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Editor's Preface

The mission of the *AUTM Journal* is to publish high-quality peer-reviewed articles for the experienced technology transfer professional. In this 2002 edition of the *AUTM Journal*, we present an editorial contributed by Maria C. Freire, Ph.D., and three articles written by Belinda Lew, Ph.D., and Joseph Contrera, J.D., Oren Livne, and Veronica de Juan, respectively.

Maria Freire's address at the 2002 AUTM annual meeting forms the basis of her editorial, "Technology Transfer's Next Frontier: Global Health as a New Bottom Line," in which she urges technology transfer professionals to envision a future beyond the bounds of traditional technology transfer. We trust that you will enjoy her editorial and that her comments will continue to be an inspiration for you.

Belinda M. Lew, Ph.D., and Joseph G. Contrera, J.D., a patent agent and an attorney with Shanks & Herbert in Alexandria, Virginia, consider some of the challenges faced by technology transfer professionals with respect to claiming small-entity status and its importance in patent prosecution and maintenance. We encourage you to read their article entitled "Licensing Agreements and Small-Entity Status." It may inspire you to work harder at keeping the lines of communication open within your organization regarding contracts other than license agreements that may affect small-entity status.

Oren Livne is a licensing officer in the University of California's Office of Technology Transfer in Oakland, California. His article, "Investigation of At-Risk Patent Filings," presents an analysis of the successes achieved over a ten-year period with patent-application filings in the University of California system. If you have ever wanted access to data regarding the advisability of filing a patent application before you have identified a licensee, this article will be of interest to you.

Veronica de Juan is a Spanish attorney who has been working recently at MIT. In her article, "Comparative Study of Technology Transfer Practices in Europe and the United States," she presents an interesting perspective on the evolution of technology transfer in the European Union. She points out that the successes achieved by technology transfer professionals in the United States provide precedents for the kind of

success that the European Union desires. Given that the European Union set a goal at the March 2000 Lisbon European Council Summit of becoming the most competitive and dynamic knowledge-based economy in the world, Ms. de Juan's article is required reading for all of us.

We trust that you find this edition of the *AUTM Journal* useful and informative. Preparation of the *2003 AUTM Journal* is already under way, and the *AUTM Journal's* editors and Editorial Advisory Board are developing plans for theme-based issues in the future. We appreciate and solicit suggestions regarding the *AUTM Journal.* Please send your comments to us via e-mail at autm@autm.net.

— Leona Fitzmaurice, Ph.D.
Editor
March 19, 2003

Guest Editorial

Technology Transfer's Next Frontier: Global Health as a New Bottom Line

Maria C. Freire, Ph.D.,
2002 Recipient of AUTM's Bayh-Dole Award

Introduction

In September 2001, Dr. Maria Freire became chief executive officer of the Global Alliance for TB Drug Development, a public-private partnership that aims to "halt the rise and reverse the spread of the world's oldest infectious disease by developing new, faster-acting, and affordable tuberculosis medicines."

For the six years preceding her CEO appointment, Dr. Freire was director of the Office of Technology Transfer at the National Institutes of Health (NIH), where she developed and implemented technology transfer policies and procedures for the Department of Health and Human Services, while also overseeing the patenting and licensing of inventions created by employees of the NIH and the Food and Drug Administration.

Prior to joining the NIH, Dr. Freire headed the University of Maryland's Office of Technology Development. Before joining the ranks of technology transfer professionals, Dr. Freire earned her doctorate in biophysics from the University of Virginia and conducted postgraduate studies in immunology and virology at the University of Virginia and the University of Tennessee respectively.

In 2002, the Association of University Technology Managers awarded Dr. Freire its highest honor by selecting her as recipient of the Bayh-Dole Award. In her acceptance speech, Dr. Freire not only paid tribute to the active role that technology transfer has played in the delivery of biomedical innovations to the public, but also defined global health as a new goal for technology transfer.

Maria C. Freire, Ph.D., is chief executive officer of Global Alliance for TB Drug Development in New York.

In the editorial that follows, Dr. Freire shares with the AUTM Journal's *readership her thoughts on technology transfer's new frontier.*

— Leona Fitzmaurice, Ph.D.
Editor

Biomedical research and all its achievements can be traced back to the first days of human history. To survive, our ancestors harnessed fire, fashioned tools, and produced medicines from plants and animals for the betterment of their lives. This ability to innovate, combined with our natural curiosity, is the cornerstone of scientific inquiry that still inspires the visionary achievements of men and women now.

Today, we find ourselves at a point in which medical advances offer an unparalleled opportunity to confront unmet health needs throughout the world. Urgent global public-health crises—the alarming proliferation of AIDS, tuberculosis (TB), and malaria—also bring us face to face with colossal economic issues and realities.

The United States and other industrialized nations have used the understanding of intellectual property as a strategic tool for business and technological development. For financially supporting the biomedical enterprise, we appropriately demand the latest tools medical science can deliver to combat deadly diseases and to extend our lives.

At the same time, however, we have grown complacent about diseases that no longer appear to be a threat to our societies. And, although the technological divide between the developed and developing worlds is certainly real, it is the economic divide between highly industrialized nations and all the others that mostly determines who gets adequate medical care.

Those of us who have chosen to be involved in biomedical technology transfer find ourselves in an extraordinary position to influence and affect the outcome and utilization of biomedical innovations. While we should understand and appreciate the business and commercial realities that move basic biomedical discovery toward drug, diagnostics, and vaccine development, the real challenge is to also ensure that the worlds of biomedical advancement and international economics converge for the benefit of global public health.

AIDS, TB, and malaria take a toll of 6 million lives a year, and nearly 30 million people on the African continent are infected with HIV. Tuberculosis is the No. 1 killer of AIDS patients. By itself, TB takes a life every 15 seconds, and it infects one in three people around the world. While therapy for TB is available, successful treatment requires a lengthy, six- to-nine month multidrug combination, and only a fraction of patients successfully comply. As a result, deadly multidrug-resistant strains have spread rapidly, now at a rate of 400,000 cases a year. But because drugs do exist, there is no economic incentive for the pharmaceutical industry to undertake the costly and risky proposition of developing more effective and less onerous treatment regimens.

Recently, more attention has been directed at the plight of those who are dying of AIDS, TB, and malaria. But it remains true that the policies of developed nations continue to leave unresolved the question of what will drive the development of new medical technologies to treat populations with the greatest need and the least economic power. As Tom Abate, the former biotechnology columnist of the *San Francisco Chronicle* cogently observed: "The free market is a powerful mechanism, but it has one and only one end—the production of profits. It depresses me to think of all the other needs that get ignored because of the market's single-minded focus."

Can the U.S. medical and technology transfer communities change market realities? Probably not, but we do have an opportunity to expand the means and ways by which these therapeutic, diagnostic, and prophylactic tools are developed. Let me propose four simple steps that might provide a roadmap for technology transfer as an agent for change.

- *First, let us broaden the definition of success.* Traditional metrics focus on number of agreements, companies formed, and financial returns. These are tried, true, and objective measures. But, they are also narrow and limiting. The AUTM survey should find a way to value and highlight a new breed of deals that provide for solid transfer of technology with global public health as the bottom line. These deals do exist and could and should serve as models for others to follow.
- *Second, let us identify technologies and innovations in our portfolios that could serve such needs and negotiate terms with partners who are thoughtful and flexible, resulting in win-win agreements.* My experience is that the private sector will welcome creative approaches. Of course,

the investment in development still needs to happen, the regulatory hurdles still need to be conquered, and the medicines still need to reach those in need. But we have to find ways to design clever terms and conditions that support development of high-impact/low-profit technologies that can offer immense benefit for those in greatest need. This is the challenge we must meet.

- *Third, we must invent novel technology transfer and development mechanisms.* The TB Alliance could serve as one such example. The goal of the TB Alliance is to develop a new, faster acting anti-TB medicine by the year 2010 that is affordable and accessible to people in endemic countries. We are a not-for-profit, international public-private partnership utilizing the best practices of industry to develop the drugs, but with a different ultimate bottom line. By in-licensing or partnering with experts, we use funds to support the development of compounds that would otherwise not move into the drug-development pipeline. This is an experiment, but it is an experiment that must succeed, because providing improved means of treating TB is a moral imperative.
- *Fourth, we need to foster the establishment of a technology transfer infrastructure in the developing world.* We can help these nations better understand our system so that they can make informed decisions and determinations that best suit them and their reality. This is a mutually beneficial endeavor since, in the process, we will also learn a great deal. In these countries, there are many important resources to draw upon, including chemists, biologists, physicians, farmers, and ethicists. These individuals and their experiences can help broaden our own linear understanding of technology development.

Beyond these efforts, there are some broader and equally important strategies that can be employed to educate those who live in the interface between science and business and to help make positive change happen.

- *Spread the word.* We can remind health-care practitioners of the devastating consequences of these diseases and impress upon tomorrow's professionals sensitivity to, and understanding of, their global impact. By motivating more students to pursue careers in this field, we can encourage nimble, creative minds to tackle and solve the mysteries of the oldest diseases by using interdisciplinary skills and techniques.

- *Advocate for more funding.* We need to convey the enormity of these epidemics to the general public and gain the support of decision-makers to reverse the infectious trends. These diseases can be conquered. We have entered an exciting era in biomedical research; it is now possible to identify new molecular targets for attack so that new compounds can be designed and formulated. We can also support increased funding of the Global Fund for AIDS, TB, and Malaria. Such support can create a market-pull mechanism that would attract investment by the private sector, as well as a market-push mechanism by increasing budgets for basic research to help develop therapeutics, diagnostics, and vaccines for these diseases.
- *Mobilize technology.* Academic institutions spawn inventions that translate into improved medical interventions. We have had important successes in technology transfer in recent years. The focus, given market realities, has been on those technologies that are pursued by pharmaceutical and biotechnology companies. While these remain important, we must also identify and create novel avenues for technology transfer with sound public health as the bottom line.

Ultimately, when we use the best medical tools to fight the most pressing global health crises, we will see dividends that go beyond lives saved—we will benefit from a healthier, more secure world, and we can take satisfaction in knowing that our efforts will benefit those in great need outside our own immediate circles.

Licensing Agreements and Small-Entity Status

Belinda M. Lew, Ph.D., and Joseph G. Contrera, J.D.

Abstract

Filing the correct entity status is usually done during the initial filing of a patent application, and then easily overlooked during prosecution and maintenance of the patent. However, small-entity status for pending and issued U.S. patents can change if those patents and patent applications are licensed to a large entity. Although the error in filing status is correctable, applicants who fail to pay correct fees during the prosecution or maintenance of optioned or licensed patents run the risk of having the patents invalidated. In this article, we review the history of amendments to 37 CFR §1.27, the federal regulation that formally defines small-entity status and show that the benefits of small-entity status clearly may not be claimed when the rights to an invention are transferred, either exclusively or nonexclusively, to a nonsmall entity.

Consider the following possible scenario: Ivan Inventor owns a small drug-development company. He discovers a novel product and hires an attorney to file a patent application on his behalf, properly claiming the benefit of reduced fees as a small entity to the U.S. Patent and Technology Office (USPTO) throughout the prosecution and issuance of the patent. PharmCo is a large drug company that wants to license rights to the product. Like many small companies and nonprofit institutions, Ivan Inventor does not have the resources to market or develop the product for sale to the public, so Ivan exclusively licenses the product to PharmCo and continues to pay small-entity maintenance fees on the patent. Years later, a former employee of Ivan's helps another large drug company, RxCo, develop a product very similar to Ivan's. PharmCo, upon learning of this

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new product, files an infringement suit against RxCo. During the course of the litigation, RxCo learns that Ivan is still paying small-entity fees on his patent. RxCo counterclaims that the infringement suit should be dismissed because Ivan's patent is invalid due to his intentional payment of small-entity fees, in violation of 37 CFR §1.27. In RxCo's motion for summary judgment, RxCo alleges that, by licensing its patent rights to PharmCo, a company not qualified for small-entity status, Ivan's company is no longer allowed to pay small-entity fees under §1.27(a)(2)(i): "A small-business concern, as used in paragraph (c) of this section, means any business concern that: (i) has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license, any rights to the invention to any person, concern, or organization which would not qualify for small-entity status as a person, small-business concern, or nonprofit organization."

RxCo further asserts that Ivan's patent is invalid due to willful failure to pay the large-entity maintenance fees as required under 35 USCS §41(b), (c). Inventor, in his opposition to RxCo's motion, would have to contend that the original filing of small-entity status was done in good faith and that there was never any attempt to defraud the USPTO.

Therefore, the appropriate penalty is the payment of the difference between the incorrect amount paid and the amount due, as provided in 37 CFR §1.28(c): "If status as a small entity is established in good faith, and fees as a small entity are paid in good faith, in any application or patent, and it is later discovered that such status as a small entity was established in error or that through error the office was not notified of a change in status as required by paragraph (b) or this section, the error will be excused upon payment of the deficiency between the amount paid and the amount due."

Based on the above facts, a district court would likely find that there was not clear and convincing evidence that the payment of small-entity status fees by Ivan Inventor was due to willful deceit. However, what that would mean is that the issue would be held over for trial and be litigated along with any other invalidity issues. Furthermore, it is possible that a jury could find for the defendants, necessitating further appellate litigation. The wasteful and expensive legal procedures described in the above scenario can be avoided by an awareness of the pitfalls involved in changing small-entity status.

Review of the Statutes and Regulations Defining Small-Entity Status

Small-entity status within the USPTO is controlled by 37 CFR §1.27 (Title 37-Patents, Trademarks, and Copyrights, Code of Federal Regulations, regulation §1.27). A review of the history of amendments to the original 37 CFR §1.27, as documented by various USPTO Notices in the Federal Register, shows that the benefits of small-entity status clearly may not be claimed by any individual, small-business concern, or nonprofit organization when the rights to an invention are transferred, either exclusively or nonexclusively, to a nonsmall entity.

Former 37 CFR §1.9[1] and former 37 CFR §1.27,[2] respectively, formally set forth the definition of a small entity and the requirement of a written verification to qualify for small-entity status. The definition of a small entity as a small-business concern, independent inventor, or nonprofit organization was added to §1.9 by amendment in 47 FR 43273[3] and 47 FR 40134.[4] As written, former §1.9(c) stated that: "An independent inventor means any inventor who (1) has not assigned, granted, conveyed, or licensed . . . any rights in the invention to any person who could not likewise be classified as an independent inventor . . . or to any concern which would not qualify as a small-business concern or a nonprofit organization under this section."

Similarly, former §1.9(d) defined a small-business concern as: "Any business concern . . . which has not assigned, granted, conveyed, or licensed . . . any rights in the invention to any person who could not be classified as an independent inventor . . . or to any concern which would not qualify as a small-business concern or nonprofit organization under this section."

Under these definitions, a small-business concern "would no longer qualify as a small-business concern if any rights were assigned to any individual or concern which could not qualify as a small-entity pursuant to §1.9(f)."[5] Former §1.27 was amended to add §1.27(c) requiring that "a request for small-entity status be accompanied by submission of an appropriate statement that the party seeking small-entity status qualified in accordance with former §1.9"[6] and that "for a small-business concern, the small-business concern had to either state that exclusive rights remain with the small-business concern, or if not, had to identify the party to which

rights have been transferred so that the party to which rights have been transferred would submit its own small-entity statement."[7]

The language of §1.27, formerly requiring that the applicant qualify as a small-business concern as defined separately in §1.9, was intended to exclude small-entity privileges from those concerns that have transferred rights to a large entity. This view is clearly supported by the USPTO's response to a comment received during the notice and comment period, following the publication of the proposed revision to §1.27. The comment stated that §1.27 should be "corrected to indicate that a small-business concern would be entitled to the 50-percent fee reduction even though it may grant a nonexclusive or even an exclusive license to a nonsmall entity," to which the USPTO responded: "The intent of . . . 37 CFR §1.9(d) and §1.27(c) is to limit the payment of reduced fees . . . to those situations in which all of the rights in the invention are owned by small entities, i.e. independent inventors, small-business concerns, or nonprofit organizations. To do otherwise would be clearly contrary to the *intended purpose of the legislation* which contains no indication that fees are to be reduced in circumstances where rights are owned by nonsmall entities. Adopting the suggestion might, for example, permit a nonsmall entity to transfer patent rights to a small-business concern which would pay the reduced frees and grant an exclusive license to the nonsmall entity.[8]" (Emphasis added.)

To simplify an applicant's request for small-entity status, §1.27 was amended to eliminate the previously required statements, including formal reference to §1.9.[9] The definition of a small entity as an independent inventor, small-business concern, or nonprofit organization holding sole possession to invention rights was incorporated into amended §1.27, and the separate section of small-entity definitions in §1.9 was eliminated.

While the changes were meant to alleviate some of the procedural hurdles to applicants who are entitled to small-entity status, applicants still need to do a "full and complete investigation of all facts and circumstances before making a determination of actual entitlement to small-entity status," and "if the business has assigned, granted, conveyed, or licensed (or is under an obligation to do so) any rights in the invention to others directly or indirectly, the same review for each other entity would also be appropriate."[10]

With regard to disqualification of small-entity status by transfer of rights to a large entity, 65 FR 54604 states: "Sections 1.27(a)(2)(i) and

(a)(3)(i) retain the requirement of former §1.27 that in order for small-entity businesses and nonprofit organizations to remain entitled to small-entity status, they must not in some manner transfer or be under an obligation to transfer any rights in the invention to any party that would not qualify for small-entity status. The absence of this requirement from former §§1.9(d) and (e) (small-business concern and nonprofit organization, respectively), notwithstanding its presence in former §1.9(c) (independent inventor), led to confusion as to the existence of such a requirement for small businesses [sic] concerns and nonprofit organizations. Former §§1.9(d) and (e), where this requirement was absent, have been deleted and it is now made clear that these [sic] rights transfer requirement applies to all parties (independent inventors, small-business concerns, and nonprofit organizations, respectively)."

Federal Case Law Involving Small-Entity Status

A review of federal case law involving small-entity status supports the argument that licensors of large entities cannot be considered small entities under §1.27. The good news for universities and nonprofit institutions that may have unwittingly filed improper claims to small-entity status or have improperly continued to pay small-entity fees is that, to date, the courts have not yet imposed the Draconian sanction of invalidating a patent when the improper claim was done without intent to deceive the USPTO.

Jewish Hospital v. IDEXX Lab (1996)[11]

Jewish Hospital had been awarded small-entity status and had paid fees concomitant with its status during prosecution of U.S. Patent No. 4,839,275. Mallinckrodt Inc. was a licensee of the '275 patent, which, under §1.27, disqualified the plaintiffs from small-entity status. The defendant, IDEXX, argued that the patent should be considered expired for failure to pay proper maintenance fees, and, therefore, no damages from infringing activities could be recovered. The court ruled that, although the plaintiffs had improperly claimed small-entity status, there was no policy reason to read into the law such a drastic sanction as the expiration of a patent because the patent owner did not refuse to pay the fee but simply paid an improper amount. The court found that no intent to deceive was shown or evidenced by the plaintiffs.

University of California and IDEXX Lab. v. Hansen Immunology (1999)[12]

The University of California and IDEXX sought to enforce their patent against the defendants from Hansen Immunology. The defendants argued that, by licensing to IDEXX, a nonsmall entity, the University of California improperly claimed small-entity status, and, therefore, the patent should not be enforceable. The court ruled that any defect from failing to notify the USPTO of a change in the entitlement to small-entity status was cured by the plaintiffs' payment of the full fees (which the plaintiffs did for business reasons and in an abundance of caution).

Ulead Systems Inc. v. Lex Computer and Mgmt. Corp (2001)[13]

The plaintiffs from Ulead Systems sold computer software products. The defendant was believed to be the exclusive owner of a patent directed to a product similar to the plaintiffs' product. The defendant asserted that the sale, manufacture, use, and/or leasing of the software infringed his patent. The plaintiffs sought a declaratory judgment that the patent was unenforceable and/or invalid due to the inequitable conduct of the defendant, who had claimed small-entity status even though a number of his licensees employed more than 500 people and were clearly not small entities under §1.27. In the court's ruling, the plaintiffs received summary judgment in a declaratory judgment action for declaration of noninfringement, patent invalidity, and unenforceability. In contrast to the previous two cases, the court here found that the licensor demonstrated bad faith as a matter of law regarding small-entity status. The court found the claims by the defendant that he was ignorant of the law and by the defendant's attorney that he was ignorant of the facts disqualifying the defendant from small-entity status to be suspect, stating that Lex only attempted to correct the alleged error after the onset of litigation had begun and only when the threat of invalidating the patent became a reality. The court found that there was enough circumstantial evidence to establish that the defendant and his attorney were so willfully blind as to preclude a finding of good faith.

Exceptions to the Rule

As shown by a review of the history of 37 CFR §1.27 and supported by precedents in federal case law, entering into either an exclusive or nonexclusive licensing agreement with a nonsmall entity would disqualify a small-

business concern, individual, or nonprofit organization from claiming small-entity status. Additionally, entering into an option agreement in which there is an obligation to transfer any rights to a nonsmall entity would also disqualify the small-business concern, individual, or nonprofit organization from claiming small-entity status. The options affecting small-entity status are not limited to only those appearing in option agreements, but also include those that are written into material transfer agreements, industry sponsored research agreements, and other agreements that may be connected with the research that generated an invention.

A material transfer agreement tends to be shorter and more informal than a license, but remains an enforceable contract between the owner of a material and a party seeking the right to use the material for research purposes. Rather than transferring the material in exchange for financial payment, the owner of the material has the option to own, or license exclusively, or obtain payments upon the sale of developments made using the material. A sponsored research agreement typically involves a sponsor, such as a private corporation, providing financial support to a research facility in return for an option to license patentable subject matter arising out of the research.

There is one exception under §1.27 where granting a license to a large entity would not bar an individual or small-business concern from entitlement to small-entity status: that is the situation where the large entity is the federal government. Although federal government agencies do not qualify as nonprofit organizations for paying small-entity fees under §1.27(a)(3), a license to a federal agency resulting from a funding agreement with the agency pursuant to 35 USC 202(c)(4) will not disqualify the licensor from small-entity status. Under the provisions of 35 USC 202(c)(4), each funding agreement between a federal agency and an individual, small-business firm, or nonprofit organization must provide that " . . . the federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention . . . ." A university or other institution of higher education located in any country, even though it has some government affiliation, also qualifies as a "nonprofit organization" under §1.27(a)(3).

Pitfalls with Sponsored Research and Jointly Owned Inventions

Under 37 CFR §1.27(a)(2), a small-business concern, as used in paragraph (c) of this section, means any business concern that: (i) has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license any rights in the invention to any person, concern, or organization, which would not qualify for small-entity status as a person, small-business concern, or nonprofit organization. This regulation means that, if there is joint ownership, or a right to license or own a portion of the patented rights, all parties must be eligible for small-entity status for small-entity status to hold for that patent or patent application.

What happens when a university enters into a sponsored research agreement with a large entity? Depending on the agreement, it means that, if the obligation to assign an invention arising from the collaborative work is to both parties, then they both have to have small-entity status to maintain it. Otherwise, the patent or patent application is no longer eligible for the reduced fees. This applies even if the small entity is the one prosecuting the patent application on the invention.

If the obligation is to assign the developed invention to the small entity, large-entity status could still apply if there is an option for the large-entity partner to license the patented invention. In that situation, the patent or patent application is no longer eligible for the reduced fees.

The converse would likely also be true. For example, if there was an agreement in place and then the large entity waived its right to the patented invention, the small entity should not have to pay large-entity status fees in the future unless another large entity is granted rights to the patented invention.

Conclusion

Universities and nonprofit organizations need to re-examine their prosecution practices to ensure that the correct fees are being paid during both prosecution and maintenance of their licensed patents. Under 35 CFR §1.27(g)(1), the patent applicant does not need to review its status as a small entity until the time the issue fee or any maintenance fee is due. Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due.

If the applicant's small-entity status has changed, the applicant must notify the USPTO, prior to or at the time of paying the issue fee or maintenance fee, that it is no longer entitled to small-entity status, pursuant to §1.27(g)(2): "Notification of a loss of entitlement to small-entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity as defined in paragraph (a) of this section is no longer appropriate."

Under §1.28(c), the applicant or patentee who has, in good faith, erroneously established small-entity status or failed to notify the USPTO of a change in status, is given the opportunity to cure the defect through payment of the deficient amount due to the USPTO. Failure to show that an error in establishing or maintaining small-entity status was done "in good faith" runs the risk of the invalidation of an institution's licensed patents.

Examination of an institution's small-entity-status fee payments is important for two reasons. First, from a budgetary standpoint, directors of technology transfer offices need to know how much USPTO fees will be in order to manage their limited financial resources. The discovery that they are now responsible for fees that are double what had been estimated may raise some financial concerns.

Second, failure to acknowledge and pay the proper USPTO fees could result in the invalidation of an institution's intellectual property that would be disastrous. Although the payment of improper fees is easily correctable with payment of the deficient amount and a showing that the error was done in good faith, what will adversely impact a technology transfer office's budget, however, are the enormous legal expenses that are likely to be incurred if the patentee becomes involved in an infringement suit to protect its patent.

The technology transfer office opens itself up to potential infringers, who will file counterclaims for invalidity of the licensor's patent based on its payment of improper USPTO fees, forcing the office to pay for the legal motions involved in defending against these claims. Therefore, the small cost to institutions to perform a small-entity status audit when USPTO fees become due is minimal when compared to the potentially damaging costs that the omission of such a status check may cause to an institution's intellectual property.

Notes

1 43 Fed. Reg. 20461 (May 11, 1978).
2 Final Rule, §1.27, 47 Fed. Reg. 40134 (Sept. 10, 1982).
3 Final Rule, §1.9(d), 47 Fed. Reg. 43273 (Sept. 30, 1982).
4 Final Rule, §§1.9(c), (e), and (f), 47 Fed. Reg. 40134 (Sept. 10, 1982).
5 Final Rule, §1.9, 47 Fed. Reg. 43273 (Sept. 30, 1982).
6 Final Rule, §1.27, *ibid.*
7 Final Rule, §1.27, 65 Fed. Reg. 54604 (Sept. 8, 2000).
8 47 Fed. Reg. 43273 (Sept. 30, 1982).
9 Final Rule, §1.27, 65 Fed. Reg. 54604 (Sept. 8, 2000).
10 *ibid.*
11 *Jewish Hospital v. IDEXX Lab*, 951 F. Supp. 1.
12 *University of California and IDEXX Lab. v. Hansen Immunology*; 54 USPQ2D (BNA) 1481.
13 *Ulead Systems, Inc. v. Lex Computer and Mgmt. Corp.*, 130 F. Supp. 2d 1137, 58 USPQ2D (BNA) 1366.

Investigation of At-Risk Patent Filings

Oren Livne

Abstract

An investigation of patent-application filings made without external financial support, or at-risk, is presented based on inventions disclosed to the University of California from fiscal 1991 through 2000. The success of the at-risk patent applications filed on these invention disclosures is investigated from the perspective of agreements executed and income generated. Suggestions are then provided for improving the overall process of at-risk patent-application filings.

Introduction

One of the most difficult decisions made by technology managers is whether or not to seek patent protection for a given technology. At a company, patents can be used to protect existing or planned products, to wall in competitors, or as a source of licensing income. The research unit that led to the innovation can assist in determining the commercial value of the invention and help define where it can be incorporated into the product line. This knowledge can be combined with the strategic objectives of the company to determine whether or not filing a patent application is warranted.

In contrast, at a university, the main focus is generally on transferring the technology to commercial entities for the public benefit, while generating a reasonable licensing revenue stream.[1] If no one licenses the rights to patents or pending patent applications, it is unlikely that the public benefit was served any more than it could have been had the inventors simply published a paper. The bottom line is that technologies are patented so they can eventually be licensed. Because universities do not sell products in the

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traditional sense and do not have competitors that do so, they lack much of the direction that a company has in determining whether or not to seek patent protection for a technology.[2] Instead, universities must evaluate the likelihood that the technology will be licensed and its potential value if it is. This makes the university technology manager's decision-making job very difficult.

An added difficulty faced by university technology managers, in comparison to their counterparts at companies, is the diversity of technologies they must evaluate. Each faculty member at a university is free to explore individual interests, so inventions range across a large number of technology areas. This diversity makes it unlikely that an individual technology manager will have expertise in all the markets in which the technologies they are managing may find commercial applications. Each new invention disclosure received often means that the technology manager must spend significant time investigating prior art and exploring market potential. Inventors can be a valuable resource in this process, but not all are commercially minded. Furthermore, some inventors can be overly optimistic about the commercial potential of their inventions.

So what is a university technology manager to do? One simple choice is to only file patent applications once a commitment has been secured from a company to license the technology or at least to cover the patenting costs, that is, to make no at-risk filings.

Unfortunately, a university is far from the ideal setting for this approach. The drive to publish means there is frequently a small window of opportunity for filing a patent application. Any significant restrictions on publication, which can be a key strategy of a company, are contrary to the concept of academic freedom at a university. To compound this, because research at universities tends to be fundamental in nature, it is often several years before companies are willing to license the technologies. In some cases, it can take significantly longer to obtain a licensee for a technology.

For example, a laser technology developed at the University of California, Santa Barbara (UCSB) in 1988 and patented shortly thereafter was not licensed until 13 years later. It took that long for the telecommunications infrastructure to develop enough for the technology to become commercially viable. If all goes well, the new laser invented at UCSB should soon be on the market, and the University of California (UC) should see a revenue stream.

To meet the public-benefit mission of universities, there is implicit in the technology transfer process a duty to protect these nascent technologies that hold promise. This duty, in turn, makes the filing of at-risk patent applications a necessity for the university technology transfer community.

The results of UC's at-risk patent-application filings on invention disclosures from fiscal 1991 through 2000 are discussed below and provide insight into steps that can be taken to improve a difficult decision-making process. For the purposes of this paper, at-risk filings are defined as patent-application filings made before there is an agreement in place for revenue generation or reimbursement of patent costs from an external source, such as a license, option, letter of intent, or interinstitutional agreement.[3]

At-Risk Filings at the University of California

The data presented in this paper were gathered from the central Office of Technology Transfer (OTT) at the University of California.[4] As background, from fiscal 1991 to 2000, 4,490 invention disclosures were made to OTT.[5] As of September 2001, patent applications were filed on an average of 43 percent of these invention disclosures. Figure 1, which depicts the percent of invention disclosures on which U.S. patent applications were filed for each fiscal year of disclosure, illustrates the dramatic increase in filings since the introduction of provisional patent applications by the U.S. Patent and Trademark Office on June 8, 1995.

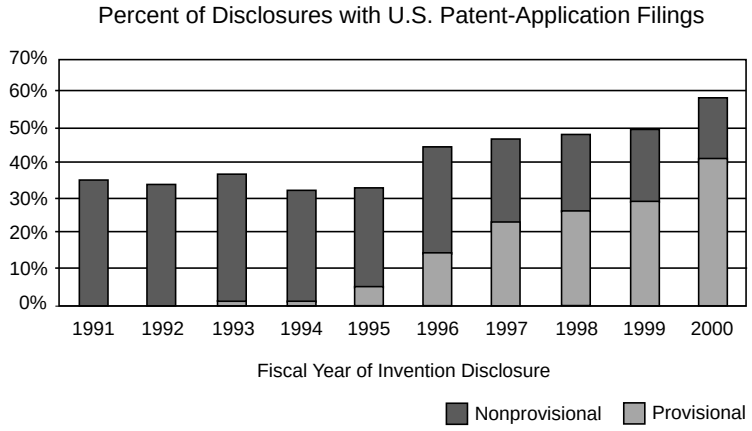

Figure 1

At-risk patent applications were filed on 1,055 invention disclosures between fiscal years 1991 and 2000. Figure 2 illustrates the increasing trend in at-risk filings at UC on invention disclosures from fiscal years 1991 through 2000. Not-at-risk filings remained fairly stable at 20 percent for each fiscal year's invention disclosures, while at-risk filings have increased dramatically from roughly 15 percent on invention disclosures in fiscal 1991 to almost 40 percent in fiscal 2000. A significant portion of this increase can be attributed to the introduction of lower-cost provisional patent-application filings.

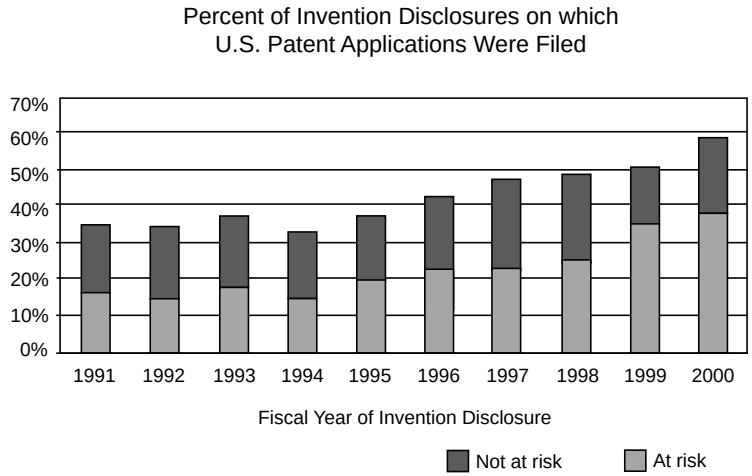

Figure 2

As of September 2001, 31 percent, or 330, of the 1,055 invention disclosures that formed the basis of at-risk patent-application filings could be deemed an agreement success. Revenue- or reimbursement-generating agreements were executed for these 330 technologies. Figure 3 depicts the year-by-year percent agreement success of the at-risk technologies. For invention disclosures received from fiscal 1991 through fiscal 1995, there is an agreement-success rate of roughly 40 percent; this success rate then declined to roughly 20 percent. (In fiscal 1994, there were significantly fewer disclosures made, and the success rate was more than 60 percent, apparently a result of a management change within OTT).[6]

As the technologies that have been disclosed more recently are permitted to mature, UC hopefully will see an increase in success into the neighborhood of at least 40 percent for all years. The hoped-for success rate of roughly 40 percent is a significant portion of the total at-risk filings and should be enough to justify the initial risk.

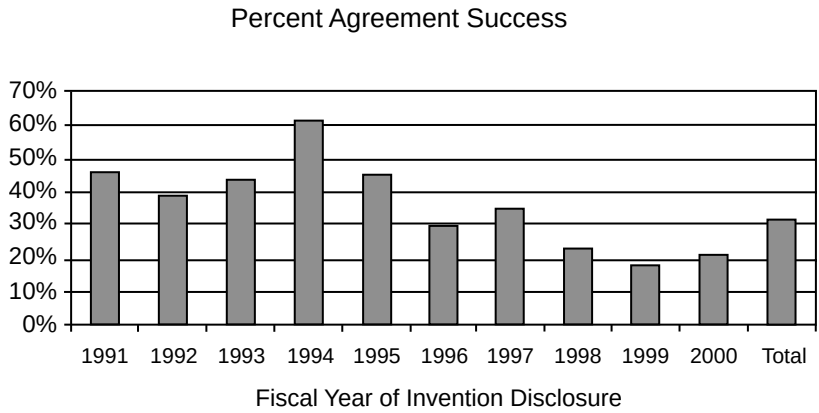

Figure 3

It is interesting to note that, of the 330 invention disclosures that eventually formed the basis of a contractual agreement, only 140, or roughly 13 percent of the original 1,055, had a positive return and could be considered an income success.[7]

Figure 4 illustrates the distribution of these 140 invention disclosures by the net income eventually generated. Each point on the chart indicates an individual invention disclosure. As depicted in Figure 4, 116 of the invention disclosures with positive income earned less than $100,000, and only three earned more than $1 million. Nine hundred and fifteen of the at-risk invention disclosures, or 87 percent, had zero or negative net income.

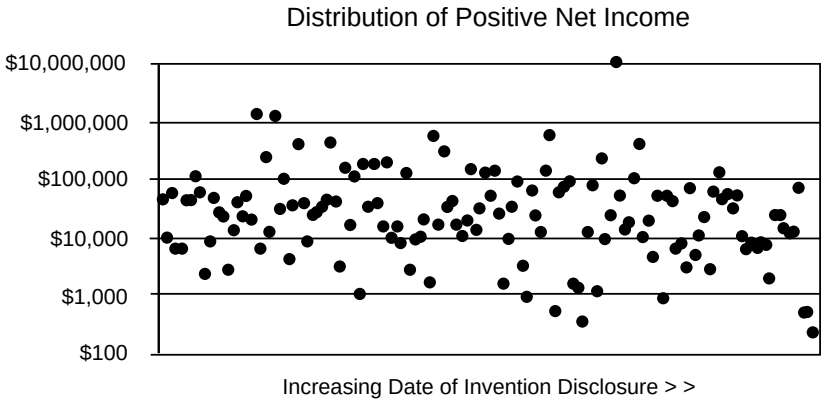

Figure 4

The total external cost to UC (those payments made to outside entities, such as patent counsel) on the 1,055 at-risk invention disclosures was $29.2 million, and the total income was $35.8 million, for a net income of $6.6 million.[8] The external cost that was risked, that is, was expended before an agreement was executed, was roughly $14 million.[9] Using the $14 million that was risked as a base, and the net income of $6.6 million, leads to a 47 percent return. To put this in the context of more traditional investments, if one-tenth of the $14 million were instead invested in a bank earning 6 percent each year, roughly the same return would be acheived.[10] For such a high-risk endeavor, the return is rather low, and, if operating costs were included in the analysis, it would be even lower. An optimistic view suggests that this picture will change with time as these inventions mature and hopefully produce a higher rate of success and return.

If the past can be used as an indicator of future success, the prior ten years of invention disclosures from fiscal 1981 to 1990 may help predict how the fiscal 1991 to 2000 disclosures will fare. For the earlier ten-year period, there were 3,072 invention disclosures made to OTT, 764 of which had a first patent application filed at risk. An agreement success was achieved with 313, or 41 percent, of the at-risk filings, a result that is consistent with an analysis of Figure 3.

The net income on these invention disclosures was an impressive $217 million, and the amount risked before any agreements were executed was $8.4 million, for a return of more than 2,500 percent.[11] Annualizing these

financial data, as earlier in this paper, indicates that a 21 percent yearly return was achieved. Positive income was generated on 196, or 26 percent, of the at-risk filings. Comparing this to the fiscal 1991 to 2000 time period shows a dramatic improvement with time: three-and-a-half times the return (21 percent vs. 6 percent) and twice the income-success rate (26 percent vs. 13 percent). It is reasonable to expect a significant increase on the income side for the fiscal 1991 to 2000 invention disclosures.

Even if the fiscal 1991 to 2000 time period is as successful as the prior decade, roughly three out of five at-risk patent applications will not achieve an agreement success, and three out of four will not achieve an income success. The distinction between agreement success and income success leads to a question of priorities. As a nonprofit institution, a university may choose to be somewhat liberal with at-risk filings to ensure that the public-benefit mission is met by getting technologies into use, with agreements as the delivery vehicle. At UC, for the fiscal 1991 to 2000 invention disclosures, 330 agreements were executed, thus bringing a significant number of technologies into the hands of companies and helping to nucleate several start-ups. Ideally, any steps to improve the success rate would not reduce the number of patent applications filed on any technologies that resulted in those agreements, still leaving roughly 60 percent of the invention disclosures available for elimination by the technology transfer office. On the income side, it would be possible to more significantly reduce the number of patent applications filed and still retain the income successes. For fiscal 1981 to 1990, 74 percent of the invention disclosures did not have a positive net income, and 84 percent of the $217 million netted on all the invention disclosures could be captured with only the top five earners (92 percent with the top ten).

Next Steps

How to improve the success rate of at-risk patent-application filings is very much a function of the specific goals of an office and the aims of the institution as a whole. What is the mission? What is the relative importance of an agreement success vs. an income success? What is the level of risk tolerance? How large an invention portfolio can be handled with the personnel available—or the personnel that can be made available—to the technology transfer office?

Regardless of the specific operating decisions of an office, there are many ways to improve the bottom line, and most do not run the risk of eliminating potentially successful technologies.

I. Increase income:

- Improve on the marketing and promotion of technologies.
- Be creative and flexible in drafting contractual agreements.
- Ensure that resources are available to support the technology from a marketing and licensing perspective before deciding to file an at-risk patent application.
- When there is an agreement success, require that the company set aside money for patent costs in advance if its future is questionable or there is the potential for disputes.
- Ask for more money up front, especially in high-risk areas where the chances of a product getting to market are low.
- Set up procedures and timelines for postagreement management to ensure diligence terms are met and payments are made in a timely fashion.

II. Reduce costs:

- Improve the initial process of selecting inventions for which patent protection will be sought using clearly defined goals.
- Establish a review board of experts, such as faculty members, who are willing to review invention disclosures in their area of expertise and provide advice regarding the technology's potential for success.
- Define the level of risk tolerance in financial terms for each invention disclosure to be pursued.
- Delay filing patent applications when possible. If it is determined that foreign patent rights are not needed, wait until a year after publication to file (assuming there are no reasons to file a patent application sooner, such as prior-art concerns or the need for a patent to issue quickly).
- Set milestones for the further development of the invention where necessary and abandon patent applications if the milestones are not met.

- Ask for cost estimates from outside attorneys and enforce them. If attorney fees are high, negotiate for a discount.
- Use internal resources, such as inventors, whenever possible to reduce outside attorney costs in drafting patent applications.

III. Transfer costs:

- Include a request for additional funds to support patent-application filings in research grant applications.
- Allow the inventors to support the cost of patent-application filings in exchange for a higher share of licensing income, as is done at the University of Washington.[12] This also increases the motivation of inventors in helping with the marketing process.

Conclusions

At-risk patent-application filings are a difficult but necessary part of the university technology transfer process. The success of an at-risk patent-application filing may be evaluated from the standpoint of both agreements and income. At UC, roughly two out of five at-risk patent applications are expected to generate an agreement, while only one out of four is expected to generate positive net income. In the past, the majority of income has been generated by a few high-earning inventions. Steps can be taken to reduce both the cost and risk of the at-risk filing process while meeting the public-benefit mission. One of the most difficult steps is improving the process of selecting which technologies are worthy of patent protection. As outlined in the introduction, universities are in a difficult position when making these decisions. It would be ideal to have some easily obtainable information available at the time a patent-application-filing decision needs to be made that could be used as an indicator of future success. Some areas, such as the level of funding dollars awarded to the research project that led to the invention, the inventor's past technology successes and the willingness of companies to sign secrecy agreements to view the details of an invention, may provide this insight. Future investigations will be directed to exploring these potential indicators.

Acknowledgement: The author gratefully acknowledges the help of Gabriel Beccar-Varela of the University of California, Office of Technology Transfer, in gathering information from the UC database.

Notes

1 In most instances in this paper, *university* can be treated to encompass other types of nonprofit research institutions.

2 In some cases, universities may wish to protect aspects of their business as a company would, such as their distance-learning programs.

3 For the purposes of this paper, at-risk invention disclosures are only those in which the first patent-application filing on an invention is made at risk. If the cost of a first patent-application filing is supported but those of a secondary filing are not, that invention is not considered to be at risk. In determining whether or not a first patent-application filing is at risk, the execution date of each agreement covering an invention was compared with the patent-application-filing authorization date. In cases where the authorization date was not available, the patent-application-filing date was used. If the authorization date or filing date was prior to the agreement execution date, then the patent-application filing was considered to be at risk. It is acknowledged that the execution date of an agreement is not a perfect measure of whether or not a technology is truly filed on at risk because it does not take into account the situational knowledge of those involved.

4 OTT oversees technology transfer for the UC system, which includes the Berkeley, Davis, Irvine, Los Angeles, Riverside, San Diego, San Francisco, Santa Barbara, and Santa Cruz campuses along with three national laboratories. For purposes of this paper, only the OTT partition of the UC database was analyzed. Currently, the OTT partition does not include certain invention disclosures from the Berkeley, Irvine, San Diego, and San Francisco campuses or the national laboratories.

5 The UC fiscal year runs from July 1 to June 30.

6 Based on discussions with employees at OTT who were present during fiscal 1994, the management changes led to a more cautious approach.

7 Financial data for invention disclosures from fiscal 1991 to 2000 were collected on May 10, 2002.

[8] Income includes reimbursements for patent costs, fees, royalties, and other payments received in association with an agreement.

[9] The amount risked includes only the external costs (generally those for outside patent counsel) prior to the execution date for invention disclosures with an agreement and all the external costs for those invention disclosures without an agreement.

[10] For a more accurate assessment, the timing of expenses and reimbursement should be taken into account.

[11] Financial data for invention disclosures from fiscal 1981 to 1990 was collected on May 17, 2002.

[12] For additional details, see the University of Washington Office of Technology Licensing Web site at http://depts.washington.edu/otl/otlrole.html.

Comparative Study of Technology Transfer Practices in Europe and the United States

Veronica de Juan

Abstract

This paper aims to provide a comparative study of technology transfer practices in the European Union, with special emphasis on Spain, and with comparisons to practices in the United States.

In the member states of the European Union, hundreds of policy measures and support schemes for innovation have been implemented or are under discussion. In particular, there are two aspects of innovation that are being specifically developed by each country because of their relevance for the global economy: industry-science relationships and protection of intellectual property rights. The first goal of this study is to present an overview of the regulatory evolution and the current legal status in the European Union with regard to these key aspects.

In the United States, the transfer of the results of academic research for commercial application and the exploitation of intellectual property rights continue to record impressive results. To identify the key factors to such success, some of the differentiating characteristics of the U.S. regulatory framework are presented.

The final goal of the present study is to identify the crucial steps to be taken in the next stage of global interaction between science and industry and international patent systems so as to manage a worldwide network of innovation that will encourage a growing competitive economy.

Framework of the Study

This paper provides a comparative study of technology transfer practices in the European Union (EU), with special emphasis on Spain and with com-

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parisons to the United States, to establish recommendations for a worldwide network of innovation.

In the member states of the EU, hundreds of policy measures and support mechanisms for innovation have been implemented or are under discussion. The diversity of these measures and schemes reflects the diversity of each member state's infrastructure, cultural preferences, and political priorities.

Despite this diversity in the EU, there are two elements that affect innovation that are being specifically developed by each country because of their relevance for the global economy: industry-science relationships and intellectual property rights.

Firstly, cooperation between firms and universities or research institutes is still not sufficiently developed in the majority of member states. On average, only 13%[1] of firms cooperate with European research and development and innovation infrastructures. Hence, it is important to pursue and strengthen the interactions among research institutes, the higher education sector, and industry because the largest part of the EU research effort is performed in the research institutes and educational institutions. This initiative should include promotion of technology transfer to industry and spinoffs from public research organizations to enhance the impact of their research on innovation and economic growth.

Secondly, it is crucial to protect the fruits of innovation by protecting intellectual property rights, especially by patents. In the EU, the patent system has been underused because of the lack of harmonization of the legislation for patent protection. A harmonization of the laws of the states and an increase in awareness that patents are essential in an innovative and competitive economy should stimulate innovation and remove barriers to trade.

In the United States, the transfer of the results of academic research for commercial application and the exploitation of intellectual property rights continue to record impressive results. An examination of the American processes for technology transfer is likely to provide useful models for the EU.

The next stage toward facilitating global interaction between research institutions and industry and development of an international patent system should be to manage a worldwide network of innovation, which would encourage a growing, competitive economy.

The structure of this paper is based on the framework represented in Diagram 1 and is intended to provide a systematic and analytical approach to this survey of innovation in Europe, Spain, and the United States.

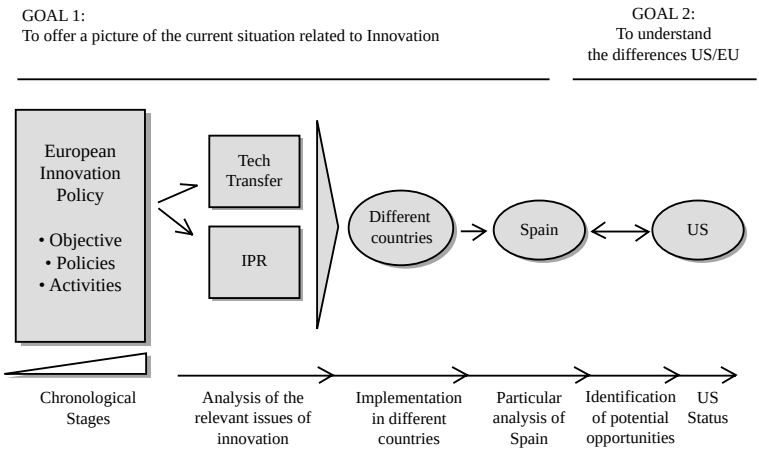


Diagram 1

Chronological Stages and Principal Actions Adopted by the European Union in Research and Development and Innovation Policy

Since its constitution, the EU has established among its objectives research and technological development. In the Treaty Establishing the European Community, which was signed in Rome on March 25, 1957, and entered into force on January 1, 1958, research and technological development was mentioned in its Title XVIII.[2]

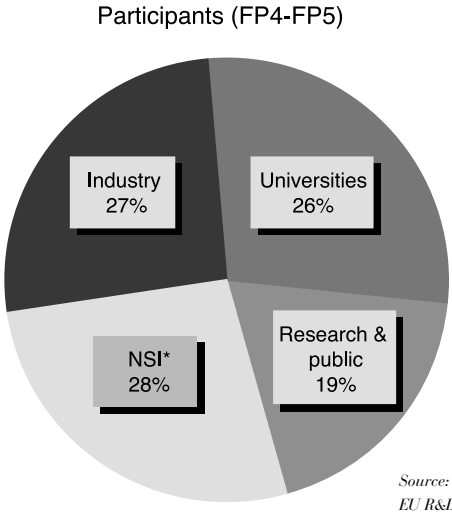
Article 163: "The community shall have the objective of strengthening the scientific and technological bases of community industry and encouraging it to become more competitive at the international level, while promoting all the research activities deemed necessary by virtue of other chapters of this treaty. … For this purpose, the community shall, throughout the community, encourage undertakings, including small- and medium-size undertakings, research centers, and universities in their research and technological development activities of high quality."

Article 166: "A multinational framework programme, setting out all the activities of the community, shall be adopted by the council…"

Thus, in accordance with the treaty, the community research and technological development policy addressed, as a matter of priority, problems of society, improvement of the international competitiveness of community industry, sustainable development, job creation, the quality of life and globalization of knowledge, aid to the development and implementation of the community's policies, and the role of the community in the world as a focal point of scientific and technological excellence.

Despite the fact that the community began providing support for research activities in the late 1950s, the first real breakthrough came in the 1980s with the establishment of the first generation of multiannual Framework Programmes, funding programs that reflect the scientific and technological priorities of a particular time, as well as the prevailing economic and political circumstances.

Since 1984, community research and development (R&D) activities have been strategically planned and coordinated under six multiannual Framework Programmes which have set out the areas that should be funded during the life of the programs. Up to now, more than 7,000 projects coming from a wide variety of sectors have been financed by the programs.



Source: R&D in Statistics in the EU R&D Frameworks Programmes
**National Statistic Institutions*

Exhibit 1

These have involved thousands of European companies, research centers, and universities. Exhibit 1 shows the proportional participation of the different parties.

The Fifth Framework Programme set out the priorities for the EU's research and technological development activities for the period 1998-2002,[3] providing a budget of 13,700 million euros.[4] It differed substantively from its predecessors due to combined technological, industrial, economic, social, and cultural aspects, because it placed special emphasis on the needs of small- and medium-size enterprises, promoting their effective participation in the EU[5] programs and their ability to benefit from them. Furthermore, the previous Framework Programme paid special attention to the dissemination and transfer of research results to innovation and to the training and mobility of researchers between universities and companies, thus encouraging the emergence of a new generation of enterprising researchers with innovative ideas.

Undoubtedly, the main purpose of the Fifth Framework Programme was the promotion of innovation, which was important to all its thematic activities (living resources, information society, competitive and sustainable growth, energy, environment, and sustainable development) to ensure exploitation and transfer of technologies.

Before the Fifth Framework Programme began, the first time that the EU delivered its concern to its members about Europe's innovation deficit was in the 1995 Green Paper of Innovation.[6] Subsequently, the EU considered it relevant to incorporate innovation in the Fifth Framework Programme, still under discussion.

Innovation was defined as "the renewal and enlargement of the range of products and services and the associated markets; the establishment of new methods of production, supply, and distribution; the introduction of changes in management, work organization, and the working conditions and skills of the work force."[7]

In addition, due to the importance that this issue had for the EU, the First Action Plan for Innovation in Europe[8] was launched independently of the multiannual framework programs, providing a common analytical and political framework by which to assess innovation in Europe. It adopted a systematical view of innovation that is now widely accepted in Europe.

Building upon the First Action Plan, the "Trend Chart on Innovation in Europe" was created, which is a practical tool for innovation policy-makers in Europe. It collects regular updates and analyzes information on innovation policies at national and EU levels. The chart focused on four main areas of innovation policy: the setting up and development of innovative businesses, the protection of intellectual property rights, financing innovation, and the transfer of technology between research institutions and industry.

The most recent strategy goal for European innovation policy was set out at the Lisbon European Council Summit that was held in March 2000. Its main objective was that the EU would become the most competitive and dynamic knowledge-based economy in the world.

Two important needs were identified and presented in the conclusions of the Lisbon European Council Summit with respect to innovation: (1) to extract the maximum benefit from the national and EU-level research effort for innovation, and (2) to create a friendly environment for creating and developing innovation-based businesses. The identification of these needs reflects, firstly, technological innovation's importance as the generator of new products, services, and processes and the specific obstacles to this kind of innovation, and, secondly, the need for innovation to reach the entire economic and social structure of society.

As a consequence of the Lisbon European Council's conclusions, the European Commission prepared a Communication about Innovation in a Knowledge-Driven Economy.[9] One of the objectives established by the commission in this communication was to "improve key interfaces in the innovation system." Traditionally, universities have focused their efforts on education and research.

However, according to this communication, universities should promote the dissemination of knowledge and technologies to industry, pursuing and strengthening their interaction with companies. Furthermore, public research organizations should provide spinoffs from themselves to industry to enhance the innovation impact of their research.

In the same way, the Lisbon European Council, as a part of its strategy for turning the EU into the most competitive and dynamic knowledge-driven economy in the world, implemented the first "European Innovation Scoreboard."

The first outline of the European Innovation Scoreboard was included in the Lisbon European Council's communication and was based on data

available at that time, creating a precedent for an annual European Innovation Scoreboard.

The 2001 European Innovation Scoreboard[10] measured the strengths and weaknesses in the capacity of innovation of each member state and of the EU as a whole. The scoreboard shows that all member states are improving, with some achieving development, but the EU as a whole still lags behind the United States and Japan.

The 2001 European Innovation Scoreboard uses 17 indicators to rate each member state's capacity for encouraging innovative business and improving competitiveness of their industry through innovation. (See Exhibit 2.)

The overall innovation development of the EU is improving according to the trends in the indicators. Countries such as Finland and Denmark, where development was already strong, are moving ahead. Greece and Spain are rapidly catching up with the EU average, although they come from a relatively low level.

Hence, by each indicator, the scoreboard provides many examples indicating that member states have made rapid progress in specific areas. The scoreboard also reveals countries that have underperformed. Data provided by the European Innovation Scoreboard show that the leading countries in innovation performance can be found among the member states.

The scoreboard has also identified two weaknesses: the lack of investment by business in research and development and a low level of high-tech patenting activity.

The EU has addressed both weaknesses in the Proposal of the Sixth Framework Programme (2002-06)[11] that was launched at the end of last year. The main purpose of the current program is the development of a more coherent research landscape in Europe through the creation of the European Research Area. (See Diagram 2.) The three main objectives of this new program are (1) to strengthen the technological capacity of small- and medium-sized enterprises by facilitating their access to the best research and technology, (2) to provide an international and global dimension to European research activities, and (3) to promote the mobility of researchers, with a view to the successful creation of the European Research Area.

Table B: Scoreboard 2001

No	Indicator	Yr[1]	Sc.[2]	EU	S	FIN	UK	DK	NL	IRL	D	F	A	B	L	E	I	GR	P	US	JP
1.1	‰ S&E grads/20-29 pop	99	1	10.4	9.7	10.4	**17.8**	*4.7*	*5.8*	**15.6**	8.6	**15.8**	*7.8*	*5.1*		9.6	*4.7*		*5.5*	*8.1*	11.2
1.2	% pop with 3rd education	00	1.2	21.2	**29.7**	**32.4**	**28.1**	**25.8**	25.0	22.2	23.8	21.6	*14.2*	**27.1**	18.3	21.8	*9.6*	*16.9*	*9.8*	**34.9**	**30.4**
1.3	Life-long learning	00	1	8.4	**21.6**	**19.6**	**21.0**	**20.8**	**15.6**	*5.2*	*5.2*	*2.8*	7.8	6.8	*4.8*	*4.9*	*5.2*	1.1	*3.3*		
1.4	% empl. h-tech manuf	99	1	7.8	8.3	7.2	7.6	6.4	*4.7*	7.3	**10.9**	7.2	6.6	7.2	*5.8*	*5.5*	7.6	*2.4*	*3.6*		
1.5	% empl. h-tech services	99	1	3.2	**4.8**	**4.3**	**4.2**	**4.5**	3.6	**4.0**	2.8	3.8	2.7	3.2	3.6	*2.1*	2.7	*1.5*	*1.2*		
2.1	Public exp. R&D / GDP	99	1	0.66	**0.86**	**0.95**	0.59	0.71	**0.87**	*0.35*	0.75	**0.80**	0.65	*0.50*		*0.43*	*0.48*	*0.38*	*0.40*	0.56	0.70
2.2	BERD / GDP	99	1	1.19	**2.85**	**2.14**	1.20	1.26	1.05	1.03	**1.63**	1.36	*0.84*	1.28		*0.47*	*0.56*	*0.13*	*0.14*	**1.98**	**2.18**
2.3a	EPO h-tech pats /pop	99	1.3	17.9	**22.9**	**80.4**	18.9	**21.5**	**35.8**	*13.3*	**29.3**	20.2	*9.8*	17.6	*9.2*	*2.5*	*4.8*	*0.5*	*0.4*	**29.5**	**27.4**
2.3b	USPTO h-tech pats /pop	98	1.4	11.1	**29.5**	**35.9**	**14.4**	**17.3**	**19.6**	*3.8*	**14.4**	13.3	*5.6*	12.8	*2.3*	*1.0*	*4.2*	*0.5*	*0.1*	**84.3**	**80.2**
3.1	% SMEs innov in-house	96	10	44.0	44.8	*27.4*	35.8	**59.0**	51.0	**62.2**	58.7	36.0	**59.1**	*29.4*	*24.3*	*21.6*	44.4	*20.1*	*21.8*		
3.2	% SMEs innov co-op	96	10	11.2	**27.5**	**19.9**	**15.7**	**37.4**	**13.8**	**23.2**	**14.7**	12.0	12.9	*8.9*	9.6	*7.0*	*4.7*	*6.5*	*4.5*		
3.3	% innov exp /total sales	96	10	3.7	**7.0**	4.3	3.2	**4.8**	3.8	3.3	3.9	3.9	3.5	*2.1*		*2.4*	*2.6*	*1.6*	*1.7*		
4.1	‰ vent capital / GDP	00	1.5	1.08	**2.04**	**1.38**	**2.58**	*0.64*	**1.62**	*0.65*	*0.68*	*0.74*	*0.11*	**1.65**		*0.36*	*0.41*	*0.04*	*0.01*		
4.2	% new capital / GDP	99	1.6	1.1	*0.5*	*0.3*	0.6	**4.5**	**5.6**	0.9	*0.6*	0.6	*0.3*	0.9	*0.6*	**4.4**	*0.1*	**1.5**		**1.9**	
4.3	% new-to-markt products	96	10	6.5	6.9	7.3	6.7	*5.1*	6.9	**8.4**	7.1	**7.9**	5.6	*2.6*		**9.8**	**13.5**		7.2		
4.4	% home internet access	00	7.8	28	**54**	**44**	**41**	**52**	**55**	**36**	27	*19*	**38**	29	**36**	*16*	24	*12*	*18*	**47**	**28**
4.5	% ICT markets / GDP	00	9	6.0	**7.4**	6.0	6.5	6.1	6.6	*4.8*	5.7	6.1	5.8	5.6		6.3	5.3	6.0	6.6	5.9	*4.3*
4.6	% h-tech value added	97	1	8.2	**18.8**	**12.5**	**11.8**	7.9	7.5	**20.5**	*3.7*	9.7				*5.0*	*5.9*			**25.8**	**13.8**
	Summary Index				*6.5*	*4.7*	*4.4*	*3.5*	*2.9*	*1.2*	*0.6*	*-0.6*	*-2.5*	*-2.5*	*-4.4*	*-5.9*	*-5.9*	*-7.9*	*-8.7*	*5.6*	*3.8*

Most recent data available.

Data sources: 1= Eurostat, 2 = OECD *Education at a Glance*, 3 = EPO, 4 = USPTO, 5 = EVCA, 6 = FIBV, 7 = Eurobarometer, 8 = US National Telecoms and Information Administration, 9 = EITO, 10 = Community Innovation Survey.

Indicators (except for the summary index) that are more than 20% above or below the EU average are highlighted in **bold** or *italics* respectively.

Scoreboard 2001

(Commission Workpaper, 2001 Innovation Scoreboard. Brussels, 14-9-2001 SEC(2001) 1414
Indicators (except for the summary index) that are more than 20% above or below the EU average are highlighted in bold or italics respectively.

Exhibit 2

Diagram 2

Source: http://europa.eu.int/comm/research/era/index_en.html

Analysis of Two Important Issues Related to Innovation

There are two important issues related to innovation that should be analyzed in depth: the interface between research and industry and protection of intellectual property rights.[12]

Interface between Research and Industry

EU countries are taking into account activities that promote the dissemination of knowledge among research institutions, universities, and companies. These activities include direct and indirect measures. Direct measures include encouraging the development of closer interfaces between research institutes and companies, facilitating university startup companies, cofinancing academic-industrial cooperation, and stimulating the dialogue between the producers and the users of the technology through forums, technology clubs, and the like.

Indirect measures include facilitating the creation and growth of technology parks; enacting regulations to achieve greater interaction among research institutes, universities, and businesses; and making intellectual property rights easier to understand. These kinds of activities are being developed at the EU level as well as at the national level.

European Level

In 1995, the European Commission established the Innovation Relay Center (IRC), which consisted of 68 Innovation Relay Centers throughout Europe, including the EU, Bulgaria, Czech Republic, Cyprus, Estonia, Hungary, Iceland, Israel, Latvia, Lithuania, Norway, Poland, Romania, Slovak Republic, Slovenia and Switzerland.

The mission of these centers is to facilitate the transfer of innovation technologies to and from European companies or research departments. Due to the importance of innovation in Europe, the IRC network has become a leading European network mainly for the promotion of technology partnerships and transfer between small- and medium-sized enterprises. It also is available to large companies, research institutes, universities, technology centers, and innovation agencies.

The role of each IRC is to enhance the ability of its clients to perform technology transfer, to audit their technological needs, to find suitable technologies and/or partners, and to assist them in negotiation processes by advising them on intellectual property rights or innovation financing.

Over the past five years, the IRCs have assisted in more than 5,000 technology transfer negotiations and have helped 65,000 client companies to meet their technology needs and to exploit their research results. Thus the IRCs are fulfilling their main purpose and creating a pan-European platform to stimulate transnational technology transfer and promote innovation services.

Success stories are actual transnational technology transfer transactions that would not have happened were it not for the IRC network.

A unique double technology transfer agreement was recently signed between two enterprises as a result of the efforts of Greek and Swiss IRCs. The agreement covers innovative high-temperature inspection equipment and systems for optimizing transient operations, such as startup or shutdown, in complex industrial processes. Considerable interest in the technologies has already been shown by Greek power generators and the agreement is likely to be extended to other technologies developed by the Swiss company.

A Polish company created a new production method for use in the manufacture of polymer/glass fiber pipes used in sewage systems. They approached the West Poland IRC and Sicilia e Calabria in Italy and found

the ideal partner to help the company capitalize on this innovative technology. Continuing IRC support has enabled the two small companies to take the new technique to the brink of full commercialization.

Keronite is an extremely hard ceramic coating for metal surfaces that confers resistance to wear, high temperatures, and corrosion. The company developing the Keronite process is licensing its use to partners in the metal-coating industry. IRCs in the UK and the Netherlands have been instrumental in bringing the technology developers and users together.

A final illustrative example of the success of the IRCs includes two IRCs that helped a German printing firm to benefit from software and process methodology developed by a Greek informatics company. With their assistance, the German company re-engineered and digitalized its business—helping it to work faster, smarter, and cheaper.

National Level

Several countries have made it a high priority to improve their policy measures for the transfer of research results between the public and private sectors. In Germany, efforts are focused on increasing the speed and efficiency of transferring existing knowledge, while in Finland, the key focus is on close cooperation among companies, research organizations, and universities.

In Germany, there are a large number of promotional programs aimed at increasing research cooperation between enterprises and the public science field. Some of the most important programs are EXIST (startups from colleges and universities) and INNoNet (promotes cooperative R&D projects among at least six research organizations and firms).

In Finland, close cooperation among companies, research organizations, and universities is often considered a strength of the national system of innovation. The most important current activities are the national technology programs of the National Technology Agency (TEKES).

Other countries have built specific joint research centers. For instance, in Austria, the K-plus initiative created collaborative research establishments between universities and companies to carry out long-term precompetitive research.

In countries such as Portugal, Greece, and Spain, the basic infrastructure in research, as well as the interactions between research providers and industry, need to be strengthened and improved. Greece launched a new

measure, Research Centers Development and Services Providing Projects with the User Participation, AKMON, in 2001 to improve the research infrastructure and support, both for the expansion of research activities already implemented and for the establishment of new ones.

Many countries are improving the expansion and support of university-based high-technology spinoffs. A specific mechanism for this policy activity concerns the creation of support infrastructure such as research and development incubators.

In Belgium, such incubators are developed in partnership with universities and public research centers, whereas, in France, there are 31 projects that involve higher education institutions, public agencies, and capital investors.

As students and researchers move from universities and public research centers to industry, the interface between science and industry is also improved. For example, in Portugal, with the financial support of the Operational Programme, Science, Technology, and Innovation (POCTI), a new program was launched to encourage the employment of master's degree and doctorate recipients in different companies.

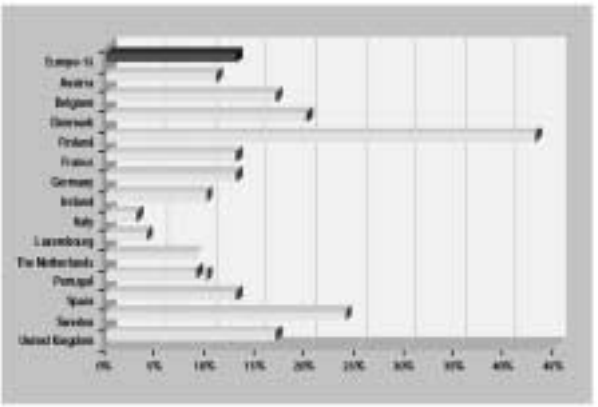
These examples have shown the different initiatives adopted in Europe to achieve a successful interface between science and industry. Each country has decided to launch programs with the purpose of improving the relationship between higher education institutions and companies, because countries appreciate their value to the country's growth. (See Exhibits 3 and 4.)

Intellectual Property Rights

The increase of new technologies has resulted in the protection of intellectual property rights (IPR), especially patents, becoming an important element to stimulate innovation and to provide a competitive advantage in knowledge-driven markets.

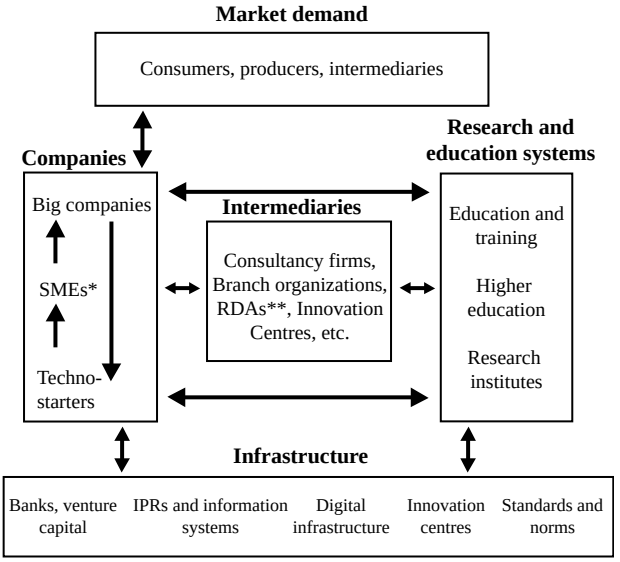
European institutions and several countries have considered the patent as an important instrument to stimulate innovation. The assumption is that strengthening the legal systems related to patents will lead to greater innovation activity and consequent economic benefits. The general idea is that, at the European level as well as at the national level, patents are very important to promote innovation, creativity, and employment, even though the patent process is not handled in the same way in each country.

PERCENTAGE OF FIRMS CO-OPERATING WITH UNIVERSITIES AND RESEARCH INSTITUTES (EUROSTAT 2000)



Source: Towards a European Research Area. Science, Technology and Innovation. Key figures 2000. Eurostat

Exhibit 3



* Small- and medium-sized enterprises
** Regional development agencies

Source: Technopolis 2000, elaborated by EIM, 2001

Exhibit 4
A Conceptual Framework of a National Innovation System

European Level[13]

At the European level, two problems are being resolved by the European institutions. On the one hand, the European patent system is underused, and on the other hand, the nonpatentability of software-related inventions is distorting competition among the EU, Japan, and the United States.

Regarding the first problem, the European patent system is underused because, although there is a single patent-application process managed by the European Patent Office (EPO), an EU patent has not been created yet. The EPO offers a single application and procedure when a patent applicant wishes to file in different countries. This application form may need to be translated into the official language of each member state to be legally valid in each territory. Moreover, the cost of translation means that it is more expensive to patent an invention in the EU than in the United States or Japan. In addition, in cases of patent disputes, a national court would resolve the claim. The problem is that there are at least 15 different procedural rules throughout the member states with the risk of different outcomes.

All of these problems have been recognized by the EU, which proposed the creation of a Community Patent in 2000,[14] giving the patent applicant the option of obtaining a single patent that will be legally valid throughout the EU. This proposal continues to be under discussion.

The second problem is the situation regarding inventions involving software. Recently, computer programs have had a significant impact on the global economy due to the emerging importance of electronic commerce. However, even though software-related programs play a significant role in the new economy, only some national patent systems permit their protection. Thus, the EU is losing competitive advantage in the software industry because the most important competitors (Japan and the United States) do not have such restrictions. Yet, thousands of patents for technical inventions using a computer program have been granted by national patent offices and by the EPO.

Harmonization of the national patent law on this issue is, therefore, necessary. This should provide greater transparency for European companies, especially for small- and medium-sized enterprises. It also should improve the competitive position of the European software industry relative to its major trading competitors.

In this context, the Proposal for a Directive of the European Parliament and of the Council on the Patentability of Computer-Implemented Inventions[15] was promulgated. This proposal aims to harmonize legislation among the member states and raise a patent's transparency; this document is still under discussion in the European institutions.

National Level

At the national level, member states have begun to carry out three kinds of measures. Firstly, national patent offices are playing an important role through disseminating information about and promoting the importance of patents. Secondly, countries are encouraging public-sector research institutions to patent their inventions to commercialize them. And thirdly, countries are improving the structure of IPR ownership within centers of higher education.

With respect to the first measure, some member states are implementing their new national patent office and/or its tasks, while other countries already have created their national patent office and are in the process of broadening its functions and activities.

For example, Italy is implementing a New Agency for Industrial Property. In Portugal, the National Institute for Industrial Property has decided to be more flexible and active through the implementation of the Industrial Property Use Incentive System.

Germany[16] has a well-established national patent office and has implemented various promotional programs to strengthen IPR-owned by industry, universities, and public research organizations administered by the Fraunhofer Patent Office of German Research. These programs help individual inventors, small enterprises, and researchers from public research centers apply for financial benefits for patenting activities.

Furthermore, in Germany, there is a huge network of patent information centers, whose main purpose is to offer small- and medium-sized enterprises access to scientific and technological information essential for innovation management in business. Examples are access to original documents and support of the companies' own information search capabilities, copies of patent documents, and free consultation with patent agents.

All of these activities carried out in Germany suggest that the number of patents registered is much higher than in countries that do not have

well-established national patent offices. Proactive efforts by the national governments and the national patent offices are likely to achieve an increase in the number of patents registered in those member states that are lagging behind, for example, Portugal and Italy. (See Exhibit 5.)

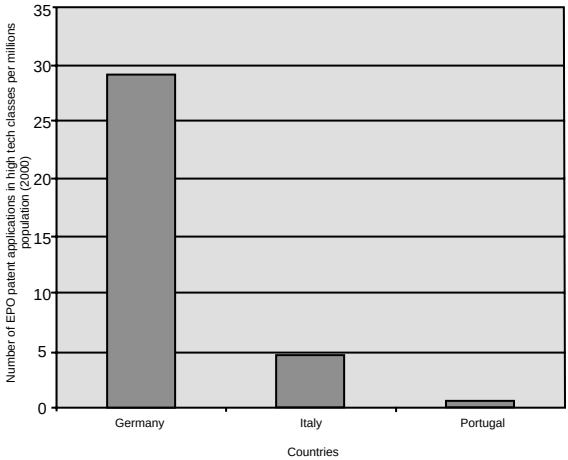


Exhibit 5

Comparison of Number of EPO Patents Registered in Different EU Countries

Source: Innovation Scoreboard, table 4, annexes

In line with the second measure, the member states should disseminate information about patents. Indeed, companies could have access to information about patents granted, in the majority of cases, by the national patent offices.

Some member states have already implemented many tools for the dissemination and publication of information on patenting within, as well as outside of, their respective countries, whereas other countries are still designing these tools.

The United Kingdom is one of the member states that has already implemented several tools, such as using the Internet through its national patent office or through independent Web sites. The United Kingdom Patent Office has developed an intellectual property Web site offering access to specific queries, frequently asked questions, and the latest news relating to IPR.[17] The "Guide to Strategic Decision-Making in Universities" currently appears in the UK Web site.

Germany has already implemented the program AkPat,[18] an Internet platform that contains all the competencies in the field of patenting available at centers of higher education with experience in patents, courses of study on patenting, patent-related training, and the various services provided by intermediaries.

Other countries are defining and implementing Web sites to disseminate or promote patents. Belgium provides an example of how these countries are adopting different initiatives. Belgium has identified a list of proposals to improve the protection and the exploitation of IPR through the implementation of online patent filing.

The common purpose of member states is to improve innovation through the use of patents even when the stages of development are at different levels.

Finally, member states are embracing decisions to retain ownership of IPR in universities and centers of higher education. Thus, in Germany, a decision has been made to change ownership of intellectual property rights within centers of higher education by removing exclusive ownership rights from professors and transferring those rights to the centers of higher education. Nevertheless, researchers will retain rights to receive two-thirds of any licensing or other income accruing therefrom.

By contrast, in the United Kingdom, several proposals have been published to provide better frameworks for widening IPR ownership and management to enable civil-service scientists to benefit from helping to exploit their work commercially (e.g. through ownership of equity in spinoff companies).

The concerns regarding ownership of IPR imply that, up to now, there has been no policy in which the IPR were considered, especially in universities and centers of higher education, where inventions created by researchers only occasionally were protected by patents.

Analysis of Innovation in Spain

Overview

Two years ago, one of the most important changes accomplished in the Spanish science and technology policy was the reinforcement and concentration of science and technology issues in a single department: the Ministry

of Science and Technology. This concentrates the supervision of all research, science, technology, and innovation, as well as the integration of research, development, and innovation into a single government department.[19]

This new political approach provided evidence of a commitment by the government to foster the integration of science and technology with industry because technology transfer and innovation still have to be addressed in such enterprises in Spain.

The measures carried out by the Ministry of Science and Technology are split into innovation action plan areas and subthemes. Overall, such initiatives are managed by the Fourth Action Plan for Scientific, Research, Technological Development, and Innovation for the period 2000-03 (IV NP). This plan seeks to strengthen the process of technological innovation in the entrepreneurial sector.

Two issues must be discussed in depth to illustrate how the Spanish government intends to promote innovation. The first issue is cooperation among research institutes, universities, and companies, and the second is dissemination of information about the patent system.

With regard to the first issue, promoting interactions between research providers and companies is one of the most important missions of the government. Therefore, the IV NP includes different subthemes to facilitate cooperation among the parties involved.

One of the subthemes launched in 2000 was designed to promote cooperative research and development activities between universities and enterprises through the creation of consortia that had to be formed by researchers and entrepreneurs.

In 2001, one of the different subthemes implemented was the PIIC scheme: concerted industrial research projects. This project is administered by the Center for Industrial Technological Development, an agency of the Ministry of Science and Technology. The PIIC aims to finance precompetitive research initiatives with high technical risk, the results of which are not immediately marketable. Projects must be presented by industrial companies and developed in collaboration with universities, research centers, and/or technology centers.

Finally, technology transfer offices, located mostly in universities, have long existed to promote interfaces between universities and public research establishments and their environments. In this context, the PROFIT pro-

gram (another subtheme) was launched to intensify cooperation between firms and universities or research institutes and technological organizations.

Toward this end, the University Act was enacted at the end of 2001, indicating further related developments. Specifically, the new act envisions the creation of centers that combine public or private research organizations and companies. Also, the act encourages interaction between universities and the private sector through the creation of technological companies where researchers and entrepreneurs can work together.

In considering the second issue, it is necessary to describe an important initiative to disseminate information related to research, development, and innovation activities, as well as to expand the IPR culture in all sectors of the Spanish industrial scene, carried out by the Spanish Patent and Trademark Office (OEPM).

This office has established a Forum for Innovation and Patents for informal discussions, consultations, and gathering opinions about patents and innovations. In November 2000, this forum approved a program to improve, disseminate, and increase information regarding the use of the patent system. Its measures include the broad dissemination of information about the patent system among business schools and universities, as well as efforts to increase awareness among small- and medium-sized enterprises about the patent system. The program also emphasizes the importance of patents as technological information documents and aims to reduce the time of a patent's evaluation by OEPM, through specialized training of judges in the patent system. Finally, it promotes free services on the Internet provided by OEPM and the implementation of a national and international patent information database.

The main idea resulting from the analysis of the Spanish system is the identification of the need to improve the patent culture in Spanish society, especially in the small- and medium-sized enterprises and universities, to achieve a competitive position in the worldwide knowledge-driven economy.

Role Played by Technology Transfer Offices in Universities

Technology transfer offices (OTRI) play an important role in the technology transfer process by supporting cooperation between universities and industry, through their approach to commercialization of technology. Specifically, there are three activities that should be discussed further in

detail: assistance to researchers with their search for funds, protection of inventions, and publication and commercialization of the results.[20]

Regarding the first activity, funds for various projects come from public institutions or companies. Public funds come from three different sources: (1) the EU, through its multiannual Framework Programmes; (2) Spain, through its national plans; and (3) the Autonomous Communities, through their regional plans. In these cases, researchers must present a proposal to the technology transfer office, which will carry out a search to identify the appropriate source of funds for the projects. (See Exhibit 6.)

On the other hand, companies provide funds to universities through research agreements. In some cases, the initiative comes from the researchers themselves, while in other cases, it comes from companies. Technology transfer offices improve the transfer of knowledge by facilitating the relationships between universities and industry.

The next activity of technology transfer offices consists of managing the protection of inventions through patents issued by the Spanish Patent and Trademark Office to maintain their commercial value in the marketplace when the ownership of the invention remains in the university.

In line with the above-mentioned trend, the Spanish Patent Law, in its article number 20, sets forth that the university shall own the inventions developed by researchers except when the parties have set forth in the sponsored research agreement that the company shall be the owner. Frequently, companies become the owners of the inventions to further develop and commercialize them and to provide funds in subsequent, follow-on projects. Up to now, universities have considered this trend as a great incentive for companies to fund research projects. Nevertheless, this is not a general practice, and each university has its own method to achieve a closer partnership between science and industry.

In other words, the ownership of the inventions will belong to universities when the projects have been funded by public institutions or by companies that have not retained the ownership under the sponsored research agreements.

The last activity of the technology transfer office, the publication and commercialization of the inventions, is accomplished by the technology transfer offices through contacts established between researchers and companies. Indeed, technology transfer offices operate as facilitators on research

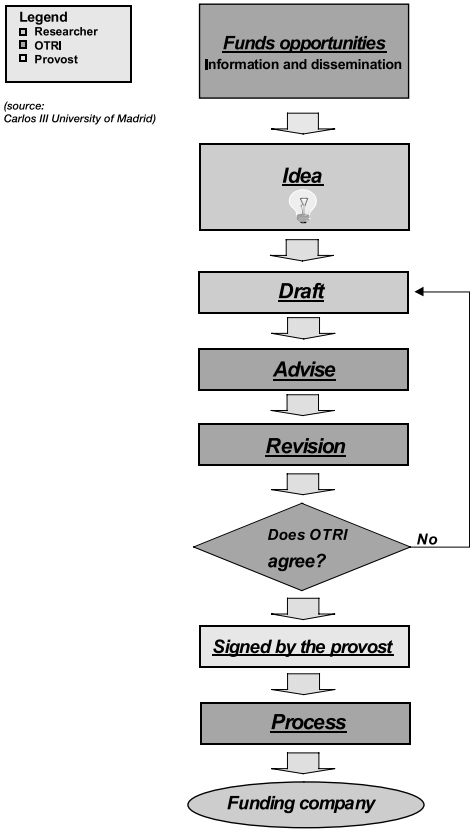


Exhibit 6

issues. At this time, licensing activity does not make up the main activity of these offices due to the fact that universities own few patents and little income is earned from licensing activities.

Analysis of Technology Transfer as Driver of Innovation in the United States

In the United States, the mechanism for effective technology transfer—the movement of ideas, tools, and people among institutions of higher education, the commercial sector, and the public—is found in the federal legislation known as the Bayh-Dole Act.

The Bayh-Dole Act is the culmination of a lengthy debate that ended late in 1980. Until that time, the federal government was the owner of federally

funded inventions and offered nonexclusive licenses to anyone who wanted to practice the inventions. Companies thus did not have an incentive to develop such federally funded inventions because their competitors could also acquire a license and could then manufacture and sell the same products.[21]

The Bayh-Dole Act encourages the utilization of inventions produced with federal funding and promotes the participation of universities and small business in enhancing the economy by increasing the flow of knowledge from universities to industry. The act permits recipients of federal funds to retain title to inventions created with those funds, subject to a nonexclusive right retained by the federal government to practice the invention for governmental purposes. The act also encourages universities to license inventions to industry and permits the granting of exclusive licenses. In other words, IPR created with federal funding belongs to the university or the research institution and not to the inventor, although the inventor is entitled to receive a share of the income earned by such an invention.

The implementation of the Bayh-Dole Act resulted in a substantial increase in technology transfer from universities to industry and, ultimately, to the public, as products became available in the marketplace. Examples range from biotechnology to the laser industry. Moreover, as a result of the Bayh-Dole Act, technology transfer involving federally funded inventions enhanced the economy by creating new companies and thousands of jobs.[22] According to the Association of University Technology Managers Licensing Survey FY 2000, 221 universities and colleges are engaged in technology transfer activities. These offices, whose structure varies among universities and nonprofit institutions, typically seek to preserve, protect, market, and license IPR created by employees of the entities whom they serve. Many of these offices did not exist prior to the enactment of the Bayh-Dole Act, which requires recipients of federal funds to undertake the transfer of research results developed with federal funds to the private sector for commercial applications for public use and benefit.

In general, university policies require that research results generated at the university must be publishable and that any resulting IPR from research projects developed by university employees with university resources belong to the university.

In this context, whereas industrial sponsors are granted an exclusive or nonexclusive option to license patents arising from research they

sponsor and to commercialize inventions resulting from such research, the federal government is granted a nonexclusive license to patents from federally funded research. If joint industrial and federal funding is involved, the company's rights are subject to the university's obligations to the federal government.

Universities typically retain title to inventions from research funded by the federal government as well as by companies. By retaining title to IPR, universities are in a position to require licensees to make diligent efforts toward commercializing those IPR. A technology transfer program structured around royalty-bearing licenses, rather than patent title assignment, helps motivate university scientists to pursue breakthrough discoveries.

For instance, at the Massachusetts Institute of Technology (MIT), three offices are involved in the technology transfer process: the Office of Sponsored Programs, the Technology Licensing Office, and the Office of Intellectual Property Counsel.[23]

The Office of Sponsored Programs is responsible for negotiating, executing, and administering all MIT research agreements with external sponsors and for ensuring that the rights of the parties (MIT and the sponsors) to technology developed under external grants and contracts are addressed in accordance with MIT's policies.

The Technology Licensing Office manages the patenting of intellectual property developed at MIT, Lincoln Laboratory, and the Whitehead Institute. The TLO has two principal goals: to facilitate the transfer of technology developed at MIT to the public for public use and benefit and to provide an additional source of unrestricted income to support research and education at MIT through the royalty revenue generated by the TLO's license agreements.

The TLO at MIT is one of the most active university patent and licensing offices in the United States, being the owner of more than 1,000 issued patents.

Finally, the Office of Intellectual Property Counsel advises the (university) community on other issues in intellectual property rights in government and industry-sponsored research agreements.

Differences between Europe and the United States in Innovation

The United States has been the first country that has taken into consideration the value of a close partnership between research institutions and industry. By contrast, in Europe, for a long time, a close interaction between research institutions and companies has not been considered a necessary measure to stimulate innovation as an important element in the new knowledge-driven economy.

The U.S. experience in this area has contributed to an increase in the number of policies and actions accomplished by the European institutions. However, although the technology transfer system developed in United States has been viewed as a model, certainly, there are great differences between the EU and the United States.

For example, the EU has not promulgated a regulation similar to the Bayh-Dole Act to foster interaction between academia and the business community. Nevertheless, in the EU, at this moment, there are two legislative initiatives under discussion. One of them is the regulation about the new European patent, and the second one is the regulation related to the patentability of software programs, the purpose of which is to harmonize the legislation related to patent protection due to the increasing awareness that patents are essential in an innovative and competitive economy.

Another relevant peculiarity of the U.S. patent system, and a major difference with the European situation, is the existence of a grace period for patent applications (first to invent). In the United States, researchers often publish their discoveries first and file for a patent later (although publishing first often can result in the loss of foreign patent rights). In contrast, EU countries operate under a first-to-file system. Under a first-to-file system that lacks a grace period, inventors would lose their patent rights because they must officially publish with the patent office. The grace period in the United States permits the inventor to disseminate research results within one year of filing a patent application for the discovery. However, the lack of a grace period in the EU prevents U.S. inventors from obtaining patent protection in foreign jurisdictions once they have published in the United States. This situation would require a change as part of an attempt to harmonize international patent law.[24]

Another important difference between the EU and the United States is that it is easier in the United States to raise funds for early-stage technologies and to bring new inventions to market than it is in Europe.

Thus, within the United States, corporations would finance research projects—even those at an early stage of development—as part of their culture. European corporations, partly due to their smaller size, would rather acquire the technology already developed. That is, European corporations prefer a fast, plug-and-play implementation customized to their business instead of relying on the uncertain promise of a tedious, developing, theoretical project that could finally turn into something, but with a lack of practical application.

The different environments for innovation in the United States and Europe described above suggest that a global innovation policy has not been achieved. New measures should be launched if the final purpose is to create an integral connection between the United States, the EU, and other nations.

Steps toward an International Network

The main measures to reach an international network of innovation resulting from the analysis of this issue in the EU and the United States are the following.

- The United States and EU should work toward a global patent harmonization through an international treaty that combines the United States grace period and the EU first-to-file patent system.
- The EU should promote the offer of IPR protection services to universities and companies. Such services should be offered as near to the inventors and researchers as possible and, at the same time, the EU should promote the coordination at the European and global levels.
- The European network of Innovation Relay Centers, which is an effective instrument of innovation, could be enlarged by opening other IRCs outside the EU to develop an effective international network.
- An international visibility of research activities and their results could be managed through conferences, fairs, and EU delegations related to technology transfer inside the United States.
- EU universities should include in their science and engineering curricula, courses of patent law, business development, and technology transfer.

- Partnerships between U.S. and EU universities should contribute to breach the existing gap by creating a platform of transferability for best practices. The Cambridge MIT Institute represents a good example of the potential that such partnerships can yield, enhancing the contribution that pioneering research and teaching excellence makes to economic success on both sides of the Atlantic.

The recent initiatives accomplished by the EU have proven that successful innovation can be achieved by providing the required regulatory and institutional support for universities and industry. Even when the EU lags behind the United States in the race to reach a good level of interaction between universities and industry, there is a current commitment to this issue within the European institutions that is helping the EU to reach a significantly competitive position in the knowledge-driven global economy.

Acknowledgement: The author gratefully acknowledges the help of Carol T. Carr, associate intellectual property counsel at the Office of Sponsored Programs at MIT.

Notes

[1] *European Trend of Innovation.* "Innovation policy in Europe (2001)." A publication from the Innovation/SMES Programme part of the Fifth Framework Programme.

[2] The Treaty of Amsterdam amended this treaty on May 1, 1999, modifying the titles and article numbers.

[3] The Community Research and Development Information Service online: http://www.cordis.lu.

[4] 1 euro = $1.07949 (the European Central Bank's daily reference rate as of February 7, 2003).

[5] With the Treaty of European Union, well-known as Treaty of Maastrich, enacted in 1992, the European Community began to be named European Union (EU) as a sign of a new stage in the process of the European integration of creating an even closer union among the countries.

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[7] *Bulletin of European Union*, Supplement 5/95.

[8] *The First Action Plan for Innovation in Europe—Innovation for Growth and Employment.* COM (96) 589 final.

[9] *Communication from the Commission to the Council and the European Parliament—Innovation in a Knowledge-Driven Economy*. COM (2000) 567 final.

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