to license other than nonexclusively. A second notice is required when the agency had selected a potential licensee. Taken together, these two notice periods could easily take five months to complete. The Morella Act authorized agencies to combine both notices in one posting for as short a time as 15 days. Thus, the agencies are now able to significantly reduce the amount of time they must spend on public notifications.

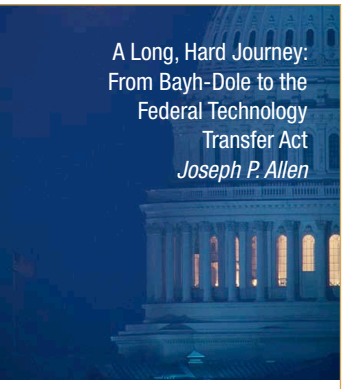
The law made clear that Congress was clearly expecting to see results from its legislative actions. The Morella bill required agencies to report annually on their technology transfer programs, including how many patent applications they filed, how many patents were issued, how many inventions were successfully licensed, how much income they generated, how many licenses were nonexclusive or exclusive and "the time elapsed from the date on which the license was requested by the licensee in writing to the date the license was executed."

Demonstrating her concern that it was simply taking too long to license federal patents, Morella cut through a Gordian knot of required public notices.

Ironically, just as the federal laboratories received unprecedented authorities to transition their technologies from the bench to the marketplace, the oversight function at the Department of Commerce was fading away. Beginning in the Clinton administration, Commerce re-organized the Technology Administration (where federal technology management oversight resided) and interest in federal technology transfer policy seemed to wane.

Next, the Department of Commerce exempted its own Advanced Technology Program (ATP),[10] designed to promote high-risk technology partnerships, from the Bayh-Dole Act. When enacting the ATP program, Congress wanted to ensure that U.S. companies were the program's main beneficiaries. Thus, it included language that ownership of resulting intellectual property would vest in businesses incorporated in the United States. The Department of Commerce took this to imply that Congress meant to exempt the program from the Bayh-Dole Act, brushing aside arguments that this was not the case.

The Commerce Department did not object when the Department of Defense created "other transactions" than grants or contracts for funding research to be exempt from Bayh-Dole. In fact, in its report, *Effective Partnering,* the Department of Commerce urged agencies to use "where available, 'other transactions' or comparable authority permitting the greatest possible flexibility" in R&D partnerships. Another recommendation was: "Where appropriate, use the 'exceptional circumstances' authority of the Bayh-Dole



Act to permit industry to own or control the rights to inventions resulting from federal funding, including inventions of subcontractors."[11]

A precedent was being set away from the goal of creating uniform patent policies across the agencies.

As the years passed, the Bayh-Dole oversight responsibilities slipped from a policy office to the Commerce general counsel responding to specific questions on interpreting the statute. Finally, in 2007 the Bush administration and Congress agreed to abolish the Technology Administration at Commerce all together. It appears that Bayh-Dole and FTTA oversight will remain a very diminished function of the department.

This does not bode well for preserving a *policy perspective* on the goals of the laws and subsequent agency practices. Time will only tell how this turns out.

Here ends our journey through a 30-year revolution in U.S. technology policies. It has taken us from a time when the linkage between federally funded R&D and the development of new products benefiting the health and well-being of American taxpayers was virtually nonexistent to a time when the U.S. model for fostering public-private partnerships between the best and brightest minds in universities, federal laboratories, and industry is recognized worldwide. But it is unclear how this achievement will be maintained.

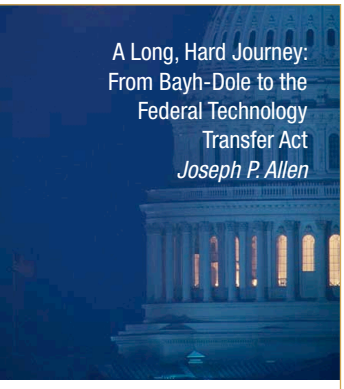
Perhaps the *Economist Technology Quarterly* (TQ) in a 2002 editorial puts the issue in the best perspective. Here's how the piece is introduced: "The reforms that unleashed American innovation in the 1980s and were emulated widely around the world are under attack at home."[12]

TQ summarized the contribution of the university and federal laboratory system this way:

> Remember the technological malaise that befell America in the late 1970s? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in reverse. An exhausted Soviet Union threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.
>
> Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.
>
> Before Bayh-Dole, the fruits of research supported by government agencies belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

Less quoted, but just as insightful, are TQ's words of warning for the future:

> There has always been a fringe that felt it was immoral for the government to privatize the crown jewels of academic research. Why, they ask, should taxpayers be charged for goods based on inventions they have already paid for?
>
> That is easily answered. Invention, as TQ has stressed before, is in many ways, the easy bit. A dollar's worth of academic invention or discovery requires upwards of $10,000 of private



A Long, Hard Journey: From Bayh-Dole to the Federal Technology Transfer Act
Joseph P. Allen

capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99 percent of the innovation's final cost…

Whatever the merits of their case, suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, not plucking for the pot.

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Notes

[1]The Bayh-Dole Act of 1980 (Patent and Trademark Law Amendments of 1980, Public Law No. 96–517) now codified as 35 U.S.C. §§200-212. Regulations for implementing the Bayh-Dole Act are found at 37 C.F.R. §§ 401.1-401.17.

[2]Public Law 99-502 amending the Stevenson-Wydler Technology Innovation Act of 1980, P.L. 96-480.

[3]Stevenson-Wydler Technology Innovation Act of 1980 (Public Law No. 96–480).

[4]Report of the White House Science Council's Federal Laboratory Review Panel, May 20, 1983, p. 11.

[5]Senator Robert Dole to Frederick N. Khedouri, associate director, natural resources, energy and science, Office of Management and Budget, August 24, 1984.

[6]Executive Order 12591, facilitating access to science and technology, 52 Fed. Reg. 13,414 (April 10, 1987).

[7]Statement of Senator Jay Rockefeller introducing S. 1537, the Technology Commercialization Act of 1993, October 7, 1993, Congressional Record, p. S. 13284.

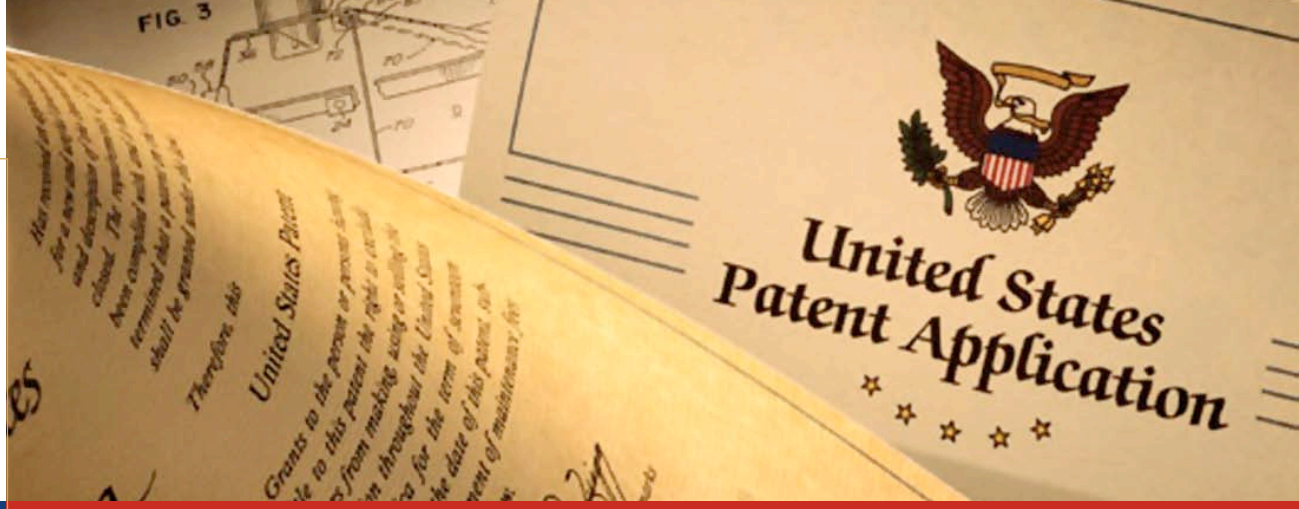
[8]Public Law 104-113.

[9]The Technology Transfer Commercialization Act of 2000 (Public Law No. 104–113) now codified as 15 U.S.C § 278n.

[10]Federal Register notice, *Advanced Technology Program,* August 2, 1993, p. 41069.

[11]Effective Partnering: A Report to Congress on Federal Technology Partnerships, U.S. Department of Commerce, Office of Technology Policy, April 1996, p. 15.

[12]Innovation's Golden Goose, *The Economist Technology Quarterly,* December 14, 2002.



U.S. Government Use of Patented Technology

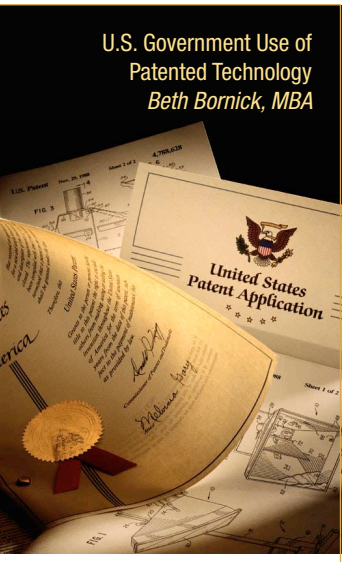
Beth Bornick, MBA

The United States has historically worked to balance the desire to promote innovation and scientific progress with the desire to facilitate government access to patents. The government awards exclusive rights to patent owners but retains some rights to use patented technology for its own purposes. If patent exclusivity is too strong, the government might be unable to obtain critical technologies. But if the government freely appropriates patented technologies, inventors may be discouraged from doing research and filing new patents. To maintain the right balance, the government needs to monitor its use of patented technologies and consider the public policy implications of its procurement procedures. However, the scales are currently tipped too far toward the government's side, and some reform is needed to give more protection to inventors and harmonize the United States government's patent use with the global marketplace.

The government has a number of ways to use patented technology at its disposal—the most straightforward is to buy or license the patents from the owners. If the patent was developed using federal funds, the government retains a nonexclusive, royalty-free right to use the invention under the Bayh-Dole Act[1] and can exercise limited march-in rights to license such patents to others for development. This weakens the patent's exclusivity somewhat and may cause concerns when licensing patents developed with federal funds, especially to government contractors.

However, the government also has more broad rights to use patents, as described in U.S. Code Title 28, Section 1498. Under §1498, the government can use any patented technology without the patentee's consent and is treated as a compulsory, nonexclusive licensee, liable only for a reasonable royalty in the Court of Federal Claims. Third-party contractors are protected under §1498 too and can use a patent for the government, with the government's authorization and consent. In universities, the focus on Bayh-Dole compliance can overshadow risks of other government use, but §1498 represents a more serious weakening of patent exclusivity. This should cause concern not only for U.S. patent holders, but also for foreign governments concerned about maintaining strong intellectual property rights worldwide.

The first section of this paper describes the early history of patent infringement by the government, when some patent owners received compensation under eminent domain and implied contract theories, but others were unsuccessful in their claims. The second section deals with the 1910 act that allowed compensation to patentees in



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more circumstances of government use, as well as the 1918 amendment that added protection for government contractors to facilitate military procurement for World War I.

In 1948, these acts evolved into 28 U.S.C. §1498, under the jurisdiction of the Court of Federal Claims. The third section covers cases for compensation under §1498 and highlights the difficulties in reaching a satisfactory resolution for the patent holder. The fourth section gives a history of patent rights in federally funded research and shows the desire to encourage commercialization that led to the Bayh-Dole Act. The final sections compare Bayh-Dole and §1498 with other compulsory licensing laws and recommends improvements to harmonize these provisions and provide a better climate for innovation.

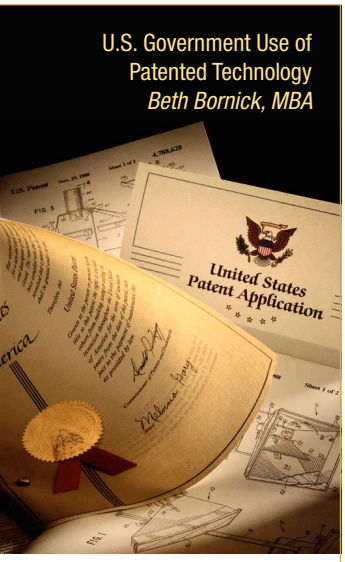
An Early History of Patent Infringement by the Government

Before §1498 was enacted, its foundations were laid through a series of Supreme Court cases beginning in the late 1800s. *James v. Campbell* was an appeal from a United States postmaster in New York City who had been enjoined from using a patented implement for stamping letters.[2] James was sued personally because no statute existed to address government use without the consent of the patent owner, and the government was immune from the tort of patent infringement. The Supreme Court clearly stated that a patentee is granted exclusive property in the patented invention, and this property cannot be appropriated by the government without just compensation. The court recognized that many patents are best utilized by the government, and if they could be appropriated without compensating the patent owner, scientific progress would be discouraged. The Court held that Campbell's stamping patents were not infringed but suggested that actions against an officer of the government could probably not be sustained and such issues should be brought to the Court of Claims and addressed under an implied contract to use the patent.

A few years later, this course of action was reiterated by the Supreme Court in *Hollister v. Benedict & Burnham Mfg. Co.,* when a collector of internal revenue appealed a patent infringement verdict involving his revenue stamps for sealing liquor casks.[3] The patent claims were invalidated (always a risk in an infringement case), but the Supreme Court suggested that if an officer of the government made use of a patented invention for official duties, it would be considered an exercise of eminent domain and compensation could be sought in the Court of Claims.

In 1888, the Court referred back to the *Campbell* opinion in deciding *United States v. Palmer,* when the government objected to the jurisdiction of the Court of Claims to award a patent royalty.[4] The patent owner had demonstrated improved infantry equipment to a military board, and the technology had been adopted by the secretary of war for use by the Army. The Supreme Court held that if a patent is offered to the government and used without a contract but with the patentee's consent and expectation of compensation, a contract is implied and the Court of Claims would have jurisdiction to award compensation.

When a patent is infringed by a government contractor, this adds another level of complexity to the issue. When landscape architect Frederick Law Olmsted was designing the U.S. Capitol grounds, the government's paving contractor used a method for laying concrete pavement that was patented by John J. Schillinger. The paving contract did not call for using the Schillinger method, and it included a patent indemnification clause holding the United States harmless from any claims of infringement. The Supreme Court in *Schillinger v. the United States* held that, because the contract did not specify use of the patent and the patentee did not consent for the government to use it, this was



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merely a tort infringement case against the contractor, not an eminent domain taking under the Fifth Amendment.[5] Because this was a patented method infringed by the contractor, the Court also declared that the United States did not take possession of any patented property in the completed pavement, so the patentee had no grounds to waive the tort and sue the government under an implied contract.

The Court of Claims considered all these rulings in *Brooks v. United States* in 1904.[6] In this case, Navy procurement contracts specified that gunboats and other vessels being constructed should be sealed using Brooks' method of caulking and also specified that royalties for any patents used in the construction were to be paid by the contractor. Unlike the situation in *Schillinger,* Brooks agreed that the government could use his patent, and the Navy's contract specified its use, so the court ruled that a contract to use the patent was implied and compensation was awarded. The Court of Claims said that if the patented method was not specified, or was specified without the owner's consent, there would be no implied government contract, and the only remedy would be against the builders.

These early cases established that patentees like Palmer and Brooks could offer their inventions to the government with the assurance of being compensated if the government used the patented technology. But patentees whose inventions were used without their consent had no certainty of being awarded royalties, as there was no precedent for compensating unwilling licensors. Government contractors were vulnerable to patent infringement lawsuits from these unhappy patent holders, even if their government contract specified use of the patent.

The Acts of 1910 and 1918: Additional Protection for Patent Owners

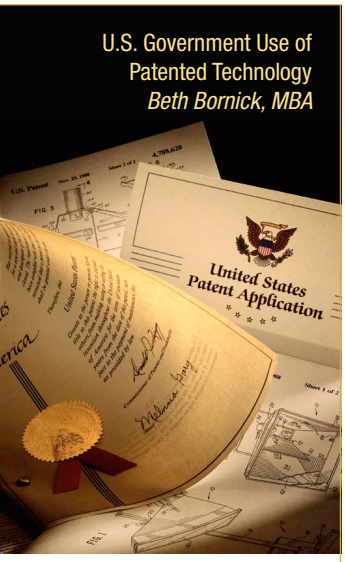
On June 25, 1910, an act was passed that later formed the foundation of §1498. It formalized the precept that whenever a patented invention was used by the United States without a license or other lawful right, the owner could recover reasonable compensation in the Court of Claims.[7] In *William Cramp & Sons v. International Curtis Marine Turbine Co.* in 1918, the Supreme Court said the purpose of this new statute was to provide compensation for situations where there had been no ability to sue under an implied contract, such as when the patentee did not consent to the use.[8]

But patentees whose inventions were used without their consent had no certainty of being awarded royalties, as there was no precedent for compensating unwilling licensors.

Prior to the 1910 Act, the Turbine Co. had successfully sued Cramp & Sons for infringing turbine engine patents in fulfilling a 1908 Navy contract. When Turbine Co. sued for infringement again for a 1911 contract, the new statute came into play, and Cramp & Sons proposed that the government's end-use made it an implied licensee. The Supreme Court held that government contractors were not officials of the United States and must fulfill their contracts without violating the rights of others. The Court also ruled that the Act of 1910 did not grant a license to the United States or the contractor, and Cramp & Sons could be sued for infringement.

Shortly after this verdict, the secretary of the Navy wrote to the Senate Committee on Naval Affairs requesting an amendment to protect contractors from liability, as the threat of litigation made them reluctant to take new contracts, which were needed to support the war.[9] The resulting Act of June 18, 1918, read in part (words emphasized are the changes to the Act of 1910):

> that whenever an invention described in and covered by a patent of the United States shall hereafter be used or manufactured by *or for* the United States without license of the



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> owner thereof or lawful right to use or manufacture the same, such owner's remedy shall be by suit against the United States in the Court of Claims *for the recovery of his reasonable and entire compensation for such use and manufacture.*[10]

This amendment relieved contractors from injunction and patent infringement liability when manufacturing for the government and was intended to encourage contractors to contribute to the war-time procurement efforts.

Government Liability for Patent Use Under 28 U.S.C. §1498

In 1948, the language of the 1918 act was incorporated into 28 U.S.C. §1498, which governs the jurisdiction and venue for patent and copyright cases in the United States Court of Federal Claims.[11] Cases brought under §1498 treat the government as a nonexclusive compulsory licensee, and the recovery is reasonable and entire compensation, usually in the form of a reasonable license fee.

Because §1498 grew out of eminent domain, recovery does not include the wide variety of damages available under a patent infringement tort, and this can be a detriment to patent holders. This was proven in *Leesona Corp. v. United States* in 1979, after the patentee had invested more than $3 million in facilities for manufacturing rechargeable metal-air batteries, based on a negotiated contract with the Marine Corps and large anticipated Marine and Army contracts.[12] When the first contract was withdrawn and the project was opened to competitive bid, Leesona lost the contract, as the lower bidders did not need to recoup any research and development costs. The United States authorized a different company to manufacture the patented batteries, and Leesona had to sue the government for compensation.

The Federal Circuit Court in *Leesona* allowed a reasonable royalty of 10 percent but overturned additional amounts based on the tort theory damages of lost profits, recapture of development costs, savings to the government, loss of exclusivity, and attorney's fees. Since the anticipated levels of procurement never came to pass (possibly because the low bidder couldn't deliver a reliable product), the royalty award with interest was just under $438,000. The *Leesona* verdict should raise a red flag for patent holders who have significant research investments to recoup or who must invest in manufacturing facilities for anticipated government business.

For a contractor's patent use to be immune under §1498, he or she must show that his or her use or manufacture is "for the Government and with the authorization or consent of the Government," as specified in the code. One way this can be demonstrated is if the government used an authorization and consent clause in the contract.[13] This clause was crucial in the 2007 case of *Sevenson Environmental Services Inc. v. Shaw Environmental Inc.*, where Shaw used Sevenson's patented process for lead remediation to clean up contaminated federal land near Colonie, New York.[14] The authorization and consent clause incorporated job specifications by reference, and Shaw's plan of work included use of the patented method. Since Shaw's specifications were approved by the Army Corps of Engineers, its use of the patent was held to be "with the authorization and consent of the government," and not an infringement by the contractor.

While §1498 is designed to provide protection for patent holders, the patentee risks years of costly litigation, as when Hughes Aircraft accused the United States of infringing patents for controlling the velocity and spin axis orientation of orbiting space vehicles.[15] Litigation continued for more than twenty years and included more than fifteen lawsuits. They argued over patent validity, government use, the extent of infringement, the cost basis for awarding damages, and interest charged

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on damages. With an awarded royalty of 1 percent and compound interest keyed to the long-term corporate bond yield,[16] calculated on a compensation base of $3.577 billion,[17] it's doubtful that the award (which I estimate at $154 million) even came close to covering Hughes' legal costs.

A troubling case in 2007 highlighted a loophole where the government is only liable for the use of a method patent if every step is practiced within the United States.[18] Zoltek Corp. had a patented process for making a carbon fiber sheet that has controlled electrical resistivity. In building the F-22 fighter, Lockheed Martin Corp. subcontracted for two such fiber products, which were partially or completely manufactured in Japan. Zoltek alleged that the products were made using its patented method and brought suit against the United States. But because §1498 states that the "section will not apply to any claim arising in a foreign country,"[19] the Court of Appeals found that the government could not be liable under §1498.

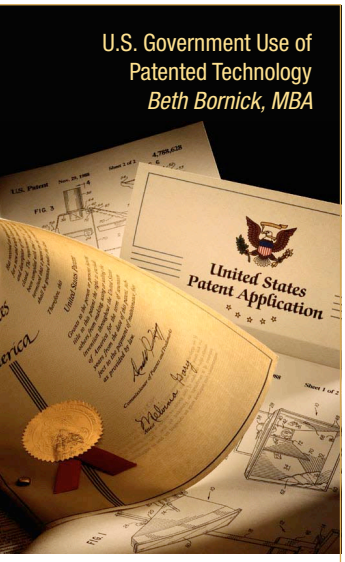
This result is difficult to justify, because if Lockheed had been using the patent for a nongovernment purpose, it could be held liable for infringement under 35 U.S.C. §271(g). This clause says that someone importing a product into the United States that is made by a process patented in the United States is liable as an infringer. This clause was added after §1498 was enacted, and §1498 was never amended to close the same loophole for process patents.[20] The Nanobusiness Alliance, an association of innovative high-tech companies, declared that the *Zoltek* decision undermined the value of process patents and allowed the government and its contractors to easily escape liability by outsourcing manufacturing to another country.[21] This problem needs to be remedied to ensure that process patents aren't freely appropriated for government use via this loophole. This change would require an act of Congress, probably amending §1498 to mirror the wording of 35 U.S.C. §271(g).[22]

Cases like *Leesona* and *Zoltek* should make universities and other patent holders mindful that the government has protections even when using patents that were not federally sponsored, and the potential for government use should be considered when evaluating potential licensees or possible infringers.

This problem needs to be remedied to ensure that process patents aren't freely appropriated for government use via this loophole.

In another significant case for universities (better known for overturning experimental use as a defense for patent infringement), *Madey v. Duke University* also addressed §1498 as a defense.[23] John Madey had resigned from the university and later sued Duke for continuing to use his patented equipment in its free electron laser lab. The Court of Appeals determined that a research grant could meet the requirements of §1498 in some circumstances, and the case was remanded to the district court to determine whether Duke could prove the affirmative defense of §1498. According to the district court's findings, government funding was not enough to show authorization and consent, so each grant was examined individually.[24] Certain grants did specify use of the Madey patent for government purposes, and others broadly authorized the use of patented technology, but some federal grants were held not to involve research "for the government" at all.

Duke University also argued that it was immune to infringement claims under the government's nonexclusive license to use federally funded patents, retained by the government under the Bayh-Dole Act, provision 35 U.S.C. §202 (c) (4). The court held that, although this license serves as a defense when the government is sued for infringement, this defense cannot be used by a third party, and the government-use license did not extend to Duke for its use



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in federally funded research.

The District Court's *Madey* decision nicely described the provisions in §1498 and Bayh-Dole as providing an overall scheme that:

1. allows the government to authorize patent infringement to obtain what it needs,
2. protects private government contractors or grant recipients who use a patented invention for the government with the government's authorization and consent,
3. protects patent holders by allowing suits against the government for reasonable royalties where the government or an authorized contractor uses a patented invention, and also
4. provides the government with a defense where the use of a patented invention is within the scope of the government's royalty-free license for inventions originally developed with government funding.[25]

A History of Patent Rights in Federally Sponsored Research

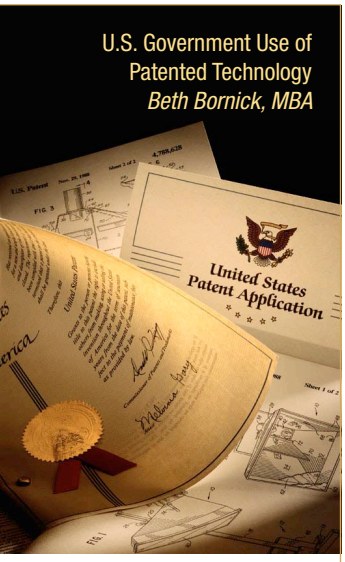
Federal research sponsorship dates back to the 1800s when the U.S. Department of Agriculture and the land-grant universities were created. More than 40 scientific agencies had been established by the late 1930s, and World War II drove military research spending to record levels. The critical role that new technology played in World War II clearly demonstrated the value of scientific research and, after the war was over, President Roosevelt wanted to mobilize the country's scientists to improve public heath, stimulate economic growth, and increase the country's standard of living.[26]

Vannevar Bush, a leader of the war-time research effort, laid the foundation for a national scientific policy in his 1945 report "Science—the Endless Frontier," which outlined research missions for new agencies that became the National Institutes of Health and National Science Foundation.[27] His report suggested a patent policy that provided a royalty-free license for government use but allowed each funding agency to decide whether patent ownership rights should be assigned to the government in special cases to best serve the public interest.[28]

One such example involved the first general-purpose data-processing machine, ENIAC (electronic numerical integrator and computer), which was funded by government-sponsored research at the University of Pennsylvania in the 1940s.[29] The research agreement gave the U.S. a nonexclusive, royalty-free right to any inventions or discoveries made or reduced to practice under the contract. ENIAC led to EDVAC (electronic discrete variable calculator), a second-generation machine. Thomas Kite Sharpless, a university engineer on the ENIAC and EDVAC development team, saw the potential of the technology and helped form Technitrol Inc. to develop computers for military and industry applications.

Sharpless continued to work on EDVAC at the university while moonlighting to help Technitrol develop a computerized reservation system for American Airlines. After he finally left the university, Sharpless obtained a patent for a magnetic data storage system and filed suit against the government for infringement. The Court of Claims held that the majority of the features of the Sharpless patent were conceived under the university contract and were integral to the EDVAC program, so the government was licensed to use all but one new feature, for which it must pay compensation.

Despite the rapid progress of technological advancement during this era, concerns about monopoly abuses made the idea of patent exclusivity increasingly unpopular, and a national debate began about whether contractors should be allowed to own patents developed under federal research.[30] Against Vannevar Bush's recommendation, the government agencies generally kept title to patents and gave the companies nonexclusive licenses, so



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few innovations were commercialized into new products.[31]

The autonomy of these federal agencies led to a wide variety of patent practices, and it was difficult for companies to deal with their different approaches. In 1963, President Kennedy issued a guidance memo seeking to promote more consistency among the agencies and improve utilization of federally financed inventions.[32] He stated that the large sums spent on federal research lead to many inventions and represented a valuable national resource. His policy encouraged agencies to award exclusive rights to established commercial contractors that were capable of commercializing these inventions and to retain nonexclusive, royalty-free rights for government.

The Bayh-Dole Act in the Context of Government Use

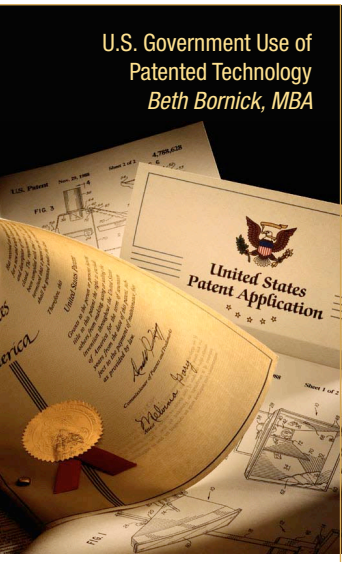
Despite President Kennedy's concerns, the U.S. government had acquired title to 28,000 patents by 1980. Fewer than 5 percent of these were commercially licensed, compared with 25 percent to 30 percent for the small number of federally funded patents that the contractors had been allowed to retain.[33] Finally the Patent and Trademark Law Amendment Act of 1980 was passed, more commonly known as Bayh-Dole for names of the bill's sponsors. The regulations for the Bayh-Dole Act are codified in 37 C. F. R. §401, entitled "Rights to Inventions Made by Nonprofit Organizations and Small Firms Under Government Grants, Contracts, and Cooperate Agreements." (A presidential memorandum extends the Bayh-Dole Act to all government contractors.[34])

This paper addresses only the Bayh-Dole provisions that relate to government use of U.S. patents. In general, contractors have the opportunity to obtain title to the patents, but they must make an effort to do so. When the contractor takes title, the government retains a nonexclusive, nontransferrable, irrevocable, paid-up license to the invention.[35] The contractor must notify the government of an invention within two months after it is disclosed by the inventor and can elect in writing to retain title if they wish.[36]

If a contractor does not notify the government of an invention, the funding agency can request title back from the contractor within 60 days after learning of the failure to notify, leaving the contractor with a nonexclusive license.[37] Even this nonexclusive right can be revoked if the contractor has not achieved a practical application and the agency believes awarding an exclusive license to someone else would be more expeditious.[38] This invention notification issue was tested in *Campbell Plastics Engineering v. Brown* when Campbell Plastics Engineering failed to submit the proper form to notify the Army of a sonic welding invention developed under contract.[39] When the patent issued, the Army learned of the failure and required Campbell to forfeit title. Their discretion to do so was affirmed by the Court of Appeals in 2004.

Under Bayh-Dole, the government can use a concept called march-in rights to require a contractor to license the patent to a third-party applicant. If the contractor refuses, the agency can grant the license itself if necessary to ensure commercialization, alleviate health or safety needs, or ensure domestic manufacturing requirements.[40] So far, no examples can be found of an agency exercising these rights.

In 1998, the National Institutes of Health's Working Group on Research Tools compared Bayh-Dole with §1498 and commented that exercising march-in rights requires that the funding agency follow a burdensome administrative process to demonstrate that the research contractor inadequately commercialized the technology. NIH recognized that, if it did obtain march-in rights, it could license the patent to another manufacturer to make a research tool commercially available. By contrast, if a patent for a critical research



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tool was not federally funded, §1498 would only allow its use for or on behalf of the government, for a reasonable royalty.[41]

When licensing government-funded technologies, questions sometimes arise about whether a licensee can sell a product back to the government if it includes federally funded research. This seems not to have been tested in the courts, but in analyzing the issue for biomedical inventions, the Government Accounting Office felt that Bayh-Dole did not give the government rights to special royalty-free discounts on commercial products that incorporated federally funded research. It said that the paid-up license under Bayh-Dole only applies when the government authorizes a company to practice a funded technology under the government's license on behalf of the government.[42]

The act has greatly increased commercialization by giving universities and other research organizations the certainty of ownership necessary to bring a multitude of new technologies into the marketplace.

Exercising Bayh-Dole's rights to use federally funded biomedical research has been suggested as a way to counter high pharmaceutical prices. However, in 2003, the General Accounting Office determined that the U.S. government had a potential ownership interest in only a handful of the 100 top brand name drugs purchased by the Department of Defense (DOD) or Veterans Administration (VA), representing only about $120 million in expenditures for 2001.[43] Procurement officials at the DOD and VA could not report any instance where a federal agency used the government's license to have a product made. Neither agency utilized government licenses for procurement because they believed that the Federal Supply Schedule already provided favorable drug pricing (at least 24 percent below average nonfederal manufacturer's pricing).[44]

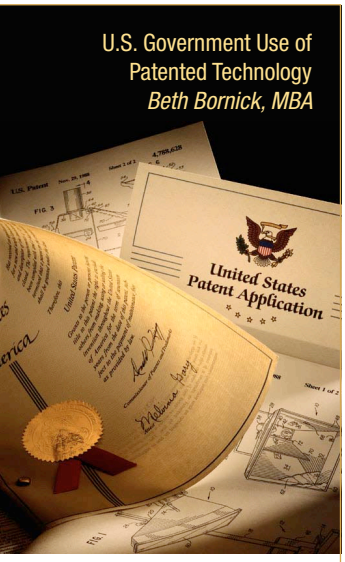
In fact, the Bayh-Dole Act is credited with supporting the development of important public health technologies including synthetic penicillin and the hepatitis B vaccine.[45] While the Bayh-Dole Act provides another form of compulsory patent licensing, the government maintains this right in return for providing broad public benefits, including significant economic impact. The act has greatly increased commercialization by giving universities and other research organizations the certainty of ownership necessary to bring a multitude of new technologies into the marketplace.

A few other laws also provide for a compulsory license to support the public interest. The Atomic Energy Act allows the Nuclear Regulatory Commission to declare a nuclear materials patent to be of public interest, allowing the commission to use the invention or license it nonexclusively in support of the commission's mandate.[46] The patent owner gets a reasonable royalty, agreed upon with the licensee or set by the commission.

The Clean Air Act offers a procedure to license a patent needed to comply with emissions standards, if the technology is not otherwise available. If no reasonable alternatives exist or a monopoly has resulted, the attorney general can petition the U.S. District Court to grant a license on reasonable terms.

Both acts extend beyond §1498, as government use is not required, but the license must be requested through established procedures. Neither act has been cited in granting a compulsory license, possibly because the existence of the regulation encourages reasonable licensing without resorting to such remedies.[47]

Compulsory licenses are granted more frequently under §1498 than under any of the other acts, but this is certainly not a widespread problem, and the claims regarding government use are few compared to civil patent infringement cases. The U.S. Court of Federal Claims reported only eleven new copyright and patent claims filed against the government during



the twelve months ending September 30, 2007, compared to 2,896 patent infringement cases commenced in Federal District Court during the same period.[48]

Conclusions

The United States government has reserved a number of rights to use patented technologies. The Bayh-Dole Act reasonably trades funding for research in exchange for rights to use the resulting technology, and the few resulting court cases should not really concern patent holders or potential licensees. But 28 U.S.C. §1498 is much more far-reaching. It allows use of any patent without notification and awards compensation only after bringing suit, making patentees risk patent invalidation and pay for costly litigation. And even though claims of public use under §1498 are infrequent compared to claims of private infringement, the government's use of patents without consent has implications beyond the U.S. borders.

International trade negotiations shine a harsh spotlight on U.S. patent policies, and the U.S. intellectual property protection has broad economic and political implications on the world stage. In the Uruguay Round of Multilateral Trade Negotiations, attempts to set boundaries on compulsory patent licensing were constrained in part by the U.S. government's right to use patents without permission or injunctive relief under §1498. The resulting Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) allows broad leeway for compulsory licensing, meaning that U.S. companies with patents in World Trade Organization member countries are at risk of having their patents appropriated by foreign governments, perhaps to control pricing of the patented technology.[49]

It would greatly enhance the United States' international bargaining power if §1498 were amended to include a clause similar to 27 F. A. R. §204.1 (b), which requires a government user of patented technology to make a reasonable effort to obtain authorization before using it, except in situations of national emergency, extreme urgency, or public noncommercial use.[50]

But a change like this is unlikely in the short term, as compulsory licensing under §1498 has been considered an important tool for the U.S. government's homeland security efforts, giving quick access to critical patents if necessary for threat response. When the 2001 anthrax mail attacks raised concerns over the limited and costly supplies of Bayer AG's patented antibiotic Cipro, the government threatened use of §1498 to justify buying the drug from overseas manufacturers.[51] While the Cipro issue was resolved without resorting to compulsory licensing, there is still concern that patent exclusivity could prevent timely response to other homeland security threats.[52] If this fear is sustained, it could make it difficult to strengthen patent holders' rights under §1498.

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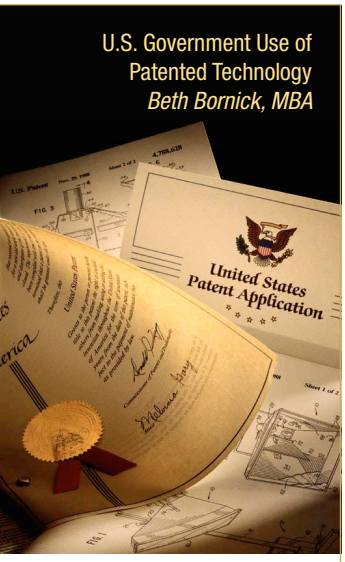
Notes

[1] Bayh-Dole Act, 35 U. S. C. § 200-212 (1980, as amended).
[2] *James v. Campbell,* 104 U.S. 356 (1881).
[3] *Hollister v. Benedict,* 113 U.S. 59, 5 S.Ct. 717 (1885).
[4] *U.S. v. Palmer,* 128 U.S. 262, 9 S.Ct. 104 (1888).
[5] *Schillinger v. U.S.,* 155 U.S. 163, 15 S.Ct. 85 (1894).
[6] *Brooks v. U.S.,* 39 Ct.Cl. 494, 1903 WL 843 (Ct. Cl. 1904).
[7] An Act to Provide Additional Protection for Owners of Patents of the United States, and for other purposes, 36 Stat. 851 (Jun. 25, 1910).

> Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That whenever an invention described in and covered by a Patent of the United States shall hereafter be used by the United States without license of the owner thereof or lawful right to use the same, such owner may recover reasonable compensation for such use by suit in the Court of Claims; *Provided however,* That said Court of Claims shall not entertain a suit or reward compensation under the provisions of this Act where the claim for compensation is based on the use by the United States of any article heretofore owned, leased, used by or in the possession of the United States; *Provided further,* That in any such suit the United States may avail itself of any and all defenses, general or special, which might be pleaded by a defendant in an action for infringement as set forth in Title Sixty of the Revised Statutes, or otherwise; *And provided further,* That the benefits of this Act shall not inure to any patentee, who, when he makes such claim is in the employment or service of



the Government of the United States; or the assignee of any such patentee; nor shall this Act apply to any device discovered or invented by such employee during the time of his employment or service.

[8] *Wm. Cramp & Sons Ship & Engine Bldg. Co. v. International Curtis Marine Turbine Co.,* 246 U.S. 28, 38 S.Ct. 271 (1918), citing "An Act to Provide Additional Protection for Owners of Patents..." (Jun. 25, 1920), 36 Stat. 851.

[9] *Richmond Screw Anchor Co. v. United States,* 276 U. S. 331, 48 S. Ct. 194 (1928).

[10] *Richmond* at 197, quoting Ch. 114, 40 Stat. 704.

[11] 28 U. S. C. § 1498 (a).

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Nothwithstanding the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States prior to July 1, 1918.

A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which Government time, materials or facilities were used.

[12] *Leesona Corp. v. United States,* 220 Ct.Cl. 234, 599 F.2d 958 (1979).

[13] See 48 C. F. R. § 52.227-1.

[14] *Sevenson Environmental Services Inc. v. Shaw Environmental Inc.,* 477 F.3d 1361 (Fed. Cir. 2007).

[15] *Hughes Aircraft Co. v. United States,* 209 Ct.Cl. 446, 534 F.2d 889 (Ct.Cl. 1976) (Hughes I).

[16] Affirmed in *"Hughes XIII,"* 86 F.3d 1566 (Fed.Cir. 1996).

[17] *"Hughes X,"* 29 Fed.Cl. 197 (1993).

[18] *Zoltek Corp. v. United States,* 442 F.3d 1345 (Fed. Cir. 2006).

[19] 28 U. S. C. § 1498 (c).

[20] *Brief for the United States in Opposition, Zoltek Corp. v. United States,* 2007 WL 1420557 at 10 (2007).

[21] *Nanobusiness Alliance Brief Amicus Curiae in Support of Petitioner, Zoltek Corp.,* 2007 WL 1434957 at 3 (2007).

[22] *Brief for the United States in Opposition* at 17 (2007).

[23] *Madey v. Duke University,* 307 F.3d 1351 (Fed. Cir. 2002).

[24] *Madey v. Duke University,* 413 F.Supp.2d 601 (M.D.N.C. 2006).

[25] *Madey,* 413 F. Supp. at 515.

[26] Office of Scientific Research and Development, *Science—the Endless Frontier, A Report to the President by Vannevar Bush, Director* (1945), available at http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm (last visited August 6, 2008).

[27] This report is also said to have introduced the concept of academic technology transfer.

[28] Council on Governmental Relations, *The Bayh-Dole Act, A Guide to the Law and Implementing Regulations* (1999), 1, available at http://www.cogr.edu/docs/Bayh_Dole.pdf (last visited August 6, 2008).

[29] *Technitrol Inc. v. United States,* 194 Ct.Cl. 596, 440 F.2d 1362, 1366 (Ct. Cl. 1971).

[30] Adam B. Jaffe and Josh Lerner, "Reinventing Public R&D: Patent Policy and the Commercialization of National Laboratory Technologies," Vol. 32 No. 1, *RAND Journal of Economics,* 167, 170 (Spring 2001).

[31] Council on Governmental Relations (COGR), *The Bayh-Dole Act, A Guide to the Law and Implementing Regulations* (1999), 1, available at http://www.cogr.edu/docs/Bayh_Dole.pdf (last visited August 6, 2008).

[32] 28 F.R. 10943.

[33] U.S. General Accounting Office Report GAO/RCED-98-126, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities,* 3 (1998), available at http://www.gao.gov/archive/1998/rc98126.pdf (last visited August 6, 2008).

[34] Presidential Memorandum to the Heads of Executive Departments and Agencies, Subject: Government Patent Policy, 1983 Pub. Papers 248 (Feb. 18, 1983), see http://www.reagan.utexas.edu/archives/speeches/1983/21883b.htm (last visited August 6, 2008).

[35] 37 C. F. R. § 401.14 (b).

[36] § 401.14 (c).

[37] § 401.14 (d).

[38] § 401.14 (e).

[39] *Campbell Plastics Engineering & Mfg, Inc. v. Brownlee,* 389 F.3d 1243 (Fed.Cir. 2004).

[40] 37 C. F. R. § 401.14 (j).

[41] *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998), available at http://www.nih.gov/news/researchtools, follow link to Appendix D: *Analysis of NIH Options Under Current Law* (last visited August 6, 2008).

[42] U.S. General Accounting Office Report GAO-03-536, *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions,* 7 (2003), available at http://www.gao.gov/new.items/d03536.pdf (last visited August 6, 2008).

[43] U.S. General Accounting Office Report GAO-03-536, *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions,* 8 (2003), available at http://www.gao.gov/new.items/d03536.pdf (last visited August 6, 2008).

[44] U.S. General Accounting Office Report GAO-03-536, *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions,* 12 (2003), available at http://www.gao.gov/new.items/d03536.pdf (last visited August 6, 2008).

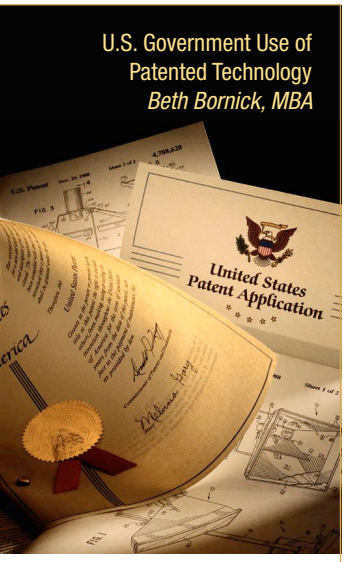
[45] Association of University Technology Managers, *The Bayh-Dole Act: Important to our Past, Vital to our Future,* available at http://www.autm.net/about/BayhDoleAct.cfm, follow link to Bayh-Dole Talking Points (last visited August 7, 2008).

[46] 42 U. S. C. § 2183 (b) (Westlaw 2007 through Pub. L. No. 110-131).

[47] John R. Thomas, Congressional Research Service Report RL32051, *Innovation and Intellectual Property Issues in Homeland Security* (January 17, 2007), 11, available at http://www.ipmall.info/hosted_resources/crs/RL32051-070117.pdf (last visited August 6, 2008).

[48] James C. Duff, *Judicial Business of the United States Courts, 2007 Annual Report of the Director,* available at http://www.uscourts.gov/judbus2007/contents.html, follow links to Table G-2A and Table C-2A (last visited August 7, 2008).

[49] Jerome H. Reichman, *Non-voluntary Licensing of Patented Inventions,* United Nations Conference on Trade and Development - International Centre for Trade and Sustainable Development (UNCTAD-ICTSD), Project on Intellectual Property Rights and Sustainable



Development, Issue Paper No. 5 (June 2003), available at http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf (last visited August 6, 2008).

[50] This article currently applies only to patent holders from countries party to the North American Free Trade Agreement and is limited by 27 F. A. R. § 204 (c) to exclude use for or by the federal government.

[51] Senator Charles E. Schumer, Press Release, *New Cipro Source Could Dramatically Increase Supply* (October 16, 2001), http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/PR00728.html (last visited August 6, 2008).

[52] John R. Thomas, Congressional Research Service Report RL32051, *Innovation and Intellectual Property Issues in Homeland Security* (January 17, 2007), 7, available at http://www.ipmall.info/hosted_resources/crs/RL32051-070117.pdf (last visited August 6, 2008).

Royalty Monetization: A Post-License Value-Creation Strategy

Louis P. Berneman, EdD, CLP

Conflict of interest disclosure: *Berneman is a paid consultant to Paul Capital Healthcare.*

University[1] technology managers handle university intellectual property assets to achieve a multiplicity of goals, including: public benefit, faculty satisfaction and recognition, community and economic development, industry ties, and income generation. Technology managers utilize a variety of licensing and business development mechanisms to achieve these technology transfer goals. The need to balance different and oftentimes competing or incompatible goals, as well as the need to consider both short-term financial needs and longer-term growth strategies can present a significant challenge even to seasoned technology management professionals. These challenges are further compounded by the complex and diverse knowledge and skills inherent to the technology transfer process, the unpredictability of intellectual property, and the diverse roles and responsibilities of technology managers.

Technology transfer agreements with companies, investors, and entrepreneurs are critical to universities' ability to move discoveries from the laboratory to the market. However, consummation of these transactions—collaborations, licenses, and startups—is not the end of the technology transfer value-creation process. Beyond negotiating agreements, technology managers also need to consider post-license value-creation strategies and manage alliance relationships with licensees and collaborators. Post-transaction management includes defending intellectual property and transfer agreements, as well as the forward-going value of these activities. The relatively recent practice of royalty monetization is a powerful post-licensing value-creation tool and intellectual asset-management strategy. In these transactions, the owners of royalty streams sell all or part of the royalty streams to a buyer (financing source) in return for cash (paid upfront and/or in tranches).

Since 2000, there has been substantial growth of the market for royalty monetization transactions in the life science arena. During 2000-2003, there were more than $500 million in product revenue stream monetizations; whereas, there was a ten-fold increase to more than $5 billion from 2004-2007. These sales include both the sale of existing royalties as well as syn-

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thetic royalties created by companies to sell product revenue interests. This dramatic increase is a reflection of the increased number of royalty buyers who understand healthcare products,[2] markets, and companies. There are also royalty monetization facilitators (i.e., bankers, attorneys, and valuation consultants) who can provide transactional expertise and experience. The increased availability of capital, buyers, and facilitators creates an excellent environment for sellers—patent owners, licensors, and others with healthcare royalty interests. This article presents points to consider in determining whether, when, and how to incorporate royalty monetization as a post-license value-creation and intellectual asset-management strategy to advance university technology transfer goals, optimize innovation capacity, and mitigate risk. Following discussion of the overarching concepts and issues related to royalty monetization is a how-to guide.

Royalty Monetization as a Strategic Tool

In its most basic sense, royalty monetization is a transaction that converts an intellectual property asset that is expected to generate a stream of future royalty income into current cash with a present value.

For most technology managers, the focus on financial terms in licensing transactions is often near- and midterm economics—fees (upfront, annual, milestone, sublicense sharing, and royalty rate), patent cost reimbursement, and equity realization. Yet, for successful healthcare product licenses, near- and midterm economics represent a relatively small portion of actual economic potential over the life of the license. Long-term value creation typically is predicated on the commercial success of products that generate royalty streams.

In the past decade, nearly thirty academic institutions and groups of faculty inventors have utilized royalty monetization to access capital and mitigate risk. The value of university royalty monetization transactions has been increasing since 2000. In 2007 alone, almost $2 billion in healthcare product royalty monetization and revenue interest financing transactions were concluded, and two university-based transactions accounted for the majority of this amount. This growth is reflected in the increasing portion of AUTM members who report that licensing income is being monetized at their institutions.[3]

Most importantly, the financial interest that universities hold in worldwide biopharmaceutical sales is growing, rising from 1.4 percent in 2001 to 3.6 percent today.[3] Current annual global biopharmaceutical sales are in excess of $500 billion, corresponding to $18 billion in royalties each year, not including sales of medical devices, diagnostics, and other life science products in which universities hold a royalty interest.

Royalty Monetization: The What and the Why

TRANSACTION STRUCTURE: THE WHAT

Royalty monetization is an emerging financing approach whereby a patent owner, licensor, or other entity or individual with an economic interest in future royalties sells or securitizes all or a portion of those future royalties in exchange for a certain set of payments. In a royalty monetization transaction, the seller transfers/assigns the right to receive that portion of the royalties sold to the buyer.

In some cases, such as those in which the licensed technology has been commercialized, the royalty stream may already be active. As the licensee generates revenue on licensed products, income flows to the licensor in the form of royalty payments. In situations in which licensed products are in development or awaiting regulatory approval, a royalty stream may be projected, but not yet realized. It is increasingly possible and may be beneficial for universities to monetize a portion of a not-yet-realized,

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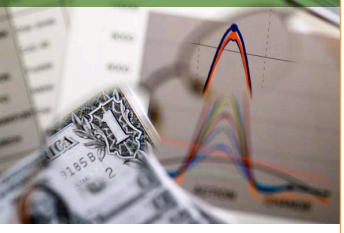


future royalty stream for products in late-stage development, with a tranche payment structure that minimizes discount for approval risk.

Regardless of whether or not there is current cash flow from a product, royalty monetization provides cash in return for a defined portion of future payments from the licensee. Given the availability of capital for these structured finance transactions, sellers are able to construct deals that allow them to meet their current financial needs while potentially, depending on structure, preserving long-term value and upside potential.

For example, royalty monetizations do not have to be a complete sale of the royalty, but rather can comprise only a portion of the royalties, allowing the seller to retain a future economic interest. The agreed-upon structure may allow the seller to limit the royalty interest being sold to certain products, defined countries/regions, or even a certain period of time, thus providing a cap on aggregate payments and allowing the seller to retain royalties in excess of the cap.

Payments also can be structured as payments over time—exchanging potential revenue for defined revenue—to allow for covering defined obligations such as technology licensing office personnel, operations, and patent expenses for a designated period of years. This approach provides a mechanism for covering these costs in the intervening period while waiting for the next success in the license pipeline.

SELLERS' MOTIVATIONS: THE WHY

The diversity of sellers' motivations reflects the different needs and interests of sellers in general, and universities and their faculty inventors in particular. It should be noted that the increasingly flexible design and structure of royalty monetization transactions allow diverse institutional stakeholders to address their unique objectives, including:

- accessing capital in the near-term,
- mitigating and diversifying risk,
- providing financial recognition for a significant innovation, and
- managing conflict of interest.

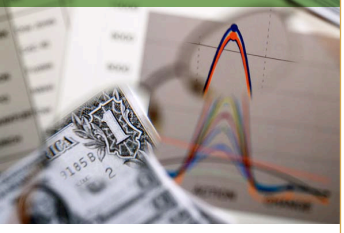
Accessing Capital

For institutional sellers, a prime motivation is early access to capital to meet current financial obligations, develop and fund programs, recruit faculty, build facilities, capitalize innovation/gap funds, and otherwise expand education, research, and innovation capacity. While current income from licensing activities provides some near-term cash flow, the significant payout is typically years into the future. In addition, given mandated use of proceeds of license revenues, as required by institutional patent policies, license income provides little, if any, flexibility, such as the funding of initiatives. In contrast, royalty monetization transactions can be structured to provide substantially larger amounts of cash over a much shorter period of time.

Mitigating and Diversifying Risk

Universities and inventors may consider royalty monetization to mitigate and diversify the risk associated with a specific asset. Universities typically derive substantial income from only a small number of licenses. As with any portfolio of assets, but especially a concentrated one, diversification is a customary and standard risk-mitigation approach. A portion of monetized royalties may be invested in other assets, including revenue-generating vehicles or even royalty monetization funds themselves, thus diversifying the institution's asset portfolio and mitigating the risk that could result from the diminution or loss of a single, substantial source of income.

Risks associated with university licensed healthcare product royalties are numerous, including patent and license challenges, regulatory stumbles (pulled from the market, product recall, label restriction), delayed launch, sales underperformance, unanticipated competition, and reduced



reimbursement by health insurance companies and managed-care organizations.

For many faculty inventors, future income streams flowing from their interest in their inventions may account for the majority of their long-term asset holdings. The failure to realize these income streams may have a significant impact on the individual's overall financial health. A key tenet of responsible investing is maintaining a diversified asset portfolio that balances risk and reward. Royalty monetization offers inventors the opportunity to take some money off the table and invest it elsewhere, enabling them to engage in prudent financial planning and asset management. While risks associated with unanticipated reduced license income may not be catastrophic to universities, they may be to individual inventors. As with institutional transactions, inventors can structure a royalty monetization to retain a portion of long-term value and upside potential.

Providing Recognition

For both institutions and inventors, royalty monetization is a dramatic expression of financial recognition for a significant innovation. While academic recognition through traditional means (such as promotion) can occur relatively soon after important discoveries are made, substantive financial recognition of academic achievement may take more than a decade.

Managing Conflict of Interest

The decision to monetize a royalty may also be influenced by nonfinancial factors, such as conflict-of-interest management. Faculty members who speak of or advocate for particular products are coming under increased scrutiny with respect to real or perceived personal financial interest. In some cases, the institution may stand to benefit from the success of the product in question even when the individual has no direct financial interest in it. In the current environment, even this indirect relationship may create a barrier for those faculty members interested in educating their peers on the latest biomedical and scientific advances.

Royalty monetization of the entire interest in an asset that is subject to such scrutiny provides a mechanism for effectively managing, possibly even avoiding, both real and perceived conflicts while allowing the institution to realize the value of the asset. Institutional and inventor involvement in clinical trials of products in which they have an existing or potential financial interest, including study of a new indication for an approved drug currently generating royalties, also creates a conflict of interest that may be well-managed by the sale of the entire royalty interest. Universities and inventors may also utilize royalty monetization to resolve conflicts that arise when the product itself or the source of the royalty is in opposition to the mission, ethics, or beliefs of the organization or individual.

Inventors Matter

As discussed above, unlike universities, faculty inventors as individuals have few alternatives to royalty monetization to access life-altering capital on a reasonable basis. In addition, as important as risk mitigation and diversification may be to institutions, it is even more critical to individual inventors.

It should be noted that institutions and inventors with beneficial interests in royalty income may have different time horizons with respect to the need for capital and may have very different risk-mitigation/diversification needs. While inventors cannot deliver to royalty buyers the full package of rights that can be provided by institutional owners of the intellectual property, they are well-positioned, with some institutional support, to participate in the structuring of these transactions.

Clearly, faculty inventors are a critical component of an institution's intellectual

Royalty Monetization: A Post-License Value-Creation Strategy

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assets. As such, the needs of these innovative individuals must be considered in the context of licensing deals and post-licensing value-creation strategies. Whether or not institutions wish to proceed with royalty monetizations, it is in their best interest to educate their faculty inventors about the risks and benefits of these transactions and cooperate with those individuals who seek to use royalty monetization to meet their financial objectives.

The Why Nots

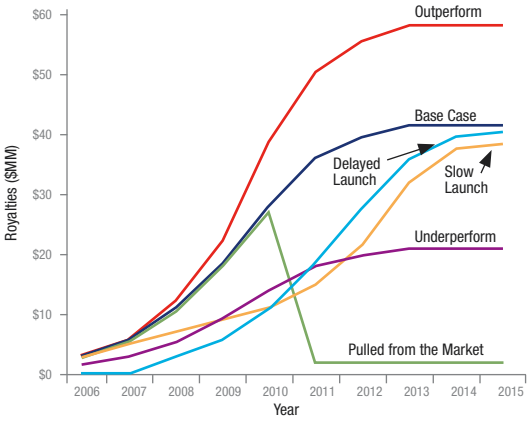
Just as there are diverse motives for pursuing royalty monetization, there are concerns that should give potential sellers pause. These concerns should be considered carefully in the context of an overall risk–benefit assessment. The growing number of transactions demonstrates that risks and concerns can be readily addressed with thoughtful transaction structures.

A key concern is that royalty monetization creates a discount in value over the life of the license. While this is almost always the case, it must be balanced against the additional value that accrues from accessing capital to fund today's needs. A well-structured deal that provides funds to further a robust strategic plan should provide sufficient return on investment to balance the discount associated with the monetization.

Thus, the real issue is the magnitude of the discount, rather than the discount per se. Moreover, it is important to recognize that, of the possible scenarios for product sales (which are the ultimate drivers of royalty income), only one provides a superior return compared with baseline assumptions (Figure 1). Given the potential for product failure, delay, and under performance and other events that may materially impair the value of the royalty stream, there is a reasonable possibility that a royalty without monetization will generate income at or below the baseline assumption.

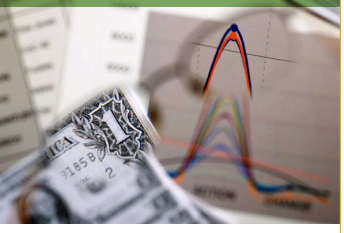
Also of concern is the potential for a royalty sale to be misinterpreted as a lack of confidence in the product. While it is possible for external audiences to arrive at this conclusion, effective communication around the transaction can reduce the likelihood of this perception. Making it clear that the transaction is part of an overall licensing, business-development, and capital-formation strategy should go a long way to providing appropriate context in which to assess its true meaning and value.

Figure 1: Revenue Forecast Scenarios



The status of the buyer also impacts a seller's ability to position a royalty monetization in a positive light and as a strategic intellectual property asset-management activity. If the buyer is recognized as highly knowledgeable, in both the scientific and commercial aspects of the life sciences, his or her interest in owning a portion of a specific royalty stream after an extensive due-diligence process may, in fact, provide additional validation for the product and the underlying intellectual property asset. Royalty monetization is and can be seen as a value-creation tool and asset-management strategy.

Time and cost concerns also create a barrier to pursuing royalty monetization, even when the benefit of the transaction is recognized. Again, technology managers and other institutional decision makers need to consider any individual transaction in the context of a global asset- and financial-management strategy. That said,



there are several factors that impact the actual time and cost requirements of these transactions.

Investment Bankers

There is an established pool of experienced life science royalty buyers (identified below) and bankers active in this area. The company making royalty payments should also be approached. Institutions may opt to directly contact the pool of known buyers. Such a direct approach may avoid costs and delays incurred when using an investment bank or financial adviser to identify a buyer. However, experience has shown that, in large transactions involving hundreds of millions of dollars, investment bankers, serving as financial advisers, can add value in terms of maximizing bids. Investment bankers' fees, however, are generally prohibitive in smaller transactions.

VALUATION CONSULTANTS

The use of valuation consultants should be considered carefully. In addition to providing a value, valuation consultants may help build sales and royalty forecast models. If such capabilities are not available from internal institutional resources, their engagement should be considered. The monetization of life science royalties has become reasonably efficient in recent years, and the value of a particular asset is as much determined by demand as any other parameter. Third-party valuations are required in securitization transactions as their independent reports establish the value for the asset.

OUTSIDE LEGAL COUNSEL

Outside legal counsel with particular expertise and experience in structured finance, generally, and a track record representing universities and inventors in royalty monetization transactions, specifically, can help make the process more efficient with respect to time and cost. These are complex, specialized transactions, and experienced outside counsel can provide invaluable support to university general counsel and inventors' personal attorneys and tax and finance advisers. Experience suggests that, in the absence of knowledge about structured finance among members of the office of the general counsel, the needs of universities and inventors are best met when outside counsel is a member of the transaction team. Institutions and inventors should recognize that buyers have substantial legal resources at their disposal, and institutions and inventors need comparable expertise representing their interests. This balanced approach is essential to executing deal terms that meet the needs of all parties involved in the transaction.

BUYERS' EXPERTISE (OR LACK THEREOF)

Buyers' knowledge and understanding of the product; its market; and the underlying patents, license, and technology also impact the hassle factor of monetizing a royalty. Selecting a well-qualified, experienced royalty buyer allows all parties in the transaction to proceed with a shared understanding and aligned interests of risks, rewards, needs, and wants. Sellers must appreciate that these are complex financial transactions and that buyers are seeking to maximize their returns on investment. Of course, the ability of the buyer to make money and the seller to achieve appropriate short-term value and, in some cases, retain long-term value, are not mutually exclusive, and a well-structured transaction will enable both.

Does When Matter?

A key question about the potential value of royalty monetization relates to timing a transaction for maximum gain. Traditionally, technology managers have focused heavily on optimizing value by market timing. However, as experience in the stock and real estate markets has shown, trying to time purchases and sales to maximize investment returns is risky not only for

Royalty Monetization: A Post-License Value-Creation Strategy

Louis P. Berneman, EdD, CLP

investment professionals, but especially for amateurs.

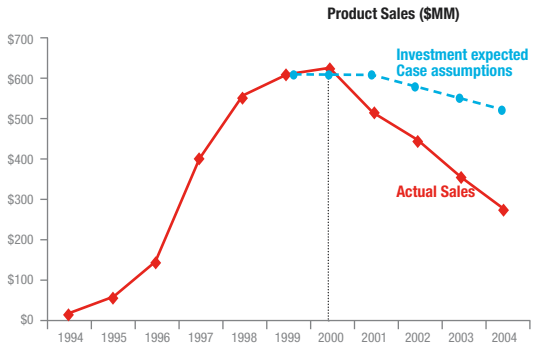
Conventional wisdom holds that monetizing early in the development-to-commercialization continuum typically may yield lower valuations, creating the potential for a significant discount over the life of the product. This depends upon many factors including: phase of development, risk for both development and commercialization, the capabilities of the marketer, and the nature of the market opportunity, to name a few.

Similarly, it is generally accepted that monetizing later in the continuum may yield higher valuations more likely to be in alignment with actual performance, although some of the same factors noted above may impact overall performance. However, it is very difficult to accurately predict the commercial trajectory of any given healthcare product, particularly if it is a new chemical entity or market opportunity. Sometimes early promise fails to bear the expected fruit, leading to a situation in which monetizing earlier might have resulted in an enhanced rather than discounted return over the life of the product.

The challenge of trying to time the market is exemplified in the following example. In mid-2000, a leading university monetized its royalty on an antiviral drug. A major pharmaceutical company markets the drug worldwide, which was approved in the mid-1990s. Under the terms of the monetization, the university sold a majority percentage of its royalty on this drug for more than $100 million. Although robust sales for 2000 and beyond were projected, annual sales of the drug actually declined precipitously (Figure 2). Looking back, it was clear that this was a timely sale for the university, and the majority of risk had been transferred to the buyers as a result of the transaction.

Other examples—and there are many—highlight the dangers of trying to outsmart the market with timing strategies and suboptimal deal structures. One case

Figure 2: Timely Royalty Sale for a University

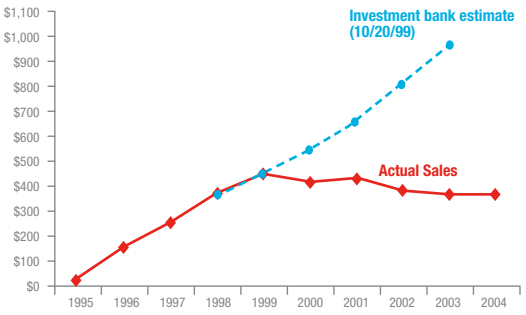


7/00 - University sold a majority of its royalty on the drug for >$100MM

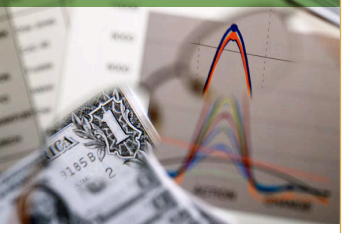
involves a well-known therapeutic product, which the Food and Drug Administration approved in the mid-1990s, that is manufactured and sold on a global basis by two major pharmaceutical companies. In late 1999, a research report from an investment bank with significant expertise in the biopharmaceutical industry estimated that annual sales of the product would continue to rise over the next five years. In early 2000, a royalty buyer submitted a proposal to monetize the royalty. At the time of the offer, actual sales had dipped below the bank's estimate (Figure 3). The holder of the royalty interest chose not to monetize the asset. In subsequent years, actual sales have been significantly below market forecasts and the potential buyer's estimates.

In another case, a top-tier institution accepted an unsolicited offer by the company paying royalties to purchase a portion of future royalties on a successful therapeutic product. At the time of the offer, the product had been on the market for a number of

Figure 3: Product Sales ($MM)



In early 2000, a buyer submitted proposal to purchase the product royalty



years and the amount offered in return for the royalty was substantial. Given the expectation that sales would decline over time and the large amount of money offered by the buyer, the seller agreed to the terms of the monetization. The product has continued to be a mainstay therapy in its indication, and it is estimated that the sale has cost the institution $1 billion in lost royalties.

Beyond playing Monday-morning quarterback, these retrospective analyses provide compelling evidence that deal timing is a risky business. Rather than trying to time the market, sellers should leverage the competitive nature of the current market for royalty monetizations and structure transactions to meet their needs regardless of whether product performance is at, above, or below expectations. Deal structure—when done well—will trump timing, transforming royalty monetization from a form of legalized gambling to a strategic asset-management and capital-formation tool. As previously mentioned, deal structure factors to consider include:

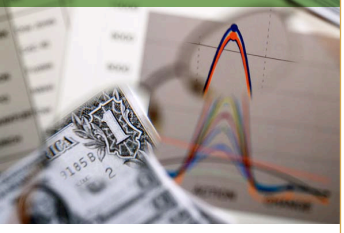
- Selling only a portion of the royalties, thus putting a cap on aggregate payments made to the buyer, with excess royalties (above the cap) to be retained by the seller. This enables the seller to retain a defined future economic interest.
- Limiting royalty interests being sold to certain indications, certain countries/regions, and/or a certain period of time.
- Providing annual payments designed to cover technology licensing office expenses for personnel, operations, and patents for a designated period of years (while waiting for the next success in the license pipeline).
- Selecting the buyer based on reputation, probability of success, and deal factors in addition to absolute price.

Who's Buying?

While a variety of financial organizations are theoretically capable of purchasing royalties, in reality, the majority of royalty monetization transactions have been executed by a small number of specialized funds, including Capital Royalty, Cowen Healthcare Royalty Partners, DRI Capital, Paul Capital Healthcare, and Royalty Pharma. These funds, generally, have a high level of understanding of the essential, underlying elements of these transactions—patents, technologies, licenses, products, markets, risks, benefits, and deal structures. Such knowledge helps to ensure that sellers and buyers enter into the royalty monetization process with a shared perspective. Given some variation in parameters other than price, these buyers have considerable expertise and experience in structuring and consummating these complex transactions. In addition, the marketer of the product that pays the royalty, the licensee, or sublicensee, should also be considered as a potential buyer as the company certainly has first-hand knowledge about the asset.

Beyond playing Monday-morning quarterback, these retrospective analyses provide compelling evidence that deal timing is a risky business.

While a few investment banks have established capabilities to facilitate royalty monetization transactions, they are not buyers themselves. Rather, these banks typically seek to run auctions for sales. Bankers active in this field include Morgan Stanley, Goldman Sachs, and Citigroup. Royalty monetizations managed by bankers are usually associated with increased costs (in the form of transaction fees) and time (in getting various buyers up to speed on the technology and market potential of the auctioned asset). While the increased time and cost of using an investment bank may provide benefit in the case of a multiple hundred million dollar sale, most selling institutions are likely to have the capabilities to manage less complex deals directly, obviating the time for additional fees and time delays.



Points to Consider Before Undertaking Royalty Monetization (The How)

FOUR CRITICAL ISSUES

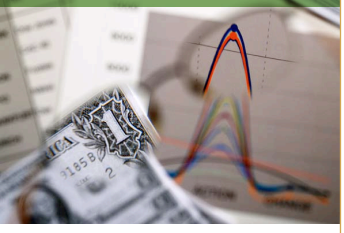
Successful execution of these transactions necessitates a forthright appraisal of what is at stake, who stands to be affected, and why the transaction is being undertaken. In preparing for these transactions, technology managers must address four critical issues:

1. understand the motivations for and goals of the transaction;
2. consider the interests of all stakeholders, including faculty inventors;
3. conduct internal due diligence in advance of the sales process to fully understand their opportunities and limitations, including a comprehensive review of the underlying license and patents, and;
4. model revenue projections so as to better understand potential income streams associated with a variety of regulatory and market scenarios.

With this information in hand, technology managers and their institutions are well-positioned to advocate effectively and pragmatically for their institutions' and their inventors' interests. Such preparation is also likely to assure the continued involvement of technology managers in the transaction, thereby increasing the likelihood that the needs and interests of the technology licensing office will be considered.

A HOW-TO GUIDE

1. **Prepare for a possible transaction.**
   a. Educate yourself so that you can help to educate others, thereby enabling an informed discussion and consideration of the opportunity.
   b. Analyze license and related agreements.
      i. Determine your ability to assign the license and requisite consents to do so (which a buyer may require).
      ii. Determine confidentiality restrictions.
      iii. Identify ambiguities that may be of concern to a potential buyer.
      iv. Assemble history of royalty and other payments from the licensee and any sublicensees, including sales and audit reports, if any, royalty rate, royalty base, possible deductions (stacking and combination discounts).
   c. Analyze the relevant patent portfolio.
      i. Identify all patent holdings including filing, issuance, and expiration dates and territories.
      ii. Consider a review of potentially competitive patent positions that may impact the value of the institution's patent.
   d. Develop a valuation model/tool.
      i. Actual or projected product revenues and royalties due
      ii. Current and future market and competition
      iii. Regulatory risks
      iv. Reimbursement risks (uptake by healthcare providers)
   e. Understand stakeholders' interests, goals, objectives, needs, and wants.
      i. Technology transfer office, including the need for license income to fund operations in future years
      ii. Inventors (both laboratory and personal shares)
      iii. Finance and administration
      iv. General counsel
      v. Deans/department chairs
      vi. Provost/president
      vii. Trustees
   f. Consider institutional review and approval processes and key personnel, including to whom, when, and how to share your considerations and what authorizations you need to initiate the consideration process.
   g. Identify internal process stakeholders and advisory teams.



i. Business issues (technology transfer office, external consultants)
ii. Legal issues (general counsel, outside counsel)
iii. Financial issues (finance and administration)

h. Develop nonconfidential and confidential information packages for review by potential buyers.

2. **Structuring the transaction**
   a. Consider the institution's and the inventor's goals.
   b. With general counsel, retain outside counsel.
   c. Develop transaction goals, needs, and wants to communicate to outside counsel and potential buyers.
   d. With outside counsel, evaluate possible deal types (sale, securitization), structures, sales, and approval processes and related issues, including accounting and tax treatment; experienced outside counsel will develop and manage the purchase agreement and related agreements.
3. **Sales process**[4]
   a. Auction: The auction process typically consists of multiple rounds of bids, with the first round used for indication of interest and subsequent rounds comprising binding bids. Consider the:
      i. Pros (perhaps a better price)
      ii. Cons (more time and confusion)
   b. Documents used in the auction process include:
      i. Confidentiality agreements with potential buyers
      ii. Process letter (informs bidders of intended process)
      iii. Information memorandum
         1. License and related agreements
         2. Patent portfolio
         3. History of royalty payments
         4. Draft royalty purchase agreement
         5. Valuation information
4. **Royalty buyers**
   a. Licensee and sublicensees
   b. Healthcare royalty buyers
      i. Capital Royalty LP (www.capitalroyalty.com)
      ii. Cowen Healthcare Royalty Partners (www.cowenroyalty.com)
      iii. DRI Capital (www.dricapital.com)
      iv. Paul Capital Healthcare (www.paulcapitalhealthcare.com)
      v. Royalty Pharma (www.royaltypharma.com)

Several of these Web sites provide case studies or lists of transactions that demonstrate how royalty monetization transactions can be deployed to achieve a variety of goals and objectives.

Conclusions

Universities and technology managers should feel confident that royalty monetization is an established, effective intellectual asset-management strategy. Royalty monetization offers flexibility with respect to deal structure and terms. Currently, an active market helps to ensure that sellers will find one or more buyers able and willing to meet their needs. A high level of knowledge on both sides of the table is critical to structuring win-win transactions. Universities and technology managers will benefit from conducting rigorous internal due diligence, addressing the interests of their various stakeholders, and identifying potential buyers who are knowledgeable and experienced.

IN SUMMARY

- Royalty monetization is an intellectual asset-management strategy that should be considered as part of the post-license process.
- Structuring royalty monetization transactions as win-win, as technology managers endeavor to do in all negotiations, is far more likely to achieve the goals of institutions and inventors than trying to time the market to optimize gains.
- Universities should alert faculty inven-

tors to the opportunity to monetize royalties and provide reasonable cooperation.

Royalty monetization transactions are able to create value long after the ink has dried on licenses.

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Notes

[1] In this article, *university* includes degree-granting academic institutions and not-for-profit research institutions, organizations, foundations, teaching hospitals, and the like.

[2] Products include therapeutics, vaccines, devices, and diagnostics.

[3] Royalty Monetization Workshop D8, March 1, 2008, at the AUTM Annual Meeting in San Diego, California.

[4] Royalty Monetization Workshop B8, February 29, 2008, at the AUTM Annual Meeting in San Diego, California.

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Tomorrow's Technology Transfer is published twice per year by the Association of University Technology Managers as a member benefit. The editors encourage high-quality articles applicable to the technology transfer profession. Articles, which can be submitted at any time, should be:

- of general interest to the AUTM membership and AUTM constituents
- timely and relevant
- original and unpublished (exceptions may be made)
- factually correct, well-researched, and documented
- representative of a variety of viewpoints, including but not limited to university, legal, and industry perspectives

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- Steer clear of metaphors and clichés.
- Favor short words over long ones.
- Write in an active, rather than a passive, voice (e.g., "Congress passed the law," instead of "The law was passed by Congress").
- Keep paragraphs and sentences short.
- Don't use jargon if there is a clear conversational equivalent. Define or explain jargon if it can be used to educate the reader about new words or concepts.
- Use examples to emphasize or illustrate a point.
- Keep language gender neutral.
- Avoid writing in first person, particularly the use of "we" for a singular author. For example, instead of writing "We like to call inventors once per month," write, "It's a good idea to call inventors once per month because..."
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- Always run spell-check before submitting.

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