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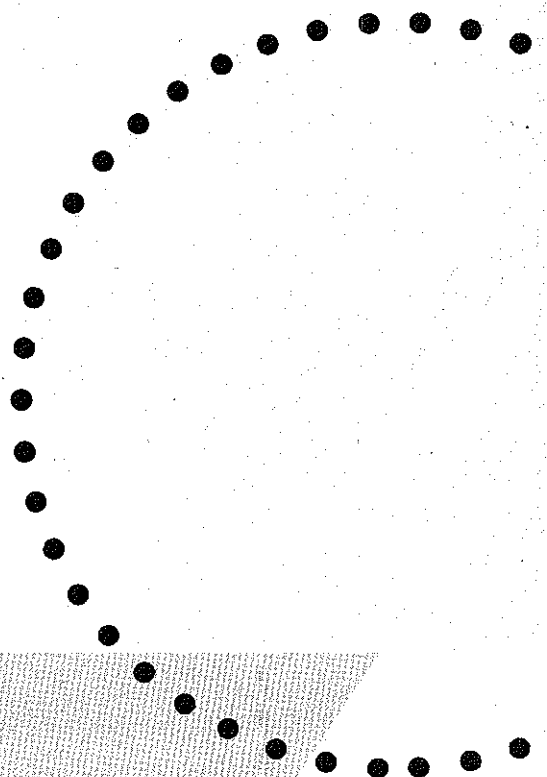

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JOURNAL OF THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

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Volume IX **1997**

Editor's Preface

In this ninth edition of the *AUTM Journal*, we offer our readers a most delicious sandwich. Between two progressive and substantial analytical pieces on the larger issues of the economics and dynamics of university licensing operations, readers will discover a fine trio of practical and valuable offerings.

In two instructive articles, Dan Burns and Jon Sandelin ("License Agreements: Are You Getting the Royalties You Bargained For?") and Vincent Kiernan ("Protecting Your Royalty Payments Using Audit Clauses in License Agreements") present instruments that all licensing professionals can use in drafting and exercising audit clauses to ensure that a licensee pays fair royalties. Mr. Kiernan focuses on actual language that licensing practitioners can use to avoid problems and to ensure a high standard of reporting and auditing royalties, while Messrs. Burns and Sandelin write from the perspective of Stanford University's experience of conducting royalty examinations, including broad recommendations to ensure that the process has minimal negative impact on licensor/licensee relationships.

David Parker's timely piece, "Biotechnology: From Enablement to Infringement," introduces readers with and without legal training to the latest trends in biotech patent coverage. He does so in a highly readable and enjoyable manner, yet provides all levels of readers, non-biotech technology transfer professional to patent attorney, with meaty material on a complex and fast-moving subject that is of increasing importance as many biotech products near the marketplace and patent holders stand to reap substantial royalties from their sale.

For long-range planning and historically interesting food for thought, the reader can consult our anchor articles first and last. David Hsu and Tim Bernstein have produced a thorough,

thoughtful, and interesting treatise on the value added by a spectrum of technology transfer activities and the dynamics of varying the emphasis upon one or another activity. "Managing the University Technology Licensing Process: Findings from Case Studies" makes thought-provoking reading, including an analysis of the history of university technology transfer and many practical and insightful suggestions on how we can use scarce resources to accelerate our goals. The authors also balance the impact that real everyday impediments have on certain of their "best-of-all-worlds" suggestions. Recommendations regarding the role of AUTM in catalyzing interaction among its members should be of particular interest to planners within the organization.

Finally, Peter Kramer, Sandy Scheibe, Donyale Reavis, and Louis Berneman have used the Pressman et al. method (see *AUTM Journal* Volume VII, 1995, showing the investments induced by patent licenses from MIT) to replicate and support Pressman's results using information on University of Pennsylvania technologies. While the authors note that further confirmatory studies would be useful, this paper verifies the "induced investment" method to measure pre-commercialization impact of university technology licensing on the economy and further underscores the importance of AUTM's activities.

Many thanks to all the authors for their efforts, attention, and time throughout the editing process. We encourage our readers to submit original papers on topics of interest to professional technology managers. Those contemplating writing an article or a letter to the Editor are asked to contact the Managing Editor for content and review procedures.

Beatrice Bryan, Editor
September, 1997

Managing the University Technology Licensing Process: Findings from Case Studies

David H. Hsu*
Tim Bernstein*

University technology licensing offices ("TLOs") face a dynamic environment in which the number of technology disclosures is rapidly increasing while the available resources for licensing technologies do not keep pace. Adopting new, strategic plans for licensing is therefore vital. This paper develops an analytical framework for the licensing process. It then presents evidence from 14 case studies and numerous interviews. We conclude that while TLOs have vastly improved since 1980, they have an opportunity to generate significant additional public value. Drawing on the analytic framework and case studies, the paper concludes with recommendations to help TLOs continue to improve their licensing strategies in this challenging environment.

I. INTRODUCTION

The number of university technology licensing offices has increased tremendously over the past seventeen years. One important cause of this growth is the 1980 Public Law 96-517 (the "Bayh-Dole" Act), which allowed universities to receive and assign intellectual property ownership rights for inventions arising from federally funded research. Consequently, university patenting and licensing activities have steadily increased since the early 1980s. For example, for a five-year recurrent sample of US universities, invention disclosures increased 29 percent over the 1991 to 1995 period (1). In addition, the Association

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of University Technology Managers (AUTM), the national association of licensing officers, has grown from less than 100 to over 1,600 members since 1980 (2). Many research universities now have licensing offices that vary in budget size, policy, and even core mission. While university TLOs have varying mission statements, many TLOs seek timely dissemination of technology to further the public good. Generally, TLOs' emphasis is *not* to maximize collection of royalties, but rather to maximize the societal benefit of technologies. In this way, university TLOs differ markedly from their private sector, profit-driven counterparts.

Given resource constraints in evaluating and licensing new technologies, university TLOs must adopt strategic plans to avoid missed opportunity in promising and potentially important technologies. This task is complicated by the inherent market and technical uncertainty typically associated with university innovations. Furthermore, the ease of university technology licensing depends on the institutional culture within which a TLO operates. In this study, we focus on those technologies TLOs decide to "pursue" (by filing for a patent) but which remain unlicensed. More specifically, we target promising technologies for which the market has failed to pair willing buyers and sellers. In addition, we address technologies that are not sufficiently developed to be of interest to companies or potential investors. While this second set of unlicensed, "embryonic," technologies does not necessarily constitute lost opportunity from society's perspective, we believe universities can pursue strategies to increase the probability of licensing them.

We address two primary questions in this study: (1) Are TLOs committing to a "good" portion of their technologies? (2) How successful are TLOs in getting committed technologies licensed?

There is little we could recommend to reduce the risk inherent to university technologies. Similarly, we cannot change university environments. This study is intended instead to offer

recommendations, based on case study evidence, to license a greater share of university technologies *given* the presence of uncertain technologies and unique academic cultural environments.

We developed fourteen case studies, drawn principally from technology originating from major east and west coast universities. These case studies encompass both successfully *and* unsuccessfully licensed technologies. For each case, we interviewed the licensee (for the successfully licensed technologies), inventor(s) when possible, the technology licensing officer associated with the license, and others (e.g., venture capitalists) who played substantial roles. In some cases in which a technology was not licensed, we were able to interview the people who declined to license the technology. The following matrix categorizes our case studies:

Case Studies	*Biotechnology*	*Non-Biotechnology*
Successfully Licensed	3 cases	6 cases
Unlicensed	2 cases	3 cases

While our case study evidence suffers the inherent limitation of case and interview-based research, the technology licensing officers with whom we worked suggested that our case studies and industry interviews offer a reasonably representative sample of their technologies and clients. Our interview base probably reflects more start-ups and higher potential technologies than the norm, however.

II. ANALYTICS OF TECHNOLOGY LICENSING

This section analyzes the two primary licensing functions. We refer to these functions, committing to and licensing technologies, as the licensing officer's "search process." TLOs face the problem of maximizing net social value through their

search process, subject to resource constraints. Underlying the search process is an implicit TLO policy regarding the number of technology disclosures to pursue. For example, if a TLO has historically decided to file patents on 50% of all disclosures, a licensing officer in that TLO might base her commitment decision on whether the current disclosure is likely to be in the top half of disclosures received this year. We introduce and analyze a "commitment spectrum" framework to explore the proportion of disclosures for which TLOs should seek patents. For the ensuing search process, we define concepts underlying a rational search strategy and briefly consider obstacles and other factors that might inhibit societal benefits. While recognizing the concept of maximizing net social value is an unattainable abstraction, we believe that a brief discussion of optimal social benefit will offer a useful benchmark with which to analyze current TLO performance. We begin by discussing the TLO commitment policy.

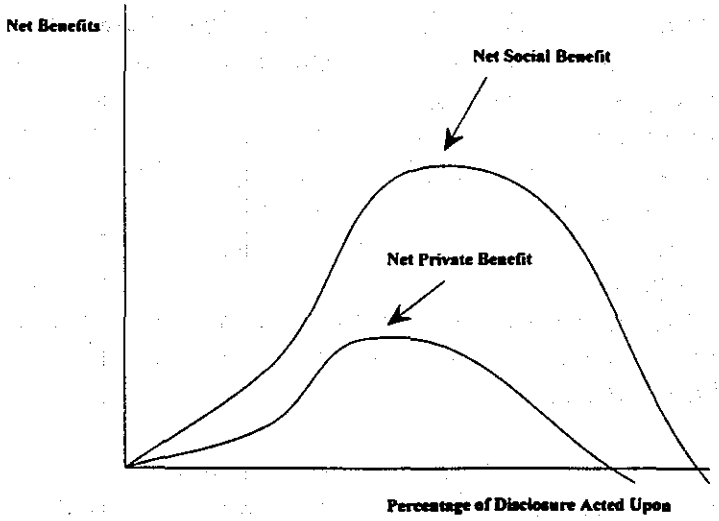
A. The Commitment Decision: How Many Technologies to Pursue?

How aggressive should TLOs be in selecting a *portfolio* of technologies to license? We now focus on policy decisions that guide the share of technology disclosures to which TLOs should commit. These policies establish the context in which licensing officers decide to accept or reject specific disclosures.

The following schematic depicts the relationship we expect between percentage of disclosures acted upon, or "pursued," (on the horizontal axis) and net societal and private returns (on the vertical axis). If the expected societal benefits (consumer and inventor benefits, royalties, and royalty-sponsored research) of pursuing a technology exceed its costs (patenting, licensing, and development costs), then the technology offers a positive net societal return. Net private return, which measures only the costs and benefits realized by a private organization, is usually a subset of net societal

return. We refer to this graph as the "commitment spectrum." Universities will differ, however, in their location along the spectrum at which they maximize social benefit.

Figure 1: TLO Commitment Spectrum



Most venture capitalists (VCs) and for-profit licensing organizations are relatively conservative in pursuing technologies. VCs choose technologies that they build into start-up companies, and hope these start-ups will go public. At this position on the spectrum, only a comparatively small number of technologies will meet the stringent criteria of technological and business potential that venture capitalists impose. These private sector organizations have a clear mission of maximizing private returns, and will probably forego significant societal benefit by not taking more risks.

Where should university TLOs place themselves on the spectrum? If a TLO's mission is to maximize net social benefit, the TLO should place itself to the right of private licensing offices. By choosing this strategy, TLOs hope to

maximize the probability of committing to technologies that would be net beneficial to society. A less tangible benefit of pursuing more technology commitments is the goodwill created with a university's inventors, often an important component of a TLO's authorizing environment.

There is a cost to moving too far to the right on the spectrum, however. In addition to increasing actual patenting costs, pursuing too many technologies might cause promising technologies to remain unlicensed, as they compete with a greater number of "unworthwhile" technologies for scarce TLO marketing resources. Furthermore, the stigma of a non-discriminating university TLO could damage the value and reputation of all technologies originating from that university. At some point, therefore, the cost of moving too far to the right on the spectrum, with too few resources to adequately devote to such a move, begins to reduce returns to additional commitments.

Maximizing social returns through placement on the commitment spectrum is, of course, uncertain in practice. To a short-sighted university administrator, the fact that a smaller fraction of committed technologies remains unlicensed may be taken as a sign of a successful TLO. This is a fallacious view, however. From a societal standpoint, if a TLO is licensing nearly all of its "committed" technologies, it should probably be pursuing *more* patents. The inevitable cost of trying to commercialize earlier-stage technologies is taking risks on some technologies that may or may not be, on balance, beneficial.

B. The Search Process

The licensing officer's search process includes committing to technologies and then attempting to license them. This section categorizes a technology's "size" and its stage of development, two important factors in a technology's value.

These two components also influence a technology's likely licensing path.

Size of a Technology. Determinants of a technology's size include magnitude of advantage over current and other new methods; size of potential market; cost-of- and time-to-development; patentability; and "appropriability" (the ability of a private firm to protect for itself profits from an innovation).

The sizes are:

- *Large*: Major innovations, for obvious ("blockbusters") or less foreseeable ("disruptive" technologies) markets.
- *Medium*: Innovations significant enough to support a start-up company or a new line of products for an existing company.
- *Small*: Innovations probably too small to support a start-up, but adequate for a product in an existing firm.
- *Embryonic/Uncertain*: Innovations with potential commercial feasibility, but with concepts as yet unproven.
- *Unworthy*: Innovations with little or no commercial potential.

Stage of Development. Stage is another component of potential technology value, and it describes where a technology stands on the commercialization path, ranging from theory-only to refined prototype. Stage includes dimensions of technical and market feasibility/risk.

A TLO's decision to pursue a specific technology will be affected by the TLO's commitment policy, which incorporates the TLO's historical percentages of disclosures accepted, the TLO's expected available resources, and the level of risk that the licensing office can undertake within its university environment. The decision will also involve the licensing officer's assessment of the technical and business merits of specific disclosures, taking into account the size and stage of development of the advances.

Licensing Paths. There are five paths for committed technologies in the licensing market:

- License to established companies
- License to start-up companies
- Develop through "ripening" mechanisms
- Out-source to private licensing organizations
- Remain unlicensed ("sit on the shelf")

Table 1: Expected Licensing Path Scheme

		If a technology is this size:			
		Large	Medium	Small	Embryonic
Then this is the expected licensing path depending on its stage of development:	Established Firm	x	x	x	
	Startup	x	x	x	
	"Ripen"			x	x
	Out-source				x
	"Sit on Shelf"				x

C. Potential Market Failures

There might be failures in the licensing market, however, which prevent a technology from progressing along its projected licensing path. In the next section, we examine case study evidence on failures, both internal and external to university TLOs, that drive a wedge between practice and theory.

III. CASE STUDY AND INTERVIEW EVIDENCE

We now present our findings regarding the licensing of university technologies. We first discuss findings from our case studies, with particular reference to start-ups. Table 2 is an overview of the cases, detailing reasons for their successful (or unsuccessful) licensing. Specifically, we present evidence on two fronts: market failure and successful and unsuccessful marketing strategies. In section three, we discuss current university positioning along the commitment spectrum. The section concludes with two overarching points. First, our evidence suggests that many unlicensed technologies may be worthy of

licensing and development. Second, an important driver of licensing success in our sample was the amount of protection afforded by patents in a given industry.

A. Case Studies Evidence

Of the five technologies in our sample that went unlicensed, one has proven not to have commercial merit, while insufficient proof of concept is the primary reason three of the other four remain unlicensed. The most important factors contributing to the successful technology transfers in our case studies, in order of importance, were effort on the part of entrepreneurs, the value (size and stage) of technologies, and financing issues.

The majority of our case studies ultimately resulted in the creation of start-up companies. Start-ups, while by no means the most common path through which university technologies get licensed, fill a critical gap in technological dissemination. As Table 2 shows, almost half of the licensed technologies in our sample would likely have remained unlicensed had a start-up company *not* licensed them.

1. Entrepreneurial Spirit

Individuals who took the initiative to organize a business around a technology were overwhelmingly the single most important factor for technologies successfully licensed to start-up firms. These entrepreneurs ranged from the inventors themselves to individuals who went to the TLO in search of a technology in which to invest. We illustrate by discussing one entrepreneur's journey through two universities' TLOs before settling on a technology that would likely have otherwise remained on the licensing office shelf.

* * * * *

Case Study: An Equipment Start-up Company

A motivated entrepreneur approached one university's TLO in 1988-89 in search of university technologies to license. A neuroscientist at the university had recently created a device that could accurately measure ion channel flows. Though the entrepreneur took an option on this technology, he was unable to secure financing for a start-up.

Still determined to license a university technology, the entrepreneur walked into another university's TLO. There, a licensing officer introduced him to a potential product, an instrument that interfaces high performance liquid chromatography with Fourier transform infrared analysis. A scientist at this university had built in his chemistry lab a prototype of the device that met regulatory requirements. A few large firms had expressed interest in the technology but ultimately felt that it did not fit their existing product lines.

The entrepreneur took an option on the technology, conducted a market study, researched the underlying issues, decided to license the technology, and formed a start-up company in December 1990. The entrepreneur thought that the existing prototype had "too many knobs" to be readily commercialized, reasoning that it would take too long to train a lab technician to use the device. The entrepreneur built another prototype of the machine and the firm had its first sale soon-thereafter, in March 1991.

Through one of their occasional telephone conversations, the entrepreneur learned from the chemistry professor that the lab had a new technology that would complement the original instrument. The scientist was about to present a paper describing the new technology at a conference in 1994. At the urging of the entrepreneur, the university's TLO consulted patent counsel. Counsel advised the university to file another patent application because the original patent did not entirely cover the new technology. The entrepreneur's start-up company subsequently licensed the complementary technology.

* * * * *

Table 2 CASE STUDIES - Successfully Licensed

CASE NUMBER	*Primary Reason Licensed*	*Primary Reason Not Licensed to Established Co.*	*Secondary Reasons Licensed*	*"Size" of Technology*	*Stage of Technical Development*	*Licensee*	*Source of Financing*	*Who Found Financing*	*Additional Licenses*
Biotech - Licensed									
1	CEO Relations with researcher	N/A (licensed to established company)	The Technology is a Sure Winner	Large	Embryonic – concept proven	Estab-lished company	Internal	CEO	Many
2	Licensing officer/VC	Venture Cap. (VC) Interest; VC Preemption	Technology has Large Potential	Large	Embryonic – concept proven	Startup	Venture Capital	Licensing Officer	Many
3	Licensing Officer/VC	Entrepreneur Preemption	Biotech Startups Trend	Medium to Large	Embryonic – concept proven	Startup	Venture Capital	Licensing Officer	Not yet
Non-Biotech - Licensed									
4	Entrepreneur	Too Small, Conservative Industry	Prototype; Equity Policy	Small	Preliminary Prototype	Startup	Friends	Entrepreneur	No
5	Inventor, TLO	Too embryonic; Disrupting	Silicon Valley; Interest in the Technology	Potentially Large	Preliminary Prototype	Startup	Self; VC; Silicon V.; ARPA	Inventor; Silicon Valley	Aggressively Looking
6	Co-Inventor	Co-Inventor Preemption	Self-financed	Medium	Concept Proven	Startup	Self, SBIR	Co-Inventor	Interested
7	Entrepreneur	Too Small	Equity Policy; Prototype	Small to Medium	Preliminary Prototype	Startup	Friends	Entrepreneur, VC	Yes
8	Co-Inventor; Entrepreneur	Industry Growing Too Fast	Minimal Financing Requirements; Prototype; Equity Policy	Small to Medium	Prototype	Startup	Self	Co-Inventor/ Entrepreneur	Interested
9	Inventor; Silicon Valley	Original Licensee went Bankrupt	Great Interest in the Technology	Potentially Large	Prototype	Startup	VC; Silicon Valley	Inventor; Silicon V.	Interested

Table 2 (continued) CASE STUDIES - Unlicensed

CASE NUMBER	*Primary Reason Will Be Licensed**	*Primary Reason for Unlicensed*	*Secondary Reasons Not Licensed*	*"Size" of Technology*	*Stage of Technical Development*	*Prospective Licensee*	*Likely Source of Financing*	*Who Found Financing*	*Additional Licenses*
Biotech - Unlicensed									
10	**Inventor; Substantial Proof of Concept**	Insufficient Proof of Concept		Large	Embryonic – concept proven	**Startup**	**Self, VC, Company Partners**	**Inventor**	Maybe
11		Insufficient Proof of Concept	Disrupting Technology; Confused Licensing Strategy	Unclear, Disruptive	Embryonic – no proof of concept				
Non-Biotech - Unlicensed									
12		Insufficient Proof of Concept	Poor Licensing Strategy; Patent uncertainty; Regulatory cost uncertainty; Passive inventor	Potentially Large					
13		Cost	Enabling only	Potentially Medium					
14	**TLO, Inventor**	Industry Structure	Competing Alternatives	Medium		**Established Company**	**Internal**		Probably Not

* Primary reason we believe these technologies will be licensed (both bolded entries are likely to be licensed imminently).

2. Value of Technologies - Stage in Development and Size of Technology

Embryonic stage of development is the primary reason three of our five unlicensed technologies remain unlicensed. Having a prototype, even a preliminary one, is especially important in the non-biotechnology start-up world. Though licensees of biotechnology demand proof of concept at an earlier stage of development than in other sectors, biotech licensees like to see the clear advantage and reliability of an advance. Probably for these reasons, a potentially disruptive biotechnology in our sample has not yet been licensed. For this technology, even having an eminent biology professor as a scientific champion has proven insufficient in successfully licensing the innovation. The diversity of "sizes" across our cases suggests that size is not the sole determinant of licensing success, though size probably influences the preferred licensing path for a given technology.

3. Equity/Financing Issues

Our cases suggest that financing issues are a key determinant of the probability of licensing success through start-ups. Financing issues, including university equity policies and up-front licensing fees, can determine whether a start-up entrepreneur licenses a technology. In addition, contacts in the venture capital community can give TLOs a competitive advantage in licensing. Equity policies are a critical component of any start-up strategy. Most of our sample start-up companies, especially in the physical sciences, would not have considered a start-up without the ability to offer equity in lieu of up-front fees. In addition, structuring high up-front license payments can sometimes be fatal. Most start-ups in the sample stressed the importance of minimizing these up-front burdens.

4. Other Factors of Licensing Success

First, granting exclusive licenses is an additional important factor in successfully licensing university technology; it was cited as critical in virtually all of our cases. Many of our case study entrepreneurs, regardless of the size of the specific technology in question, would not have licensed their technologies without an exclusive license. The threat of direct competition in a niche market is usually too daunting for the licensee. Therefore, exclusive licenses are often necessary economic incentives for would-be licensees (3).

This is not always true, however. One of the important factors contributing to the enormous success of the Cohen-Boyer patents, for instance, was the non-exclusive licensing strategy taken by Niels Reimers and the Stanford TLO (4). The Polymerase Chain Reaction advance, a process that allows rapid DNA synthesis, was licensed by Cetus Corporation under a very successful strategy that included both exclusive and non-exclusive components (5).

Second, having an established network of related technology firms and a well-developed, start-up support infrastructure in close geographic proximity can sway a potential start-up entrepreneur to license. Boston's Route 128 and Northern California's Silicon Valley have a "critical mass" of technology firms in which a wealth of experts, complementary materials, and social capital are available in a centralized location (6).

A third factor contributing to licensing success is the need for patent protection in order to assure private entities a reasonable chance of capturing profits from their development efforts and expenses. Withdrawing the risk that other entities will duplicate the product makes

the technology more valuable to a potential licensee. These concerns are also important to established firms.

B. Licensing to Established Companies: Interviews and Case Evidence

TLOs license most of their patents to established firms. However, the majority of licensing failures, both in our cases and as reported by our interviewees, were in building ties to existing companies. Through interviews with private sector directors of technology licensing and heads of research and development, we learned about the process of licensing at established firms and about TLO marketing strategies these firms find effective (and ineffective). Following a brief discussion of the importance of university-generated technology, we present findings regarding actual sources of market failure. We then synthesize from our findings a collection of successful and unsuccessful marketing strategies.

Without exception, the people we interviewed expressed their belief that university-originated technologies are important to the competitive advantage of their firms. Even research directors from companies that license only through sponsored research agreements spoke of the importance of university-generated technologies. Given this relationship between university research and industry competitive advantage, we might expect the licensing market for these technologies to work efficiently.

1. Evidence Regarding Internal Sources of Market Failure: TLOs

(a) *Inappropriate Incentives to Licensing Officers.* Several of our experts suggested that incentives for licensing officers are less than ideal. These experts suggest that incentives may encourage officers to pursue short-run royalty returns, to avoid up-front, unremunerated costs, and to lower numbers of committed technologies in their

portfolios in order to increase ratios of successfully licensed to total committed technologies. These incentives thus shift TLOs too far to the left on the commitment spectrum at the expense of long-term TLO, university, and societal benefit.

(b) *Licensing Officers Unable to Specialize.* Our cases and interviews suggest that licensing officers must invest significant amounts of time learning about unfamiliar products and technologies. Given the importance (suggested by our cases) of establishing personal relationships with target licensees, larger-scale licensing offices seem attractive. Several of our interviewees also suggest that there is a critical mass of university research activity required before a TLO can become minimally efficient. Smaller universities (as measured by size of research budgets) might be better off combining licensing office resources, or at least, resorting to the outsourcing alternative.

Outsourcing seems to offer limited value to any university that has committed reasonable levels of resources to licensing. The one circumstance under which outsourcing *does* make sense is for universities that do not maintain significant internal licensing office resources. For example, one east coast university has one licensing officer who is responsible for managing both the university's 80 new annual disclosures and the school's portfolio of existing licenses.

(c) *Licensing Officers Holding onto Technologies.* Several of our experts reported that TLOs sometimes stay with a technology too long, for example, to keep an important professor satisfied.

2. Evidence Regarding External Sources of Failure: Established Companies

(a) *Imperfect Information.* Our cases suggest that licensing officers generally find the right sets of target companies. This effort is easier when the inventor is knowledgeable of target companies, and more difficult and time-consuming when the licensing officer must generate the targets on her own. Many of our company interviewees, however, reported their desire for more proactive outreach on the part of TLOs beyond "cold letters."

(b) *Private Sector Organizational Failures.* This failure hypothesizes inappropriate firm organization as an obstacle to the fair assessment of technologies. Our experts and cases suggest that this category, from ineffectual gatekeepers to the "not invented here syndrome" (unwillingness to consider technologies generated outside their company) is not generally a source of failure in licensing markets. Furthermore, in cases when TLO marketing letters were sent to the wrong people within a firm, the letters generally made their way to the desks of appropriate company officials.

(c) *Disrupting Technologies.* The Haloid-Xerography technology is one of the most recognizable examples of a high-potential technology under-appreciated and shunned by investors. Two of our case studies may have experienced this phenomenon.

(d) *Embryonic Technologies.* Several of our case studies were of technologies that either were not licensed or took years to license, principally because the technologies were at a stage too early to interest the private sector. However, several of our cases also suggest that there is sometimes little distance separating early stage from licensable technologies. Researchers in two

cases suggest that an extra six months or year of funding and effort could be enough to raise significantly the licensing potential of their technologies. (As noted by one experienced technology licensing officer, however, inventors often underestimate the resources and time needed to establish proof of concept.) Several other cases illustrate the potential benefits of ripening mechanisms. These technologies may still be years away from market, but additional development effort can sometimes be sufficient to convince the private sector to invest.

There are several organizations that ripen technologies. These organizations have succeeded in bridging the gap between basic research and commercializable development. One executive we interviewed from such an organization commented that his group would be interested in closer ties with universities, suggesting a viable market to ripen technologies.

We conclude this section noting that our evidence suggests two pathways that mitigate market failure problems. First, if companies already have significant knowledge regarding a research project, they are much more likely to consider licensing the advances generated by that research. Usually, companies gain such knowledge when they have entered into sponsored research agreements with a university research lab. The other pathway for such knowledge is through personal ties to inventors. In such cases, as long as conflict of interest and intellectual property issues have been well thought out in advance, the licensing process usually proceeds smoothly.

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Case Study: Fire Ant Repellent

A professor of parasitology at a university characterized a tick secretion that he believed repelled fire ants by disrupting their social organization and communication abilities. A strong advantage of this technology, if it proves effective in repelling fire ants, is its environmentally-safe attribute. Field tests on the repellent have not yet been conducted, however, and the technology has not been licensed by the university's TLO despite two years of effort. A patent has recently issued on the advance.

In early 1994, the university's technology licensing officer sent letters to a group of (insecticide) companies she thought would be interested in licensing the technology. Several signed non-disclosure agreements to get more details on the technology. One of these firms was a large chemical company. The marketing letter from the university eventually reached the gatekeeper, the technology acquisition officer for the firm. The technology fit in the firm's commercial arena, but did not address a product concept of priority to the company. A third stage of the assessment would have judged the technical merits by conducting tests on the technology.

A second insecticide firm also expressed interest in the technology. The head of research at the firm believed the technology had potential. He knew that the demand for the environmentally-safe product would be high, and believed his company should explore the technical feasibility and development costs of the innovation. The company had just changed ownership, however, and the new top management was re-evaluating its priorities on development projects. The executives ultimately rejected the fire ant repellent technology because they did not want to commit to long-term technologies. In addition, the technology might have required registration with the US Environmental Protection Agency, a costly and time-consuming process.

* * * * *

We do not observe evidence of our theorized market failures in licensing to either insecticide company. Both directors of technology acknowledged the importance of university-originated technologies to their firms. In particular, the internal organization of these firms did not prevent a fair assessment of the technology.

3. Successful Marketing Strategies

Having presented evidence regarding actual sources of market failure, we now synthesize the findings into successful and unsuccessful strategies for marketing technologies.

Our interviewees and case evidence suggest two strategies that seem to improve the odds of successful technology transfer to established firms. They are: networking with "captive" current licensees (firms that already license from TLOs) and adopting customer-driven approaches to existing companies.

Captive licensees from our case studies appear to be a resource underutilized by licensing officers, especially as sources of leads and suggestions for their industries. These licensees unanimously reported willingness to provide such information. Existing licensees are also potential "repeat" customers who are interested in licensing additional technologies. Table 2 highlights the extent of captive licensee interest among our sample cases by showing the number of additional licenses taken by each licensee. Captive licensees are also interested in networking opportunities among themselves.

A second successful strategy is adopting a customer-driven approach to existing companies. Our non-captive interviewees suggest that several factors are critical to catching the attention of their companies: establishing and maintaining personal contacts in industry; on-site

visits to firms; standing offers to industrial research and development leaders to visit the university and its research labs; and frequent personal follow-ups with target companies. Even if a particular technology is not licensed immediately through this strategy, these efforts may allow licensing officers to establish more contacts and spread information regarding the university's research. Under this strategy, the fewer internal resources a TLO has, the more it should think about how and where to concentrate its personal contact with industry.

4. An Unsuccessful Marketing Strategy

The majority of our interviewees from well-established companies are deluged with technology licensing opportunities. The companies in our sample have found little or no value in technologies marketed through the mail by TLOs. These companies typically have better understood, better focused (for their needs), more strongly-championed internal research and development projects. It is generally not worth the effort for companies to devote resources to consider all of these university-generated advances. Thus, TLO marketing letters might end up on the desks of the right people within companies, but those people often bury the letters at the bottom of their "to-do" piles.

We have thus found that "shotgunning," or casting a wide, untargeted net in search of a licensee is generally not effective. University TLOs that pursue shotgunning may also tend to spread their resources too thin, leading to inadequate research and understanding of the technological needs of established companies.

When a shotgunning strategy is used, licensing officers run the risk that their letters will not be read. There is a greater risk with untargeted mailings, though. In

response to the flow of indiscriminate one page descriptions or comprehensive lists advertising university technologies, some technological gatekeepers have developed a belief that all technologies advertised through the mail are "bottom of the barrel" technologies. Sending advertisements of marginal or irrelevant technologies to a company contributes to a technology director's negative impression of TLOs sending untargeted mailings. Our research suggests that focused research and networking may result in better targeting of appropriate companies and better knowledge of market demand.

C. University Policies and TLO Positioning

In this section, we discuss TLO positioning on their "commitment spectrum" and its impact on societal value creation. Our discussion is based on our observations and the insights of the participants we interviewed (sixteen current and former licensing officers and two university administrators).

Where are Universities on the "Commitment Spectrum," and Where Should They Be?

Licensing industry participants and observers all agree that TLOs have improved significantly since the passage of Bayh-Dole. We also received a strong sense from a majority of our established company and licensing experts that there is much room for improvement in the licensing world.

We did not find statistics, for the most part, that measure TLO performance or even where the TLOs lie on the commitment spectrum. Most TLOs do not publish statistics that truly describe their licensing performance, though there are several notable exceptions. Royalty collection is widely cited, but we believe, a very misleading measure of performance in generating societal benefit. More accurate

would be statistics on invention disclosures, number of technologies pursued, and number actually licensed. Judging TLO performance from these statistics can be difficult as well, because a low fraction of technologies licensed to technologies pursued does not necessarily imply a poorly managed licensing process—a TLO in this situation may be pursuing earlier-stage technology that it feels will (eventually) generate net benefits to society.

D. General Observations

1. Serendipity

Our evidence suggests that there are two almost serendipitous conditions under which the role of the licensing officer is made easier. First are those cases in which entrepreneurs take on the responsibility for funding and developing technologies. Second are those cases in which the eventual licensee has a pre-existing relationship with the inventor. These cases suggest that there might be benefit to TLO efforts to enhance the conditions that generate such occurrences: for example, by sponsoring "open houses" on technology and financing for inventors, venture capitalists, and entrepreneurs.

2. Industrial Sectors, the Power of Patents, and Licensing

The second of our general observations is that many factors and characteristics can drive industry attitudes toward universities and the licensing process. However, our cases and interviews suggest that the underlying economics of patents, and of firms' abilities to capture profits deriving from their investments, is the most influential factor in determining industrial sector attitudes toward licensing. The greater the power of patents to protect profitability in an industrial sector, the more interested that sector is likely to be in a license,

and the greater is the likelihood that universities will successfully license to that sector.

Of the sectors represented in our case studies, the biotech and high temperature superconducting companies were the most attentive to university-generated technologies. Interviewees and companies from these sectors cite two motivations for their interest. First is the strength of patent protection. Second is the fact that technologies being created in universities are particularly important sources of competitive advantage for these companies. Patents hold minimal importance for our interviewees in the process-driven semiconductor industry and can be easily circumvented according to our interviewees in the electronics industry. One eminent chemistry professor remarked that chemically-based materials companies with which he interacts are simply not economically compelled to reserve the rights to a chance at some big new advance. Consequently, these firms are much more reluctant to work through conflicting interests with universities and TLOs or to pay royalties.

These observations fit well with the research of Scherer (7) and Levin et al. (8), who found, respectively, that the power of patents varies among industries and that patents were rated as most powerful in the drug-related pharmaceutical and biotech industries.

3. The Biotech Sector

University-generated biotechnologies are licensed, on average, at a more embryonic state than other technologies. The reason for this appears to be two-fold. First, as Dr. Joseph Davie of Biogen (Cambridge, MA) says: "Probably more than half of the products in biotech as a whole came from discoveries in university laboratories" (9). Though industry devotes enormous

budgets to R&D, the funds are spent *developing* technologies often created in universities. It therefore pays for biotech firms to maintain in-house R&D capacity and license earlier stage technology. Second, as mentioned in the previous section, patents have empirically been quite powerful in the biotech and pharmaceutical industries. For these reasons, our experts suggested that the market for university technologies in the biotech industry has become competitive and that basic biological research discoveries are currently driving both academic research and commercialization.

There are several additional, well-understood reasons for the close ties and relatively efficient market in university biotech licensing. First, as one industry executive observed, many biotech companies have one decision-maker with the authority to invest in new technologies. This emphasis makes clear sense when placed in context of the importance of acquiring university technologies early in their development. Second, as suggested by our interviewees, venture capitalists seem fairly patient with the long time horizon typically associated with developing biotechnology. Increasingly, however, venture capitalists demand broader "platform" technologies before agreeing to invest in a start-up. More and more, young biotech companies are becoming alternative licensors of technologies that used to be the basis for start-ups. Third, where there is a critical mass of biotech activity in a geographical area, there is typically greater industry access and interaction. Biotech licensing is exceptional, for example, in the Boston area because of the strong research generated at Harvard, MIT, and the area teaching hospitals. Finally, the biotech industry *originated* from universities, and many of the founders of biotech firms come from academia. Their cultures are similar, and comprise high levels of mutual familiarity.

IV. RECOMMENDATIONS

Based on findings from our case studies and interviews, we offer two sets of recommendations. The first set is tailored to university TLOs. While these visions may be controversial, we believe that TLOs can benefit by considering strategic future directions for their organizations. TLOs operate with limited budgets and resources. We fully recognize these constraints and have designed our recommendations with them in mind. We focus on latent resources in order to broaden licensing officers' reach. Most TLOs do some of these, but few or none do all. The second set of recommendations is targeted to the Association of University Technology Managers (AUTM).

A. Recommendations to University TLOs

The first half of the recommendations sets forth three conceptual categories, which are general strategies for TLOs. The second half presents a *menu* of potential paths for universities to consider, depending on their individual circumstances. For each recommendation, we also discuss potential obstacles.

Category #1: Harnessing Resources

- Increase "captive" audience networking. Draw more frequently on the expertise and advice of existing licensees and previous investors. The licensees we interviewed in this category believe they are underutilized, and expressed unanimous willingness to help licensing officers with strategies and leads. The captive audience also expressed strong interest in networking opportunities with other existing licensees.

- Aggressively draw on inventors' resources, contacts, and strategic guidance. TLOs recognize inventors as perhaps the most important source of contacts and licensee ideas. However, almost all the inventors we interviewed felt they

could be more strongly utilized. We recognize that few inventors will be willing to do all of these (and some may not be able to offer much help). Yet many inventors will do more of these things at least some of the time, with great potential benefit.

> Ask inventors to establish industry contacts at seminars and conferences, contact colleagues for advice and leads, and think seriously (albeit briefly) about possible licensing strategies. Contacting former students and researchers (who might now be at established firms or interested in starting up a company) from the inventor's lab may also be useful.

- Draw (*informally*) on professors and other experts within the university, especially those with previous experience in licensing technology, for marketing strategies and leads. Aggressively follow up on the contacts and leads from these experts.

- Hire interns. Students from local business and management schools, for example, can conduct detailed, targeted market research. Law school students can help in patent searches. This strategy might take some of the workload off licensing officers.

> A potential obstacle to this strategy is the ramp-up time necessary for interns to become familiar with the licensing process. One option would be to work with professors to structure longer internships, potentially making this recommendation viable. A second would be to target students who already have relevant knowledge in fields closely allied with a TLO's needs.

- Target business school graduating students. Many of these students are interested both in commercializing technology and in entrepreneurship and may be interested in licensing technologies. Our cases also strongly suggest that often only a motivated entrepreneur will do the leg-work and networking required to attract investors. In fact,

the VCs we interviewed stated that commitment of an entrepreneur is a very important determinant of success.

Category #2: Non-captive Audience Networking

Almost all of our existing company interviewees explicitly expressed willingness to respond to personal, targeted outreach efforts. They were up front about tactics that do not work (such as untargeted mass mailings), and about the stigma such efforts can create, both for technologies that are marketed in these ways, and for a TLO's reputation. Our interviewees also offered advice regarding potentially fruitful tactics, including:

- Careful research: use university resources to identify companies and the right people within those companies for the specific technology in question.

> Face-to-face contact with follow-up is essential. Licensing officers should visit industry heads of technology acquisition and heads of research and development, or invite them to the university campus (in collaboration with the inventor, if possible).

- Conduct site visits to firms once or twice a year, focusing on licensee targets with broad potential, or perhaps on the most promising non-moving technologies.

> We recognize that in addition to budget and time constraints, TLOs would face a multitude of choices in implementing this recommendation. Our suggestion is that they start by choosing one or two companies which make strategic sense.

- Do not push imperfectly matched or insufficiently-proven technologies on valuable potential licensees.

Category #3: Strategic Focusing of Effort

- Undertake second round marketing efforts for promising unlicensed technologies. This is especially applicable for technologies in industries just recovering from economic downturns, or for technologies after a major technical advance. Furthermore, several of our cases suggest that researchers sometimes achieve important advances subsequent to an initial round of licensing effort; and these technologies might very beneficially be showcased a second time. Possible strategies include assigning an intern to such cases, or setting up systems to monitor unlicensed technologies for such developments.

Category #4: Performance Measurements

- TLOs should adopt measures to better evaluate their performance in delivering social value. TLOs could measure *annually*: (1) technologies licensed as a share of total committed technologies; and (2) total committed technologies as a share of total disclosures received.

> As mentioned previously in this paper, these two measures are also imperfect; while low ratios and high ratios for both (1) and (2) unambiguously suggest poor and excellent performance, respectively, it is unclear how to evaluate the performance of a TLO that has a high ratio in one measure, but a low ratio in the other.

The following is a menu of longer-term, overarching options available to university TLOs. Though potentially controversial, we believe that TLOs moving toward a broader conception of technology transfer would generate greater benefits for society.

Alternative #1. Adopt a more aggressive licensing strategy. One of the first tasks in implementing this alternative is to gain top level university support for greater risk taking and

an aggressive stance toward technology licensing. Other steps might include:

- Promote a willingness to commit to commercializable technologies, including bearing the risks and up-front costs, even if a prospective licensee has not yet been identified.

- Concentrate more on managing and using resources. Engage networks and let them do some of the work. TLOs enjoy a wide array of potential resources, including prior licensees, professors (as advisors), students (as interns), and, perhaps even alumni.

  One specific idea for drawing on alumni is to seek out alumni in target companies and secure information on best marketing approaches and appropriate contacts.

- Plow back some royalty revenues into the licensing process. Reinvesting would allow TLOs to move further right on the commitment spectrum.

- Build a search *strategy*. This includes: focusing on the highest value-added technologies; categorizing technologies by size, stage, and potential licensing paths; adopting more flexible financing arrangements for licensing, royalty, and milestone payments for small business or start-up licensees.

Alternative #2. "Ripen" technologies too embryonic for private markets. TLOs might actively seek mechanisms, including sponsored research and private ripeners such as Battelle Memorial Institute and similar institutions, to perform the applied research necessary to bridge the gap for high potential, embryonic technologies.

Alternative #3. TLOs might begin to consider more functional alliances across universities. Licensing officers in even the larger TLO offices spend significant amounts of time learning new sectors and new technologies. Creating mechanisms to capture the advantages of scale offered by

cross-university cooperation might produce significant benefit for universities in general.

> In addition to a very tricky question regarding implementation, there are at least two potential costs to increasing scale. First, increasing scale risks losing individual contact with the inventors, a critical asset. Second, conflict of interest issues could become quite complicated.

Alternative #4. Recognize the reality of limited resources and concentrate only on a limited number of cases. By trimming their portfolios, licensing officers would be freed to spend more time, effort, and care with each technology to which they commit. This includes greater marketing efforts, stronger collaboration with the inventor in building a licensing strategy, more thorough patent searches, and more research about and approaches to the right people in the right companies.

We believe that universities, each with a unique history, culture, and set of resources and constraints, should initiate the process of building community-wide support for the option(s) most consistent with their core missions.

B. Specific Recommendations for the Association of University Technology Managers (AUTM):

1. Offer a listing of university-sponsored start-up firms by industry and specific product. Start-up firms have unanimously reported interest in further licensing opportunities. Broadening the pools of both university generators of technology and potential licensees increases the likelihood of producing significant benefits.

> Details would have to be carefully thought out, but would probably include, at least, coordination through the responsible licensing officers.

2. Systematically tap into networks of private sector research directors. AUTM could forge formal mechanisms to enhance the ability of licensing officers to easily identify and contact appropriate targets and to increase the likelihood that those targets would respond.

   One idea could be to establish a relationship with hard to reach but promising industries, perhaps through their trade associations, or through research collaboratives such as Sematech or the Microelectronics and Computer Technology Corporation.

3. Create a mechanism to allow licensing officers to locate, quickly and unobtrusively, licensing officers with recent experience in a specific industrial sub-sector.

   A possible mechanism to share expertise might be Internet-driven pages containing files (and searchable keywords) for recent licensing deals or industry intelligence by industry sub-sector. Recent innovative or successful deal structures or relations with resources might also be included.

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TLOs have come far since 1980 in learning how to license university-generated technologies. We believe that TLOs also have great potential to further enhance the public benefit. The challenge of licensing will become even more difficult, however, as the number of university technology disclosures quickly increases. We hope our insights and recommendations help TLOs as they assess their licensing strategy in this dynamic environment.

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License Agreements: Are You Getting the Royalties You Bargained For?

Dan Burns*
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INTRODUCTION

While the audit of trademark licenses is common, today it is a fairly rare event for university technology licenses. Holders of a trademark license expect to be audited on a regular basis. As trademark licensees typically have licenses with a large number of universities, as well as the professional sports leagues, there is the opportunity for cost-sharing of the audit. A university will typically have to pay only a few hundred dollars to participate in an audit of a trademark license.

A technology license audit generally related to a single license transaction is much more complex. The procedure may cost in the thousands or tens of thousands of dollars. It will probably be a surprise to the licensee when such an audit is requested. There is the potential danger that the licensee may consider such a request as a challenge to the mutual trust between the parties.

Thus, university licensing professionals around the country are debating the merits of auditing their licensees, and it is an interesting debate. While the licensing professional may harbor

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well-founded suspicions that licensees are underpaying, an audit may have adverse consequences for the relationship with the licensee.

Increasingly, university-industry licensing occurs in a complicated web of relationships involving university administrators; inventors who are also licensee consultants or on licensee advisory boards; research funding that may involve industry/university consortia; and donations of equipment or money to the university by the licensee. The licensing professional may be quite unsure as to who is the spider and who is the fly. However, it is generally possible to protect the university's intellectual property, and even to conduct audits, without becoming ensnared in an adversarial process that damages the delicate relationship between the parties.

This article is based upon a workshop in which the authors participated at the 1997 AUTM Annual Meeting in San Francisco. The authors also conducted a survey of attendees concerning royalty examinations. The results are presented at the end of the paper.

Experiences at Stanford

As of the writing of this article, Stanford has conducted two significant royalty examinations, and has launched a third. The first involved the "Cohen/Boyer" licensing program. The technology is the process for inserting genetic material into certain cell types that results in protein "factories." This is the foundation of the biotechnology industry, with over 300 licensees worldwide, and royalties to date of over $250 million. One of the "Big 6" accounting firms was selected to perform the audit. Twelve companies have been audited to date; their selection was based upon the amount of royalties they had paid to Stanford. Although to date the total recovered royalty revenues of $56,000 (from three licensees) are exceeded by the audit costs of $211,000, all licensees may be a bit more diligent

in reviewing the calculation of royalties knowing that this audit program is underway.

The second royalty examination involved a licensing program for Phycobiliproteins, a tag used in medical diagnostic devices. The program had 50 licensees and total royalties of over $10 million. Another "Big 6" accounting firm was selected as the auditing firm, and questionnaires were sent to the licensees. Three companies were selected for audit. The results were that two of the three companies, when given notice of the impending audit, determined that they had underpaid royalties by $247,000. The payments were received prior to the audits. It was found, during the audit of the third company, that $75,000 of royalties had not been properly reported. Fees to develop the questionnaire, evaluate the responses, plan and conduct the audits, and report the findings to Stanford amounted to $27,000.

Licenses Must Be Monitored. How Can It Be Done Properly?

A license permits one or more companies to use patent-protected technology to develop new products or processes. Once the license is signed, however, the work is not over. License agreements must be monitored to ensure compliance with diligence and royalty requirements. Every licensor knows the feeling of uncertainty that accompanies the receipt of an unsupported royalty report that includes only the number of units sold and the amount of the royalty remitted. Has the royalty been calculated correctly? Has the licensee accounted for all of the products sold? Why is there a significant change, upward or downward, in the amount of royalties paid? Is the licensee taking proper deductions to determine net sales? These and many more questions are legitimate concerns.

That said, a licensee may not take kindly to being audited. How can the university audit a licensee without causing possible harm to their relationship, especially if the licensee has other relationships with the university, such as sponsoring research?

Difficult as it may seem, the university licensing professional should not abdicate the responsibility of ensuring that the proper stream of royalties is received. If the university decides to audit certain licensees, how should the candidates be selected? How should the licensor identify and retain a suitable professional services firm to perform the work? How will the work be performed? Are there issues of confidentiality? How will the professional firm charge for its services? These questions and others will be considered in this article.

ARE ROYALTY "AUDITS" MISUNDERSTOOD?

In exercising its right to "audit" a licensee's books and records, the licensor seeks to determine the methods of calculation used and accuracy of royalties remitted by the licensee. To an accountant, this procedure is not an audit. When an accountant audits a company's financial statements, he or she is evaluating financial statements prepared by company management for issuance to shareholders and the public in accordance with generally accepted accounting principles (GAAP). The accountant's level of effort in a financial statement audit is often based upon testing the representations of management (the accountant's client). By contrast, a royalty examination is a detailed examination of a limited set of transactions and activities related to the manufacture, distribution, and sale of goods resulting in payment of a potentially incorrect royalty to the accountant's client. The circumstances of the engagement, and the approach of the accountant should differ significantly between a financial audit for purposes of reporting to shareholders, and a royalty examination.

Accounting for royalties under a license agreement is not generally subject to GAAP. Indeed, for many public companies licensing-in, the royalties payable to a licensor may escape the scrutiny of the licensee's external auditors because the amount of royalties due may be immaterial in the context of the financial statements, and auditors express opinions on the fairness with which the company's financial statements

materially present the company's financial condition. Thus, be cautious about accepting the licensee's contention that "our auditors would have looked at it." If the royalties paid under the license appear insignificant when compared with total sales, there is a good chance the licensee's auditors did not test the accuracy of royalty payments made by their client.

WHY UNIVERSITIES SHOULD CONSIDER ROYALTY EXAMINATIONS

Many university licensing professionals feel that a royalty examination may strain the relationship with the licensee. In our view, however, licensees generally accept the notion that licensors must monitor their license agreements, and part of that oversight function should include royalty examinations. After all, these same businesses keep their cash in the bank, insure their hard assets, and attend to them when they need repair. They spend vast sums to protect their brands, trade secrets, and other intellectual property. Why wouldn't they understand the university's use of the same sound judgment in protecting its own assets, which include license agreements?

Three Main Benefits of License Examinations

In addition to sound business practice, there are at least three good reasons why universities should conduct regular royalty examinations. First, underpayments regularly arise for a variety of reasons. Second, other licensees will get the message, and the quality of royalty reporting will improve. Third, you will have greater confidence in the licensee's attention to, and adequacy of, its royalty reporting.

Uncovering Underpayments

There are as many reasons why underpayments occur as there are licensees. In our experience, most are unintentional. Why do such errors occur? Generally, such underpayments may be traced to several causes, of which the three most significant may

be poor internal controls, poor communications, and ambiguous language in the agreement.

Poor internal controls of the licensee reflect the inattention of a licensee to the agreement. Simply stated, the licensee may not have designated anyone to have primary oversight responsibility for the accuracy of royalty payments, or may not have communicated internally the importance of reporting accurate royalties on a timely basis. In addition, many companies use integrated accounting software programs that are very effective at taking orders, creating invoices, causing product to be shipped and receivables to be collected, but have no mechanism for identifying royalty-bearing sales and calculating the proper royalty resulting from such sales. In other words, the calculation of a royalty often involves the collection of data from different information systems that may then be manually entered to determine the royalty to be paid, leaving considerable potential for error.

A second fundamental reason that royalties often are underpaid is indirectly related to the first. Licensees frequently develop derivative products from the licensed technology. However, the fact that they are royalty-bearing is not communicated to the analyst preparing the royalty report. This problem is particularly acute in the licensing of both biotechnology and software. To illustrate, a patented biotech property is licensed and the licensee immediately incorporates the element into four of its products. For three years, sales grow. In the fourth year, sales of one of the products fall to zero and sales of the remaining three have flattened or declined. Normally, a licensor might not be concerned. However, in this case, the property had been licensed non-exclusively, and other licensees were enjoying growing sales. A review and comparison of the royalty reports of the other licensees quickly showed that most of them were reporting additional product codes on their royalty reports, suggesting that new licensed products were replacing the sales of older licensed products. In the subsequent examination, it was observed that the first licensee's product development

personnel never communicated the new replacement licensed products to the company's internal accountants, leading to a substantial amount of unpaid royalties.

For significant licensees, we recommend the licensor obtain current product catalogs and perform occasional reconciliations between the products listed on the royalty reports and the products sold by the licensee. Such a reconciliation can identify possible products being sold where no royalty is remitted.

Another frequent cause of underpayments is the unclear or ambiguous language in the royalty and audit sections of the license agreement. Licensors will, quite rightfully, interpret the language in ways favorable to them. The license terms must be very clear on exactly to what the royalty rate applies (e.g., the entire product sold by the licensee, just a portion of it, or a derivation of it) and how the royalty will be calculated. The agreement should also define if there will be many transactions that will not produce royalties, such as products provided for testing or evaluation purposes. Be alert to ensure that the licensee is not providing your licensed product for free or at a large discount, if coupled to other products or services; although with respect to the latter, unless your license agreement is explicit, the licensee may argue that discounts are permissible. Also, if sublicensing is allowed under the agreement, be sure to cover explicitly whether or not the licensee may issue essentially royalty-free licenses as part of a cross-licensing arrangement. In the audit section of the license agreement, ensure that the language permits a complete and thorough review of records and allows interviews of key licensee personnel. The audit section should include such provisions as satisfactory books and records, audit periods, recovery of expense and interest, notice, access to key people, right of access to the manufacturing facility, right to copy documents, and a required retention period for records.

Sending a Message to Other Licensees

A second benefit licensors typically enjoy as a result of conducting regular royalty exams is that licensees should begin to pay closer attention to the timing and quality of disclosure in their royalty reporting. This seems especially true where a technology is licensed non-exclusively, but also occurs where a licensor has issued multiple exclusive licenses in different fields of use. One explanation for this is that licensees talk to one another. Once licensees learn that the licensor has conducted one or more exams, they are more likely to examine internally their royalty-reporting practices. They also may have reason to anticipate that the audited licensees (especially under a non-exclusive license) will divulge information to the licensor concerning the propensity for other licensees to follow accounting or business practices that have the effect of reducing their royalties payable. After all, those licensees have no desire to see their competitors "get away with" paying less, because it would place them at a competitive disadvantage.

Peace of Mind

The third principal benefit to licensors is peace of mind. Licensors often express frustration that their expectations are not met by outcomes. In other words, they don't receive the royalties they think they should. This dissonance is not likely to improve unless the parties address it directly. Ideally, the outcome of the royalty examination is that the licensor and licensee share a common understanding regarding interpretation of the royalty and accounting provisions of the license agreement. The examination will permit the licensor to understand what the licensee is doing, and to adjust expectations if the licensee is reporting properly, or to influence the licensee's reporting behavior to become consistent with the requirements of the agreement.

Thus, the main benefits from royalty examinations include possible cash recoveries, the communication to your licensees

of your intent to protect your intellectual property, and greater peace of mind. Collateral benefits that a qualified examiner will provide in the process include tips on drafting audit clauses, tips on royalty provisions, help in selecting licensees to examine, and even assistance in identifying companies that may be interested in taking a license.

LICENSOR'S "HOT POINTS"

Once the decision has been made to conduct one or more royalty examinations, the licensor is faced with three decisions, each of which may have real consequences for the licensing professional and the university. First, which licensees should be audited? Second, how should they be notified? And third, who should conduct the examination? The importance, and inter-relatedness, of the answers to these questions should be understood before conducting many examinations.

Selecting Licensees for Examination

The selection criterion employed by a licensor may encompass a variety of considerations, such as the amount of the royalty stream under the license, the adequacy of the licensee's royalty reporting (quality, clarity, and timeliness), the nature of the reporting (degree of fluctuation between reports, or the extent of adjustments taken), or information regarding the licensee's practices that the licensing professional may have gained through one or more sources. All else being equal, licensees reporting in a clear and timely manner, showing evidence that some measure of care was used in determining and reporting the royalty, are less likely to warrant an examination. However, thoughtful licensors will maintain a database of royalty reports that permit the licensor to evaluate a licensee's royalty reporting over time, or, in the case of non-exclusive licensees, to compare and contrast the reporting of licensees.

In some cases a questionnaire may be useful for alerting licensees to the licensor's intention to scrutinize royalty

reporting. Indeed, some licensees, upon reviewing a questionnaire, will undertake an internal review. In one examination conducted by a major accounting firm for a university, a licensee's questionnaire-inspired internal review resulted in a check being remitted to the licensor for a six-figure sum, representing over 25% of average annual royalties.

Giving Notice Properly

A second "hot point" is the manner in which the licensee is notified of the impending examination. Some licensors think it is perfectly acceptable for the firm that is going to perform the examination to notify the licensee. However, hearing that an accounting firm is coming in to pore over the books and records is not a message the licensee should hear from someone it does not know. The licensing professional should notify the licensee in writing, with sufficient warning to permit the licensee to gather the materials the examiner will need. It is important to advise the licensee that it is not being singled out. Instead, the royalty examination should be seen as part of the licensor's ongoing efforts to monitor its intellectual property. The explanation as to why the examination is warranted need not venture beyond sound business practice. Indeed, for public universities, there is a good argument that the university owes a duty to the public to assess the accuracy of licensing revenues.

Who Will Perform the Examination?

A lack of internal auditing resources usually causes universities to retain outside audit firms. Many large accounting firms have professionals who have performed royalty examinations. However, licensors are strongly recommended to seek out firms with groups that specialize in royalty examinations. (They are not "audits," remember!) If possible, interview the leader of the royalty-examination team to gain an understanding of their qualifications and their sensitivity to the special circumstances and needs of university licensors.

In addition, the examination workpapers are private documents belonging to the public accounting firm. This would not be the case if the internal auditors of a public university perform the examination. Thus, using a public accounting firm means there is a greater likelihood that the examination workpapers will remain confidential (one less objection for the licensee to make) than if a public institution's internal auditors do the work.

Public accounting firms will bill for their services. You should therefore obtain a letter of engagement that discloses billing rates and provides an estimate of budgeted fees. The fee arrangements a firm may use to bill for its services can vary. Billing for royalty examinations can be on an hourly, fixed-fee, or contingent basis. Many firms generally will be reluctant to bill on a fixed-fee basis having only a limited sense of the scope of work to be performed. While contingency fees may appear attractive at first, the situation can become complicated if the licensee learns about the billing arrangement, especially if the examiner appears overzealous. If the licensee disputes the examiner's findings, will a provision requiring the licensee to pay for the audit, if underreporting is found, be honored? If the matter then goes into dispute resolution, how credible is the testimony of an examiner whose fees are tied to the outcome of the arbitration or trial? For these, and other reasons, the licensor should, in most cases, retain the CPA on an hourly rate basis. To keep control of the fees, the licensor should insist on a detailed work plan and frequent progress updates during the fieldwork.

DURING THE EXAM: WHAT SHOULD AN EXAMINER DO?

As a prelude to visiting the licensee, the examiner should review the license agreement and any amendments, the royalty reports, and any relevant correspondence. The examiner should then develop a work plan. The initial interviews with the product development and accounting personnel should provide

information as to the assumptions and documents used in preparing the royalty reports. At this point, the examiner should consider whether the licensee's approach appears consistent with the license agreement. The examiner may then perform the procedures detailed on the work plan and prepare a report of preliminary findings for discussion with the licensor and the licensee. In communicating the results to the licensee, it is best to do so in a manner that achieves the licensee's "buy-in" to the approach taken by the examiner in order to obtain payment for back royalties owed, and to get the licensee's cooperation in implementing procedural changes to improve reporting.

AFTER THE EXAM: WHAT SHOULD THE LICENSOR EXPECT?

The examiner's report to the licensor should include:

- the scope of the engagement;
- the examiner's understanding of the license agreement;
- the examiner's understanding of the licensee's accounting system; and
- the approach the licensee used to determine and remit royalty payments.

The report should set forth the examiner's findings and the licensee's reactions to the examiner's conclusions and recommendations.

SUMMARY

University licensing professionals face a difficult decision in whether to examine the royalty-reporting practices of their licensees. By selecting qualified professionals and giving notice properly, the licensing relationship is less likely to be compromised. In our experience, the benefits to conducting examinations unquestionably outweigh the costs.

The results of our survey of attendees of the 1997 AUTM Annual Meeting held in San Francisco are presented at the end of this article. The purpose of the survey was to determine what universities are doing with respect to royalty exams and how they are doing it. Our findings confirmed certain preconceptions and shed valuable light on other issues of concern. While virtually all universities include a right to audit in their licenses, only slightly more than half of the respondents have ever exercised that right; of those, only about 13% had conducted more than three separate royalty exams.

The primary reason for conducting examinations appears to relate to the inadequacy (timing, quality, completeness, etc.) of the licensee's royalty reporting. For those that had not conducted examinations, most felt they had never been given a compelling enough reason to do so. Surprisingly few said the cost of the procedure was prohibitive. Indeed, a majority of responses understood that a thorough royalty exam could result in fees of $20,000 or more. Almost 90% of the respondents turned to "Big 6" accounting firms, while 20% sought assistance from smaller firms or from their own internal audit staff (i.e., certain licensors used "Big 6" firms in one matter and a smaller firm in another). A significant majority, 83%, engaged the firms on an hourly-rate basis, with the balance paying for the work on a fixed-fee or contingent basis.

The area of the survey about which we were most curious concerned the interest on the part of universities licensing the same or similar technologies to a common licensee to "band together" to share audit costs. We were encouraged to find that 65% of the survey respondents saw merit in this concept. The potential for cost savings when auditing agreements unlikely to be audited on a stand-alone basis suggests this approach could be attractive to many universities. We expect this question will receive further consideration as the volume of agreements and amount of royalty income increases over time.

SURVEY QUESTIONS

1. Do your license agreements include an audit provision?

   Yes: 100% No: None

2. If "yes" to Question 1, have you ever exercised the audit provision of one of your licenses?

   Yes: 55% No: 45%

3. If "no" to Question 2, what reasons can you give for not ever doing so?

   78% said they never had a good enough reason to audit.
   44% said the amount of royalties did not justify an audit.
   30% said they were concerned about damage to the relationship with the licensee.
   11% said the cost of the audit would not justify the effort.

4. If "yes" to Question 2, approximately how many separate examinations have been performed by your institution?

   87% had conducted between one and three separate examinations.
   13% had conducted more than three separate examinations.

5. If your institution has performed royalty examinations, how were those licensees selected?

   83% stated that inadequate royalty reporting had prompted an examination.
   66% said the size of the royalty payments warranted an examination.
   40% credited their own research or feedback from third parties.
   11% stated that the length of time the license agreement was in place prompted the exam.

6. Do you commonly include the following provisions in the audit provision in your license?

Right to audit	100%
Audit fees may be paid by licensee	80%
Use independent CPA firm	80%
Frequency of audit	75%
Identify documents available during exam	70%
Licensee may pay interest on balances	65%
Exam results will be confidential	60%
Examiner may make copies of documents	20%
Examiner may interview selected personnel	10%

7. Who conducted the examinations for you?

"Big 6" CPA firm	88%
Other accounting firm or internal auditors	20%

8. Where you have retained outside firms to perform examinations, how have their fees been charged to the project?

Hourly rates	83%
Fixed fee or contingent fee	16%

9. Would you consider "banding together" with other universities licensing the same/similar technologies to perform royalty examinations of a particular licensee in an effort to save costs if the accountants' costs could be split among the universities?

   Yes: 65% No: 35%

10. Would you be willing to exchange information with licensing professionals at other institutions to identify potential licensees which could be the focus of a "joint" royalty examination?

    Yes: 75% No: 25%

11. What would you consider to be a reasonable fee for a royalty examination of a single company?

    A variety of figures were provided; the most frequent responses centered in the $10,000 - $20,000 range, with a maximum of $50,000.

Protecting Your Royalty Payments Using Audit Clauses in License Agreements

Vincent J. Kiernan*

One of the most overlooked areas of many license agreements is the section dealing with "audits." "Audits," for the sake of this article, are the accounting reviews performed to verify the accuracy and completeness of the sales data used in calculating royalty payments. Many times in the course of drafting licenses, writers do not give enough thought to how the agreement will be monitored from a financial perspective. The "honeymoon period" ends and both parties then have to cope with how sales, unit data, and royalties will be accumulated, calculated, and paid. All too often, clauses in the agreements are too general and provide insufficient guidance on how the agreement will be monitored. These clauses typically just state that an audit may be performed by the licensor, if deemed necessary. For example, a common clause is:

> "Licensor shall have the right to audit the books and records of the licensee to determine the accuracy of the royalty reports. Licensor shall use an independent accounting firm that is mutually agreeable to both parties."

This clause leaves much open to interpretation. The actual logistics and interpretations of how to perform the audit are left unaddressed, and thus will be dealt with if and when problems arise. Unfortunately, problems often do arise. For example, the

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licensor believes that there might be unreported sales, or that the licensee's definition of sales is incorrect, or that certain products are not covered by the agreement. Whatever the reason, the vagaries of a less than specific agreement can lead to exasperating contention on the interpretation of the agreement.

This article provides some ideas that can help reduce potential misunderstandings and disagreements down the road. In addition, it provides some sample clauses for agreements that may be used to help ensure that licensors and licensees of intellectual property spend more of their valuable time nurturing and profiting from their relationship.

1. Include Clear Definitions of Terms

Good definitions help reduce the "gray" areas of what is meant by key terms. In most cases, the most important term involves the definition of "selling price." While selling price may appear fairly germane at first glance, in the give and take of the marketplace, many adjustments can be made to encourage the sale of the relevant products. These adjustments can include credits for such items as commissions, promotional give-aways, volume discounts, etc. Thus, the licensee may define the selling price as net of all these discounts, while the licensor would likely argue that it is a gross amount (akin to a "list" price). The parties need to determine what credits, if any, are to be included or excluded. By clearly defining in the agreement exactly what is included (or excluded) in the selling price, future misunderstandings can be reduced. For example, a clause defining selling price might be:

> "The selling price is the total product revenue, or list price per unit, without regard for any marketing incentives (marketing incentives being defined as any discounts to the selling price), rebates, or pass-throughs."

In short, the definition should include any possible scenario that can modify the selling price. This requires a good understanding

of where the product will be sold. For example, is it common for the seller to discount the item to move the product? Depending on the amount and volume of discounts given, this can greatly reduce the amount upon which the royalty is calculated.

2. Include Penalty Provisions for Underreporting

The licensor should emphasize that it wants accurate and timely data that serve as the basis for calculating royalties. A commonly used clause to help emphasize this point is what is known as the "5% rule." This rule states, in short, that if an audit is performed and it is found that there was more than a 5% underreporting of royalties, the licensee will reimburse the licensor for the cost of performing the audit. A suggested clause would be:

> "Licensor shall have the right to audit relevant licensee books and records, including work papers, through the use of independent auditors upon written request once during the year. If the royalties actually reported by licensee for the period of the audit are under paid by more than five (5%) percent of the royalties determined payable by the audit, the licensee shall pay for the entire costs of performing the audit. Costs include the accountant's professional fees plus expenses."

Example of Penalty Provision for More Frequent Audits:

> "Licensee shall reimburse licensor the costs and expenses of any such audit that reveals an underpayment to licensor of five percent (5%) or more. If any such audit reveals an underpayment of royalties by the licensee, then the licensor reserves the right to subsequently audit more frequently than once per year upon advance notice of ten days."

3. Right of Audit Should Extend to Sublicensees

It is also common to find that a licensee sublicenses the technology to another party, a sublicensee. However, the audit clauses are not always transferred to the sublicense agreement.

This should be required in the original license agreement. An example of contract wording could include:

> "Sublicensees shall be required by the licensee to provide accurate records of the manufacture and distribution (including, without limitation, the amount and type of products distributed) of the product, and licensee agrees to disclose information that relates to the product that includes licensor's product to licensor upon request. Licensee shall require that sublicensee maintain the same types of accounting and sales records, for the purposes of performing an audit, as required by licensee, and will permit the licensor's auditors to audit sublicensee's records."

It also is important to extend the penalty provision discussed above to the sublicensees.

4. Audit Provision Should Designate a Specific Audit Firm

In many agreements there is a clause that indicates that auditors, mutually agreed upon by the parties, will perform the audit. However, disputes can arise regarding which specific firm will do the work. In many cases, the licensee does not want to use the licensor's firm. Likewise, the licensor does not want to use the licensee's firm. There is often a perception that the use of the other side's firm will deprive the audit of its independence. Therefore, identifying a mutually agreeable, independent firm, and documenting in the agreement who the firm is, help eliminate the lost time spent trying to resolve this matter. Moreover, it eliminates future questions as to the meaning of "independent auditors." A mechanism for subsequently changing the initially designated firm, should that be desired, also should be included in the agreement.

5. Late Payment Provision Should Also Include Interest on Late Payments

The receipt of royalty payments should be timely. Many licensors rely heavily on this cashflow. Its interruption can seriously disrupt other operations, so there should be a clause

calling for the accumulation of interest charges due to any late payments, such as:

> "If licensee fails to make any payment on the date it is due, the unpaid amount shall earn interest at the rate of xx% per month or the statutory rate of interest, whichever is higher, until paid."

This interest provision is particularly useful in the event of audit results indicating underreporting. The statutory interest is determined by state law and varies from state to state. It is added to any award for damages or late payments. It is also a good idea to set the interest rate at an amount that emphasizes the importance of timeliness. Thus, consider using above market rates.

6. Be Specific About the Types of Documents Made Available During an Audit

All too often the only information a licensor receives from a licensee is a sales schedule and a summary showing how the royalties were calculated. Without access to the proper source documentation, it is difficult to verify the data and confirm the accuracy of the calculation. However, carefully worded clauses in the agreement that detail certain information that is to be submitted along with the periodic royalty payments can assist in monitoring the reasonableness of the royalty remittances. In other words, itemize within the agreement what information should be sent with the royalty payments, as well as the records that should be maintained or produced when a royalty audit is performed. An example of a type of clause that specifies information to be remitted with each royalty payment to the licensor might be:

> "Licensee shall prepare and deliver to Licensor a best estimate...itemizing licensing and distributing activity for the previous calendar month (or other defined period) and calculating the resulting royalties due and payable to Licensor..." Further, "itemizing" to include the number of customers, customer names, quantity distributed, description of products, and product number (stock

keeping units). [Also specify the receipt of reports to be in electronic format (diskette, platform specific etc.) as well as in hardcopy.]"

One possible clause identifying the records to be provided when an audit occurs might be:

"Licensee shall keep all records that permit auditors to ascertain the proper payments due as a result of [define the relevant transaction] and auditors shall have access to relevant records bearing upon the amount payable."

7. Perform an Audit in the First Period

It is strongly suggested that an audit be performed at the end of the first period in which royalty payments are made (period is left to be determined by the agreement, whether it be at the end of the month, quarter, or year). The main advantage in performing an audit at the end of the first period is that it establishes the protocol and expectations of the parties. All of the "gray" areas in the agreement are exposed and can be resolved early in the relationship. This leads to a mutual understanding throughout the term of the agreement. It can minimize disputes that might arise years later if an audit is performed many years into the agreement.

Also, the frequency of an audit depends on the size of the royalty payments. Unless there are significant royalty payments being made, the audits need not be performed more than once per year. In addition, there needs to be a cost benefit in having the audit performed. The audit plan can be tailored to ensure that the value attained from reviewing the financial records is commensurate with the size of the royalty payments. In general, though, the audits should be performed every two to three years, at a minimum.

Another consideration is how long the licensee will be required to maintain good records. Frequently accountants are asked to go in and "look at the numbers" several years after the fact. At that point, it is a much more difficult (and expensive) process.

In most cases, there has been no understanding of what records would be maintained and how the data would be organized. As a result, performing an audit becomes a more expensive and challenging task. In some cases, the source records are not maintained in a usable format that makes the audit effective. The data need to be reorganized. In other cases, the records have been destroyed due to record retention policies or, worse, simply cannot be found at all. The licensee's most common response is that they were never asked to keep the detailed data. Many of these problems could be eliminated had the audit been done at the end of the first period; that is, when the opportunity best exists to establish the standards and to outline how data are to be maintained and organized. In sum, if an audit is only going to be done once, do it at the end of the first period.

Conclusion

The drafting of license agreements can be a painstaking and time-consuming process that often focuses on how a relationship between the licensor and licensee should work. However, frequently the monitoring of the relationship is not addressed in sufficient detail to allow for the generation of detailed and accurate data that can be confirmed by third parties. Moreover, the identification of these problems often does not occur until several years after the agreements have been in place. This makes it much more difficult to perform an accurate verification of the amounts. Inclusion of specific and detailed audit clauses can help minimize the headaches and misunderstandings down the road, allowing both parties to focus on the real mission of the agreement: maximizing the profitability to both the licensor and licensee.

Biotechnology: From Enablement to Infringement

David L. Parker*

Introduction

The Federal Circuit has been very active in deciding biotechnology patent issues for almost a decade, and we can now see some clear trends developing in a wide variety of issues, ranging from prior art considerations to those of enablement and utility, as well as inequitable conduct, inventorship, and infringement, to name a few. While there are certainly exceptions, the general trend of these cases has been to hold biotechnology inventions to a strict disclosure standard, both for patentability and for infringement purposes. Yet, where the inventive contribution is properly framed by the claim—where the scope of the claim is reasonable in light of what was accomplished by the inventors—the cases show a tendency to uphold patentability over the prior art.

This article is intended to be a general introduction for non-patent practitioners to a few of the issues prevalent in biotechnology cases. Certainly, the overriding theme characterizing these cases is that the inventions deal with subject matter that is inherently "unpredictable," and are thus held to a relatively strict patent application disclosure standard. In a number of cases, biotech patent claims have been

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invalidated, or found not entitled to a certain filing date, on the basis of "overbreadth" of the claims. Yet, even where biotech claims are found to be enabled, they have sometimes been interpreted narrowly for literal infringement purposes. In the *Genentech v. Wellcome* case discussed below,[1] the Federal Circuit overturned a jury verdict of infringement on the basis that no reasonable jury could have found infringement.

Another trend in the cases, with some exceptions, is the general tendency of the courts to uphold biotech inventions in cases involving obviousness challenges. In these cases, again due to the perception that the technology is "unpredictable," it is often the prior art that is held to a high standard. This is not particularly surprising: the "obvious to try" doctrine holds that an invention is not "obvious" merely because it might have been "obvious to try." To find such an invention obvious, it must also be shown that the invention would have been readily achievable by the ordinary worker in the field.[2] The more unpredictable the science, the less ability there is to show that the invention was readily achievable (i.e., that a "reasonable expectation of success" existed).

Yet, there have been notable exceptions to the general trends. For example, the Patent Statutes provide that a patent to a particular process for preparing a product covers the product of that process (35 U.S.C. § 271(g)). In a case involving the practice of a biotech process claim overseas, the Federal Circuit has found infringement based upon the importation of a subsequent product not directly set forth in the claim. Furthermore, in a pharmaceutical case involving a rejection that the invention was not sufficiently demonstrated to be "useful," the Federal Circuit has issued a strong opinion reaffirming the requirement that the Patent and Trademark Office (PTO) accept applicants' laboratory evidence of utility absent a reasonable, scientific basis for doubting the veracity of the disclosure.

The Enablement Standard in Biotechnology Cases

The courts' strict treatment of biotechnology patents in terms of enablement are generally founded in the 1991 case of *Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd.*,[3] which has had far reaching implications in almost all subsequent biotech cases in a number of respects. The *Amgen* court invalidated Amgen's claims directed to DNA segments that purported to cover essentially any gene that would encode a particular hormonal "activity," in this case the hormone erythropoietin (EPO), which stimulates red blood cell production. The court reasoned that such claims were generic in scope, yet the specification contained "little enabling disclosure of particular analogs and how to make them." The Court concluded that "...Amgen has claimed every possible analog...with a disclosure of only how to make EPO and a very few analogs."

The general principle of overbreadth as a basis for invalidity has been applied by the Federal Circuit to a number of other areas of biotechnology well beyond DNA sequences. For example, the case of *In re Wright* involved claims directed to processes for making and using antiviral vaccines, which would encompass vaccines against HIV.[4] The court held these claims invalid because the patent specification included only one working example of a vaccine for chickens against a single strain of avian virus. In *In re Goodman*, claims directed to the recombinant production of proteins in any plant were invalid in light of evidence that the recombinant production was not possible in all plants by the particular techniques disclosed.[5] Similarly, in *In re Vaeck*, claims directed to the use of "cyanobacteria" in general for the recombinant production of proteins were invalid where the patent specification disclosed only one strain of cyanobacteria.[6]

The application of these Federal Circuit tenets of enablement by the district courts is perhaps best exemplified by a recent decision out of the District of Delaware, *Enzo Biochem Inc. v. Calgene, Inc.* (depublished).[7] The *Enzo* case involved an

infringement action brought by Enzo asserting that Calgene's FLAVR SAVR™ tomatoes incorporated genetic "antisense" technology covered under Enzo's patents. The Enzo patents included broad claims that purported to encompass antisense technology in general, without regard to whether the technology was applied to bacteria or to higher organisms such as plants and animals. The court held these claims invalid on the basis that the patents' examples demonstrated the use of the technique only in the context of the bacterium *E. coli*, and that "undue experimentation" would have to be practiced to achieve antisense in cells other than the ones specifically described in the specification.

In *Enzo*, the court also considered whether Calgene's later patent claims to the use of antisense in plants were rendered unpatentable in light of the earlier Enzo work. Here, the court held that Calgene's claims were not obvious, for essentially the same reason—that the earlier work of Enzo did not demonstrate how one of skill could use antisense technology in the context of plants.

Other district courts have been similarly strict with respect to the enablement issue. The *Regents of the University of California v. Eli Lilly & Co.*[8] was an action brought by the Regents against Eli Lilly, for infringement of claims directed to gene sequences for human insulin. The Regents' patent included broad claims to insulin genes of "a vertebrate." Lilly attacked the validity of these claims, arguing that they were overbroad in that the patent specification disclosed only the rat insulin gene. It was argued, thus, that a specification based solely on the rat insulin gene could not enable and provide an adequate description for all such genes. The court concurred with Lilly's position, and held that isolation and characterization of an insulin gene from one member of a genus is not sufficient to support or enable claims to that of thousands of other species of the genus.

The *Eli Lilly* case is of interest from a general standpoint because of the severity with which the district court appeared

to deal with the Regents' patent, in finding the patent invalid, unenforceable, or not infringed on several distinct bases, some of which were very suspect. For example, in a somewhat strange holding, the court found that the Regents' failure to advise the Patent and Trademark Office that the inventor had employed a genetic engineering technique that was not approved by the National Institutes of Health constituted inequitable conduct. The basis for such a holding is unclear.

The Federal Circuit, in a recently issued decision, affirmed the Indianapolis district court's holding that the Regents' patent could not validly cover the human insulin genes.[9] The opinion appeared to suggest that since the nucleotide sequence of the human insulin gene was not known, and the specification only disclosed the rat insulin gene, then claims that generically cover the human gene were not adequately described.

The Federal Circuit, as expected, reversed the district court's holding of patent invalidity on the basis of inequitable conduct. The court reasoned that the researcher's use of an unapproved technique was irrelevant to any issue of patentability, and thus could not form a basis for a charge of inequitable conduct.

The case that may best characterize the Federal Circuit's present stance on enablement in relation to biotechnology patents is the recent decision in *Genentech, Inc. v. Novo-Nordisk.*[10] In *Novo-Nordisk*, the court took what appears to be the unprecedented step of finding Genentech's patent invalid on enablement grounds in an appeal of the district court's entry of a preliminary injunction. The district court held on the issue of Novo-Nordisk's infringement of Genentech's patent to human growth hormone fusion gene constructs, that it was likely that Genentech would prevail at trial, and entered a preliminary injunction in Genentech's favor. Novo-Nordisk appealed the preliminary injunction and succeeded not only in overturning the injunction, but also in having Genentech's patent held invalid for lack of enablement.

Infringement in Biotech Cases

The principles underlying the *Amgen* case and its progeny have also had a significant impact on the infringement issue in biotech cases. This is best seen in the various Genentech litigations involving the drug tissue plasminogen activator (tPA), which is a naturally occurring enzyme for dissolving blood clots. Genentech scientists had prepared recombinant tPA by genetic engineering techniques through the isolation and manipulation of the tPA gene.

In *Genentech v. Wellcome Foundation Ltd.*, the district court, in a summary judgment context, considered the scope of Genentech's claims to a "DNA sequence encoding human tissue plasminogen activator."[11] The defendant Wellcome's tPA differed slightly from naturally-occurring tPA in that it had a different amino acid at a single position (out of several hundred amino acids). The court held that even though Genentech's claims did not specify a particular tPA sequence *per se*, they were nevertheless limited to the sequence of natural human tPA and thus did not literally cover the Wellcome product.

The foregoing tPA case was subsequently allowed to go to the jury for a determination of infringement under the doctrine of equivalents, and a verdict of infringement was handed down by the jury. While Genentech and Wellcome ultimately settled (with Wellcome agreeing to discontinue its proposed plans to market its tPA product in the United States), an appeal was lodged by a second defendant, Genetics Institute. Genetics Institute had developed its own tPA product, which contained fairly substantial modifications relative to natural tPA. At trial, the jury had also found that the modified tPA of Genetics Institute infringed Genentech's patent.

On appeal, the Federal Circuit construed Genentech's "human tPA" DNA claims to be limited to naturally occurring human tPA, and could not cover Genetic Institute's modified tPAs, and overturned the jury's verdict.[12] The court relied in part on what

it found to be conflicting definitions for "human tPA" in the specification, which was said to reflect either "inartful drafting," "a conscious attempt to create ambiguity," or a "desire to claim a wide variety of materials not described or enabled." With respect to the jury verdict, the court found that no reasonable jury could have found that the modified tPA of Genetics Institute performed "substantially the same function," in that certain key biological parameters were missing in the modified material.

It is perhaps of some note that the Genentech human tPA patent specification contained significant disclosure on how one of skill could modify the tPA gene and still obtain a biologically active tPA molecule other than natural human tPA. However, the Genentech specification did not disclose the particular modification found in the Genetics Institute material, nor did it disclose the modified biological function of this material.

Conception and Reduction to Practice

The lack of predictability of the biotechnological sciences has also played a significant role in issues of prior inventorship and reduction to practice. The *Amgen* case is again the principal precedent, but for a slightly different set of facts. In *Amgen*, the issue arose whether Amgen's claim to recombinant EPO had been earlier invented by scientists of another company. The other scientists appeared to have the idea of genetically engineering the EPO gene earlier than the Amgen inventors, and had what later turned out to be a workable plan for achieving the invention. Yet, it was Amgen scientists who first actually achieved the isolation and sequence characterization of the EPO gene. The court held that the other scientists did not know the actual sequence of the specific gene that was disclosed and claimed, the human EPO gene. It was not until the technique was actually carried out by Amgen scientists, and the resultant molecule adequately characterized—i.e., when the invention was actually reduced to practice—that there occurred an adequate conception "of the complete and operative invention."

This theme was carried forward in the case of *Fiers v. Sugano*,[13] which was a "first to invent" contest in the Patent and Trademark Office (i.e., an "interference") involving three parties vying for a patent to the genetically engineered pharmaceutical "interferon" prepared by recombinant DNA technology. In *Fiers*, the court held that the "invention" of a DNA sequence does not occur until detailed chemical structure of DNA sequence coding for a specific protein, along with the method of obtaining it, has been envisioned. Where such detailed definition of the chemical entity is absent, the invention is not achieved until reduction to practice has occurred, that is, until after the gene has been isolated. The court further opined that definition of a chemical substance merely by its functional utility is not enough to achieve complete and operative conception of the invention.

In both *Amgen* and *Fiers*, the court appeared to leave open the question of just how much characterization of a biotech molecule must be shown for a reduction to practice to occur. For example, the *Amgen* court noted that the claimed molecule must be sufficiently characterized in order to adequately describe the invention and distinguish it from the prior art. Since the Amgen scientists had fully characterized the molecular structure of the particular EPO gene, that was found adequate evidence of reduction to practice of the claimed sequence. Nevertheless, the court suggested that something less than full characterization might be adequate under certain circumstances. The claim in *Fiers* also involved a DNA molecule, and the court there held that conception and reduction to practice required determination of the underlying chemical structure of the gene. Yet, the court observed in passing that it was not considering whether a product-by-process claim could be earlier reduced to practice through a showing that the inventors possessed a process that would later prove to be operative in achieving the claimed product, irrespective of its chemical structure.

The district courts and, indeed, a more recent Federal Circuit opinion, have tended to apply the *Fiers* and *Amgen* holdings

strictly, generally finding that a detailed characterization of the invention must be made in order for a conception and reduction to practice to occur. In *Chiron Corporation v. Abbott Laboratories*,[14] the Northern District of California, in vacating and reversing its own earlier "tentative" opinion, held that Abbott's earlier, less detailed characterization of a DNA sequence did not anticipate Chiron's claim to the actual chemical structure of the DNA in question. The court found that the uncertainty surrounding the ability to make use of such an invention was very high, absent specific sequence information.

More recently, in *Schendel v. Curtis*, the Federal Circuit considered this issue in yet another case involving a claim to a "fusion" protein formed by "fusing" the genes of two distinct proteins.[15] In *Schendel*, the court held in favor of the senior party to an interference based upon the failure of the junior party to make a *prima facie* showing of prior invention. The junior party had submitted declarations that purported to show that the molecules had indeed been prepared prior to the operative date. Yet, the court found Schendel's proofs to be inadequate as they had not actually determined the sequence of the fusion protein prior to the operative date.

Inventorship

Closely allied to the issue of conception and reduction to practice is that of inventorship, in that inventorship is said to arise out of an individual's contribution to the conception of the invention. An interesting question is whether an individual is an inventor if that person is only involved in the reduction to practice of a biotechnological invention. It is often the case that scientists contribute their expertise in the form of testing for the activity of a compound, or putting a particular procedure into practice. These are activities that, in a predictable field such as mechanical inventions, would be considered contributing to a "reduction to practice," but would likely not rise to the level of inventorship. However, the question arises whether these

activities would be considered "inventive" if performed in an "unpredictable" art such as biotechnology or medical pharmacology.

In *Burroughs Wellcome v. Barr Laboratories*, the Federal Circuit had occasion to consider the issue of inventorship in an unpredictable technology.[16] The facts are of particular interest: Barr Laboratories sought to produce a generic form of AZT, the anti-HIV drug marketed by Burroughs Wellcome. The Burroughs Wellcome patent in question was directed to a process of inhibiting HIV replication by administering an effective amount of AZT to an HIV patient. Note that product claims were not available to Burroughs Wellcome due to the fact that the AZT drug had been known for years as a possible anti-cancer agent. Rather, the patent was based upon the alleged discovery by Burroughs Wellcome scientists that AZT had anti-HIV activity in preclinical testing.

Barr Laboratories undertook an investigation which suggested that the Burroughs Wellcome scientists had been aided in their discovery by scientists from the National Institutes of Health. The NIH scientists had developed a particularly useful technique for screening for anti-HIV activity, and had carried out most of the actual anti-HIV testing of the AZT. Rationalizing that conception was not complete until an actual reduction to practice had occurred, and the fact this did not occur until the active compound was identified from among many others by the NIH scientists, Barr reasoned that the NIH scientists should have been named joint inventors of the AZT treatment method along with the Burroughs Wellcome inventors. From this, Barr reasoned that the NIH was an equitable owner of the AZT invention, and obtained a license to practice the invention from the NIH.

This was all to no avail. The Federal Circuit affirmed the district court's finding that the NIH scientists were not joint inventors, holding that the invention had been shown earlier by Burroughs Wellcome scientists to have some promise as an

anti-retroviral agent in somewhat rudimentary studies prior to sending the AZT and other compounds to the NIH for testing. Notably, though, the court appears to have left open the question of joint inventorship by a "testing" party where no prior studies are carried out by the named "inventors." This holding, at first study, appears to be at odds with the *Amgen* and *Fiers* cases. It suggests that a conception could be achieved in an unpredictable science prior to the invention being sufficiently tested to be reduced to practice. Perhaps the better reading of *Burroughs Wellcome* is that when invention is achieved is a question that will always turn on the facts, and courts should not be tied to any hard and fast rules. Under the facts of this particular case, the Burroughs Wellcome scientists had sufficient information that AZT could serve as an anti-retroviral to constitute conception prior to the NIH testing.

Non-Obviousness of Biotech Inventions

The flip side of unpredictability of biotech inventions is the tendency of courts to find these inventions non-obvious. Yet, there have been (and continue to be) many hard-fought battles related to obviousness in the prosecution of biotechnology applications in the Patent and Trademark Office. Two of the most significant are set forth below.

One of the more interesting patentability questions raised in biotechnology involves the patentability of genes and their corresponding protein products. In part, this stems from a rather unique situation where the character strings that represent a protein and its gene are integrally related, but completely distinct on a physical basis. A gene, which is made up of nucleic acid bases (adenine, guanine, cytosine and thymidine), encodes a given protein. The bases are grouped in consecutive triplets, or codons, with each codon identifying an amino acid in the encoding protein. Thus, a gene with 300 bases will encode a protein having 100 amino acids. Interestingly, there are 64 different codons (4^3), but only 24 amino acids. Thus, some amino acids are encoded by up to six different

codons, where other amino acids have a unique codon. Thus, while the possession of a DNA sequence will allow an exact deduction of the corresponding protein sequence, the possession of a protein sequence only permits an educated guess at the corresponding DNA. In this context, the cases of *In re Bell*[17] and *In re Deuel*[18] arise.

In *Bell*, the patent applicant claimed the natural coding sequence for two human proteins, insulin-like growth factors I and II (IGF I and II). The entire protein sequence for these molecules was known, but the genes had not yet been cloned (isolated in a discrete and reproducible form) or sequenced. Bell sought to claim the sequenced genes and certain fragments that would hybridize thereto. The examiner rejected the claims as obvious over the protein sequences *per se*, which were known, and also over general references that would show how to use these proteins to design reagents and then go about isolating the genes themselves.

On appeal, the Federal Circuit did not adopt either of these positions, arguing that the structure of the *naturally-occurring* genes for IGF I and II could not have been predicted with only the knowledge of the protein sequence. Though a gene *could* have been modeled that would code for either IGF I or II, *the claimed gene* was only one of 10^{36} such possibilities. The Court found that a claim to the particular DNA sequence could not have been obvious, given these odds.[19]

More recently, the Federal Circuit has had occasion to consider the obviousness of a DNA sequence in a case involving slightly different facts. In *In re Deuel*, the claimed invention concerned any DNA coding for a particular protein, and was not limited to a specific DNA sequence as in *Bell*. During patent prosecution, the examiner rejected the claims as obvious over references that discussed, in general, how one could proceed to isolate the gene. Yet, the Federal Circuit strongly reaffirmed, and indeed broadened, the underlying message of *Bell*. The *Deuel* court found that merely because a particular protein is

known and has been characterized, does not in itself obviate claims to DNA sequences that code for the protein.

Nevertheless, there are some notable exceptions to the general tendency of the courts to find biotech inventions non-obvious. In an early biotech case, *In re O'Farrell*, concerning the obviousness of basic gene expression technology, the Federal Circuit held the invention unpatentable over the inventors' prior related publication.[20] The inventors' prior publication was found to detail the basic invention. It was conjectured at the time that the *O'Farrell* case came out the way it did partly due to the fact that the relevant prior art was an earlier publication by the inventors. More recently, in an "unpublished" opinion,[21] the Federal Circuit has again held a biotech invention obvious on the basis of the existence of a reasonable expectation of success.[22] As in *O'Farrell*, one of the prior art publications (a U.S. patent) was authored by a named inventor.

Utility and Enablement

One of the most difficult aspects of obtaining patent protection for biotechnology inventions is the demonstration, to the PTO's satisfaction, that the invention will function as claimed. Throughout the late 1980's and early 1990's, this rejection was advanced under the rubric of utility, as codified in 35 U.S.C. §101, which states that an invention must be "useful." Historically, utility has meant that the applicant need only show some use for the invention, no matter how minimal, and utility rejections have been reserved for those inventions that are considered incredible or unbelievable to the person of skill in the field. For example, perpetual motion machines have long been considered unpatentable based on the natural laws of physics.

In 1995, the Commissioner promulgated guidelines for review of utility in biotechnology cases. Some considered these guidelines to place a significant new burden on the examiner in making out a *prima facie* case of no utility. Most felt, instead,

that the standard set forth in the Commissioner's guidelines had been established long ago by case law developed in the 1960's and 1970's, when the utility of many pharmaceutical inventions was argued in front of the Court of Customs and Patent Appeals (CCPA). In any event, the guidelines clearly were at odds with the current practice, and the examiners were faced with the prospect of allowing many cases they believed to be overly prospective.

In an attempt to circumvent the new guidelines, the examining corps turned its attention to the first paragraph of 35 U.S.C. §112. The "enablement requirement" of this statue requires, in part, that the patent specification teach one of skill in the art how to "make and use" the claimed invention. Examiners latched on to this language and began advancing an "enabling use" rejection under §112 that they deemed to be free of the constraints of the Commissioner ' s *utility* guidelines. Though the issues presented by utility and enablement can merge, they can be quite distinct as well. Most examiners, when a rejection under §112 is challenged on the basis of usefulness, simply proclaim that the rejection is not based on §101, and comments regarding utility are inapposite. Unfortunately, much of the time utility *is* the real issue and it is difficult to make any headway without being able to invoke the relevant case law.

This practice came to a head in the case of *In re Brana*.[23] In *Brana*, the appeal involved claims directed to antitumor pharmaceutical compounds. According to the examiner and the Board of Appeals, these claims were unpatentable under §112, first paragraph. The examiner stated that the specification failed to state any specific disease against which the compounds were active and that the testing disclosed did not establish that the compounds had a practical utility. Though noting that the same rejections also could have been advanced under §101, the Board affirmed the rejection solely on §112 grounds.

The Federal Circuit opened by noting that the Commissioner's guidelines relating to utility are applicable to §112, first

paragraph rejections, when the issue is really one of utility. Next, the panel refuted the examiner's contention that there was no treatable disease disclosed, pointing out that testing for activity against tumor cells lines was a clear statement that treatment of related tumors *in vivo* was contemplated. Finally, the opinion provided a long recounting of the evolution of the law regarding the use of animal models to establish utility/enablement. Included in this portion of the opinion are the clear statements that (i) the PTO has a burden to show *prima facie* that utility should be questioned *before* any testing is required; (ii) animal models may obviate clinical results in many cases; and (iii) FDA approval is based on factors distinct from patentability and, therefore, constitutes a much higher showing than that required under §101 and §112.

The Scope of Product-by-Process Claims

Biotech cases have generally been thought by non-biotech patent practitioners to be on the "fringes," perhaps with some justification. For example, in 1991, the Federal Circuit held in the case of *Scripps Clinic and Research Foundation v. Genentech, Inc.,*[24] that claims set forth in product-by-process format were not limited in their scope to products actually made by the process specified in the claim. The claims at issue in *Scripps Clinic* were directed to a human blood clotting factor, purified from natural sources by a very detailed and specific isolation process from human plasma. Nevertheless, the court held that these claims literally covered the human blood clotting factor made by an entirely different genetic engineering process that did not involve isolation from plasma.

Yet, just a few months later, another Federal Circuit panel, sitting in a non-biotech case, held that claims to a shoe innersole made by a particular process did not cover indistinguishable shoe innersoles made by an admittedly different process.[25] The *Atlantic Thermoplastics* panel refused to follow the earlier holding of the *Scripps Clinic* panel, finding that the earlier panel failed to consider relevant Supreme Court

precedent. A motion to rehear *en banc* was denied, in a close vote, with vigorous dissents filed by a number of Federal Circuit judges that characterized the failure to follow the *Scripps Clinic* holding as "heresy."[26] Curiously, though, one judge's dissent impliedly sought to distinguish the *Scripps Clinic* decision as being based upon the peculiarities of biotechnology.

Nevertheless, most of the holdings that deal with biotechnology issues are being decided upon more traditional precepts of chemical patent law practice. The overriding theme that pervades most biotech cases is the supposition that biotechnology subject matter, like chemical subject matter, is in general highly unpredictable. It is this fact, rather than some unique characteristic of biotechnology, that forms the basis of the developing case law in this area, and it is this fact that indicates the relevancy of biotech case law in any case where the subject matter is unpredictable. This has led to a large number of decisions that have tended to hold biotech inventors to a very strict disclosure standard, and limit the scope of biotechnology-related claims to what was actually accomplished by the inventors. However, due to the presumed "unpredictability" of biotech inventions, there has also been a general tendency of the courts to find that biotech claims, where properly limited, are directed to non-obvious subject matter.

Infringement Under the "Product-by-Process" Provisions of the Patent Statutes

The Federal Circuit has recently issued an opinion, in *Bio-Technology General Corporation v. Genentech Inc.*,[27] that is believed to be the first decision to construe the scope of infringement under the so-called "product-by-process" provisions of the Patent Statutes. (35 U.S.C. § 271(g)). Under this statute, process patents are given product coverage over products that are made by the patented process, to the extent that such products are not *materially changed by subsequent processes* and not simply a trivial or non-essential component.[28] There has

been some uncertainty over the effect that the two exclusions would have on the infringement issue, particularly in the context of biotech inventions, where there is the real possibility of post-process modification of the product.

In the *Bio-Technology General* case, the Federal Circuit somewhat surprisingly construed the "product-by-process" provisions broadly. One of the process claims at issue involved a process for preparing a type of DNA segment ("a replicable cloning vehicle," i.e., a recombinant plasmid) that was capable of producing human growth hormone ("hGH"). The defendant, BTG, admittedly practiced this process in Israel, then used the DNA segment in Israel to prepare quantities of human growth hormone that were subsequently modified and imported into the United States. The defendant argued that since the claim was directed to making of a DNA segment (plasmid), and it was in fact the protein hGH that was imported, there could be no infringement under the product-by-process provisions.

The Federal Circuit upheld the entry of a preliminary injunction by the Southern District of New York,[29] and on the basis that the preparation of the hGH cloning vehicle was an "essential part of the overall process for producing hGH." This is a broad reading indeed, particularly in that a cloning vehicle is, in terms of chemical composition, a polymer of nucleic acids, whereas the hGH protein is a quite distinct polymer of amino acids. While the two are related functionally and biologically, there is no relationship either chemically or structurally. It appears from the opinion that the court recognized that the literal language of the statute was inadequate to precisely cover the situation, yet the legislative history included language that anticipated the precise scenario.[30]

Conclusion

In conclusion, clear trends are developing in the biotech case law, with the courts emphasizing the need to frame claims more precisely to the actual disclosure. The courts have shown a

general unwillingness to extend the claims beyond the examples set forth in the specification, where there is no ready ability to show that one of skill would have been enabled to arrive at the subject matter of the claim at its broadest interpretation, without undue experimentation. This tendency has manifested itself both in the context of enablement and infringement. Yet, where biotech claims are properly framed and supported by the disclosure, the courts have shown a willingness to uphold their validity in the face of a prior art challenge.

NOTES

1. *Genentech, Inc. v. Wellcome Foundation Ltd.*, 29 F.3 1555, 31 U.S.P.Q.2d 1161 (Fed. Cir. 1994).

2. *In re O'Farrell*, 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988).

3. 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

4. 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993).

5. 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993).

6. 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

7. Case No. 93-110-JJF (D. Del. Feb. 2, 1996); The opinion has been withdrawn by the Court upon motion by Calgene, who requested that certain matters be clarified in the opinion.

8. 39 U.S.P.Q.2d 1225 (D. Ind. 1995).

9. *Regents of the University of California v. Eli Lilly Co.* ___F.3d___, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

10. 108 F.3d 1361, 42 U.S.P.Q.2d 1001 (Fed. Cir. 1997).

11. 14 U.S.P.Q.2d 1363 (D. Delaware 1990).

12. *supra* note 1.

13. 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993).

14. 902 F.Supp. 1103 (N.D. Cal. 1995).

15. 83 F.3d 1399, 38 U.S.P.Q.2d 1743 (Fed. Cir. 1996).

16. 40 F.3d 1223, 32 U.S.P.Q.2d 1915 (Fed. Cir. 1994).

17. 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993).

18. 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995).

19. Bear in mind, though, that although the Bell claims were found to be patentable, they were narrowly drawn to a specific DNA sequence.

20. *Supra* note 2; The *O'Farrell* court set forth the now-standard tripartite test for determining whether a prior art reference(s) can properly form the basis of an obviousness rejection, including whether the reference(s) contain (1) detailed enabling methodology for practicing the invention, (2) a suggestion to modify the invention in the manner claimed, and (3) a reasonable expectation of success.

21. Federal Circuit opinions are "unpublished," and therefore not citable as legal precedent, if the Court concludes that the opinion would not add to the existing "jurisprudence," i.e., if it is "old hat."

22. *In re Nunberg, supra* note 3.

23. 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

24. 927 F.2d 1565, 18 U.S.P.Q.2d 1001, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991).

25. *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 23 U.S.P.Q.2d 1481 (Fed. Cir. 1992).

26. *Atlantic Thermoplastics*, 974 F.2d 1299, 24 U.S.P.Q.2d 1138 (Fed. Cir. 1992).

27. 80 F.3d 1553, 38 U.S.P.Q.2d 1321 (Fed. Cir. 1996).

28. Section 271(g) provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent...*A product which is made by a patented process will*, for purposes of this title, *not be considered to be so made after—*
>
> (1) *it is materially changed by subsequent processes*; or
>
> (2) it becomes a trivial or non-essential component of another product.
>
> 35 U.S.C. § 271(g) (emphasis added).

29. See 36 U.S.P.Q.2d 1169.

30. 38 U.S.P.Q.2d at 1327.

Induced Investments and Jobs Produced by Exclusive Patent Licenses — a Confirmatory Study

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ABSTRACT

In 1995, Pressman et al. (1) analyzed the investments induced by the exclusive, active, patent licenses of technologies discovered at the Massachusetts Institute of Technology (MIT) before the commercialization of products resulting from the technologies. They concluded that these induced investments averaged $0.98 million for every year of each license and exceeded license revenues received by MIT by a factor of 24. We have replicated such a study of induced investments using the exclusive, active, patent licenses of technologies discovered at the University of Pennsylvania (Penn). Using this information we have determined that the induced investments averaged $0.93 million for every year of each license and exceeded the license revenue received by Penn by a factor of 33. Biotech start-up companies represent a significant fraction of the induced investments averaging $2.75 million for every year of each license (compared to MIT's average of $3.16 million). The similarity of these results supports the overall approach and conclusions of the work of Pressman et al. We found that Penn's 43 exclusive, active, patent licenses generated $151

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million in induced investments and created 242 full-time jobs. Extrapolating these results to all universities in the United States using the most recent data from the Association of University Technology Managers (2) suggests that in 1995, university licenses induced investments of $4.6 billion and created 27,000 jobs in research and development towards the commercialization of university research results.

INTRODUCTION:

Universities license research results to induce closer ties to industry, attract industrial research funding, provide employment opportunities for graduates, facilitate commercialization of technology for the public good, and generate income (3). The Center for Technology Transfer (CTT) at the University of Pennsylvania obtains and manages the intellectual property assets of the University. CTT's strategy is to use patents and licenses as tools to turn research results into research dollars in the short-term, and generate income from fees, patent reimbursements, equity, and royalties from the commercialization of patented and licensed technologies in the long-term. The basis for academic-industry technology transfer is the Bayh-Dole Act of 1980 (Public Law 96-517) and numerous subsequent congressional and executive orders that granted universities title to inventions conceived and developed with federal research funding. The Bayh-Dole Act was intended to promote investment by the private sector in the commercialization of federally funded basic research discoveries for the public good. Such investment and subsequent commercialization are enabled by securing intellectual property rights and granting licenses to commercialize products based on those rights. In addition to products and processes, university technology transfer has significant positive growth impact in the U.S.; companies are induced to invest in developing, manufacturing, and marketing products based on academic discoveries licensed to them. These private sector investments create jobs and economic growth. Measurements of companies'

induced investment in commercialization indicate that such induced investment far exceeds university license revenues in the near term.

ECONOMIC IMPACT:

Technologies discovered at universities contribute to economic growth both before and after the commercialization of products made possible by these technologies. Post-commercialization, the economic impact can be considered to be associated with the sales revenue generated by such products. Post-commercialization economic impact can be estimated through the royalty revenues generated by licenses to university technologies (4).

Royalty income from product sales does not indicate the pre-commercialization economic impact of licensed university technologies. In 1995, Pressman et al. reported a methodology to determine the economic impact of university licenses by calculating the investment in research and development induced by the licenses of MIT. This "induced investment" method can be used as a measure of the pre-commercialization impact of university technology licensing on the economy.

We have taken the approach developed by Pressman et al. and applied it to the exclusive, active, patent licenses of Penn technology. Our analysis supports the findings that induced investment significantly exceeds license revenues (by a factor of 33 at Penn compared to a factor of 24 at MIT) and that, on average, about $1 million of induced investment ($0.93 million at Penn, $0.98 million at MIT) is generated per year for every exclusive, active, patent license. The quantitative similarity of these results supports the induced investment methodology as a useful approach to evaluating the economic impact of university licensing efforts prior to product commercialization.

METHOD:

We followed the method reported by Pressman et al. Data were collected in the summer of 1996. Questionnaires were sent to 40 licensees associated with Penn's portfolio of 43 exclusive, active, patent licenses. Initial responses and follow-up telephone calls resulted in usable data on 24 of the 43 licenses (9 of the 18 physical sciences licenses and 15 of the 25 biotech licenses). We analyzed these responses as our sample group and extrapolated results to the entire group of licenses.

The questionnaires asked each licensee for information relating to those investments that were made in conjunction with the development of the licensed technology and to the number of research and development jobs associated with the further development of the licensed technology. We used internal information to determine both the age of each license and the revenues received by Penn from the licensee. Additionally, we used our knowledge of each licensee to classify the company as either a start-up venture predominantly focused on developing the licensed technology, a small company developing multiple technologies, or a large company (over 500 employees).

The start-up companies, and particularly the biotech start-ups, generated more induced investment than the other types of companies. Therefore, the MIT group chose to analyze separately each technology category (i.e., physical sciences or biotech) and each company category (i.e., start-up, small, or large). The information on each of these groups was used to extrapolate from the sample group to the entire group of licenses. We followed this approach.

RESULTS:

Table 1 (physical sciences sample) and Table 2 (biotech sample) summarize the results according to company category. The physical sciences sample represented 9 of 18 exclusive,

active, patent licenses and consisted of 4 start-ups, 4 small companies, and 1 large company. The biotech sample represented 15 of 25 licenses and consisted of 11 start-ups, 2 small companies, and 2 large companies.

Table 1	Physical Sciences Sample			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	9	4	4	1
Avg. Age of License in Years	3.9	3.4	3.8	6.2
Induced Investment	$11.6M	$7.7M	$1.2M	$2.7M
Induced Investment per License-Year	$0.33M	$0.56M	$0.08M	$0.44M
Full-Time Equivalent (FTE) Employees	41	25	13	3

Table 2	Biotech Sample			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	15	11	2	2
Avg. Age of License in Years	3.3	3.2	4.0	3.6
Induced Investment	$103.3M	$96.9M	$2.0M	$4.5M
Induced Investment per License-Year	$2.09M	$2.75M	$0.25M	$0.63M
Full-Time Equivalent (FTE) Employees	129	118	3	8

A total of $115 million in induced investment was associated with the 24 licenses in the two samples. The biotech start-ups represented 84% of the total induced investment but only 46% of the licenses and 41% of the license-years. Because of the differences in induced investment per license-year for each

technology and company category, as demonstrated by the biotech start-ups, it is helpful to create an independent accounting for the induced investment from each technology and each company category. To accomplish this, the induced investment was divided by the corresponding number of license-years to yield a scale factor of "induced investment per license-year" for each technology and company category. Note that the biotech start-up companies have a significantly higher induced investment per license-year ($2.75 million) than all other categories.

The data on research and development employees were approximated by many of the respondents. Some provided data spanning the life of the license while others provided the number of employees currently working on the licensed project. From the information provided on each questionnaire, we estimated the number of full-time equivalent (FTE) research or development employees currently working on the licensed project. A total of 170 FTE employees was reported by the 24 licensees. The biotech start-ups represented 69% of the FTE employees. To account for possible differences between groups, the number of FTEs was divided by the number of licenses to yield a scale factor corresponding to the average number of FTEs per license for each technology and company category.

The data associated with the sample group were extrapolated to the entire set of licenses using the scale factors derived for each technology and company category. The induced investment for all licenses in a group was determined from the induced investment per license-year for that group times the number of license-years in that group. The number of FTEs in a group was determined from the number of FTEs per license for that group times the number of licenses in that group. The results for the physical sciences licenses, the biotech licenses, and the combined licenses are shown in Tables 3, 4, and 5. The 18 physical sciences licenses created $30 million in induced investments and 76 FTE employees. The 25 biotech licenses

Table 3	18 Exclusive, Active, Patent Licenses Physical Sciences			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	18	6	6	6
Avg. Age of License in Years	4.6	4.0	4.3	5.4
Induced Investment	$30M	$14M	$2M	$14M
Full-Time Equivalent (FTE) Employees	76	38	20	18

Table 4	25 Exclusive, Active, Patent Licenses Biotech			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	25	12	6	7
Avg. Age of License in Years	3.3	3.1	3.6	3.2
Induced Investment	$121M	$102M	$5M	$14M
Full-Time Equivalent (FTE) Employees	166	129	9	28

Table 5	43 Exclusive, Active, Patent Licenses Physical Sciences and Biotech			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	43	18	12	13
Avg. Age of License in Years	3.8	3.4	4.0	4.2
Induced Investment	$151M	$116M	$7M	$28M
Full-Time Equivalent (FTE) Employees	242	167	29	46

created $121 million in induced investments and 166 FTE employees. The total induced investment was $151 million with $102 million of that (68% of the total induced investment) coming from the 12 licenses with biotech start-up companies (28% of the total licenses).

A total of 242 jobs was associated with this induced investment, with 129 of those jobs (53%) associated with the biotech start-up companies. If all 242 FTE employees were assumed to be working over the average age of each license (i.e., 76 FTEs times 4.6 years for the physical sciences licenses and 166 FTEs times 3.3 years for the biotech licenses) then there would be a total of 897 FTE-years associated with the $151 million in induced investment, corresponding to $168,000 in induced investment per FTE-year for each reported research employee. This value for induced investment per research employee exceeds the amount typically reported as a cost-per-employee. This difference may be a result of induced investment including expenditures not typically associated with the costs of a research employee. Alternately, this difference may be a result of a higher cost per research employee associated with biotech start-up companies, which represent a significant fraction of the induced investment in this study.

The induced investment created by these licenses can be compared to Penn's license revenue derived from these licenses. Tables 6, 7, and 8 list the license revenue (including license issue fees, license maintenance fees, patent reimbursements, and due diligence payments) received by Penn from the licensees for each company category for all of the physical sciences, biotech, and combined licenses. The ratio of induced investment to license revenue is also shown. Note that the induced investment is significantly greater than the license revenues for most groups and that, over the entire portfolio of licenses, the induced investment is 33 times the license revenue received by Penn.

Table 6	18 Exclusive, Active, Patent Licenses Physical Sciences			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	18	6	6	6
License Revenue to Penn (A)	$1.80M	$0.17M	$1.19M	$0.44M
Induced Investment (B)	$30M	$14M	$2M	$14M
Induced Investment per License-Revenue (B)/(A)	17	80	2	32

Table 7	25 Exclusive, Active, Patent Licenses Biotech			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	25	12	6	7
License Revenue to Penn (A)	$2.83M	$1.57M	$0.37M	$0.89M
Induced Investment (B)	$121M	$102M	$5M	$14M
Induced Investment per License-Revenue (B)/(A)	43	65	14	16

Table 8	43 Exclusive, Active, Patent Licenses Physical Sciences and Biotech			
	Total	Start-up Cos.	Small Cos.	Large Cos.
Number of Licenses	43	18	12	13
License Revenue to Penn (A)	$4.63M	$1.74M	$1.56M	$1.33M
Induced Investment (B)	$151M	$116M	$7M	$28M
Induced Investment per License-Revenue (B)/(A)	33	67	5	21

The sampling approach used in this survey differentiated the survey respondents from the survey non-respondents. Results from the respondents were used to calculate results for the entire group. To support this approach, it is helpful to compare various characteristics measured over the sampled group to those same characteristics measured over the entire group. Table 9 compares the average age of the licenses, the average license-revenue per license, and the induced investment per license-revenue between the sampled groups and the entire groups for the physical sciences, biotech, and combined groups. The relative agreement between the sampled group and the entire group supports our survey approach.

Table 9	Avg. Age of License		Avg. License-Revenue per License		Induced Investment per License-Revenue	
	Sampled Licenses	All Licenses	Sampled Licenses	All Licenses	Sampled Licenses	All Licenses
Physical Sciences	3.9	4.6	$101K	$100K	13	17
Biotech	3.3	3.3	$140K	$113K	49	43
Combined	3.6	3.8	$125K	$108K	38	33

Outliers in the sampled data could adversely affect the ability of the sample to be used to predict the results of the entire group. The induced investment per license-year for each of the sampled licenses is shown in Figure 1, which is sorted according to increasing induced investment per license-year. Note the relatively smooth distribution of induced investment per license-year over a wide range of values, rather than some small fixed value for induced investment per license-year with multiple outliers. The two licenses with the greatest induced investment per license-year are both biotech start-ups. Were they removed from the sample, along with the two biotech start-ups with the

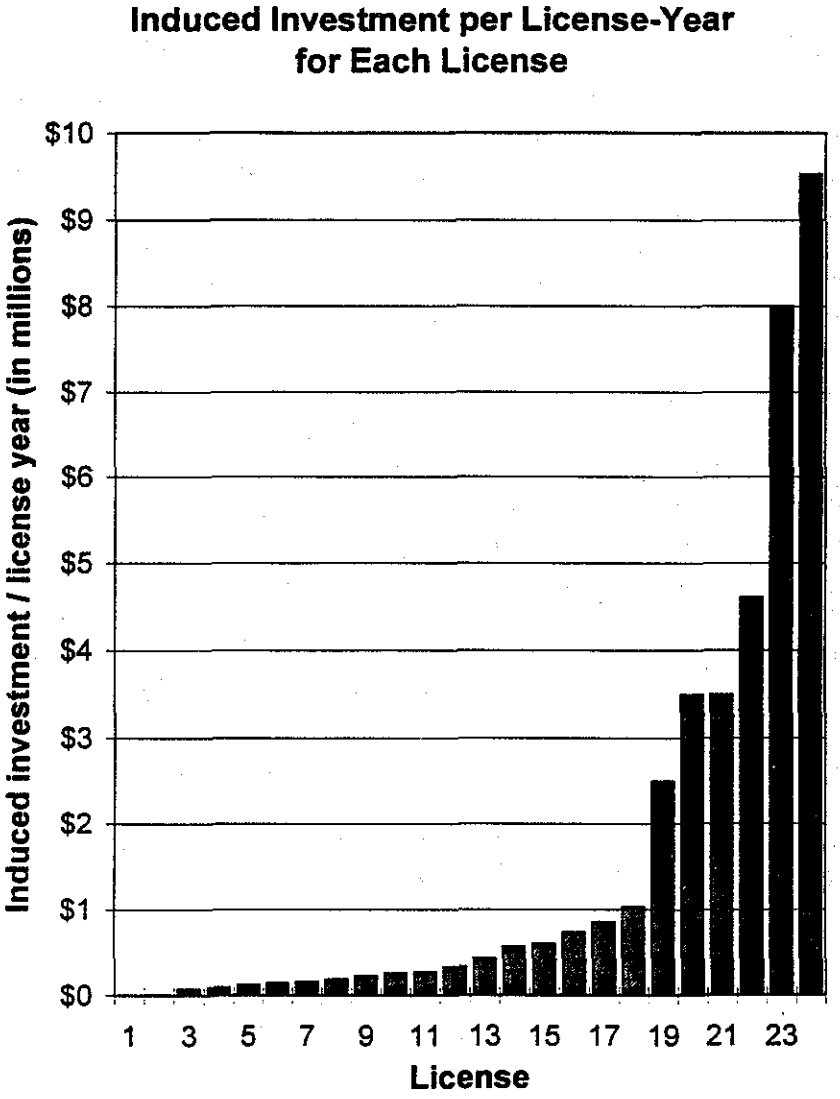

Figure 1. Induced Investment per License-Year for Each License. The licenses were sorted according to increasing ratio to evaluate whether any license is an outlier. Only the highest two values appear to be possible outliers in what otherwise is a uniform distribution.

lowest value, the induced investment per license-year for biotech start-ups would be reduced from $2.75 million to $1.62 million. This reduction in induced investment indicates that this type of analysis is sensitive to the "home-runs" in the portfolio of start-up companies—those ventures that have been sufficiently successful in raising capital to fully invest in developing the licensed technology. Nevertheless, we do not consider that change in induced investment per license-year indicative of an outlier bias in the sampled licenses. To the contrary, we believe that the smooth distribution of Figure 1 indicates that there is no outlier in the sampled licenses.

The induced investment per license-revenue for those licenses included in the samples is shown in Figure 2, which has been sorted according to increasing induced investment per license-revenue. Two of the licenses did not generate any license revenue, resulting in an arbitrarily large ratio (not graphed in Figure 2). These two licenses are not considered outliers. One license generated significantly more induced investment than license revenue, with a resulting ratio of 470. This license is one of the "home-run" biotech start-up ventures considered as an outlier above. Removing this one license from the entire set of licenses would reduce the ratio of induced investments per license-revenue from 33 to 20, indicating some sensitivity to this outlier, and would bring the results from this study even closer to the results from the MIT study.

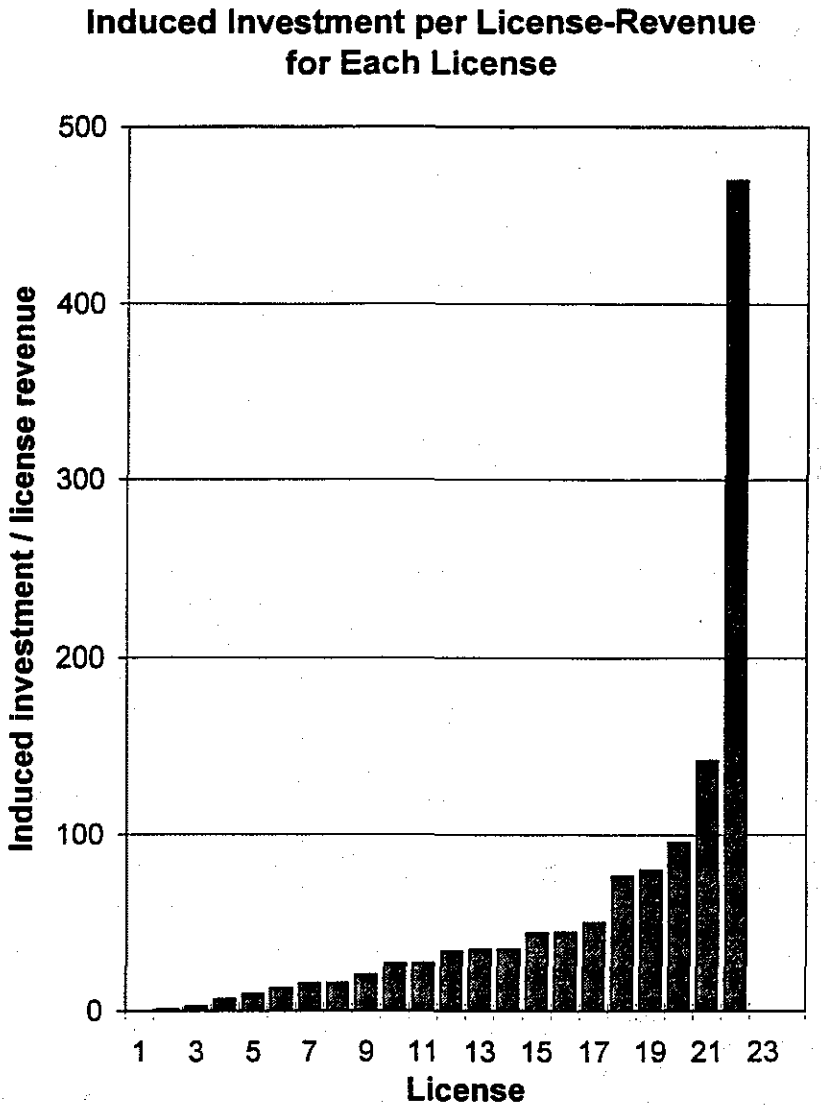

Figure 2. Induced Investment per License-Revenue for Each License. The licenses were sorted according to increasing ratio to evaluate whether any license is an outlier. The highest value appears to be a possible outlier in what otherwise is a uniform distribution.

COMPARISON WITH MIT DATA:

This analysis of the licenses of Penn can be compared to the analysis of Pressman et al. of the licenses of MIT through the scale factors of induced investment per license-year and induced investment per license-revenue. These results are shown in Table 10 for both physical sciences licenses and biotech licenses and each company category. The close relationship between these results is further demonstrated in the correlation plot of Figure 3. With a few exceptions, perhaps explainable by the small number of licenses in some categories, the correlation is strong. Note the agreement between the induced investment per license-year for the biotech start-up companies (Penn $2.75 million; MIT $3.16 million), the most significant contributor to induced investment in both surveys.

Table 10 Scale Factors of Penn Study and MIT Study For each Technology and Company Category

		Physical Sciences Licenses			Biotech Licenses		
		Start-ups	Small Cos.	Large Cos.	Start-ups	Small Cos.	Large Cos.
Induced Investment per License-Year	Penn	$0.56M	$0.08M	$0.44M	$2.75M	$0.25M	$0.63M
	MIT	$1.32M	$0.14M	$0.61M	$3.16M	$0.50M	$0.04M
Induced Investment per License-Revenue	Penn	80	1.6	32	65	14	16
	MIT	21	11	14	71	14	0.75

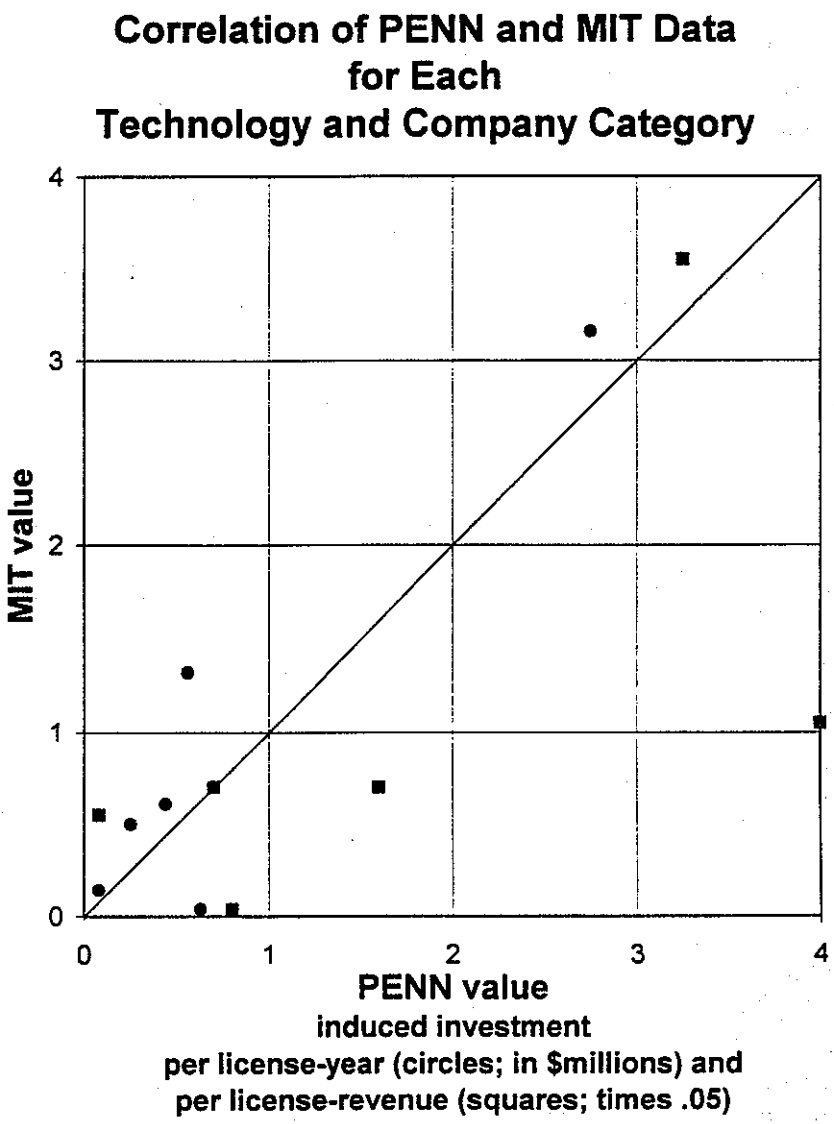

Figure 3. Correlation of PENN and MIT Data for Each Technology and Company Category. The Penn ratio of induced investment per license-year and per license-revenue for each category is compared to the corresponding MIT ratio. The points fall along the line of equality indicating correlation.

Even more startling is the similarity between the portfolio averages of the scale factors over the portfolios of licenses at Penn and MIT. Table 11 compares the induced investment per license-year and the induced investment per license-revenue averaged over the start-ups, other small companies, and large companies in the portfolio of licenses at Penn and MIT. The strong correlation between these results is shown in the correlation plot of Figure 4. Note that Penn's portfolio average induced investment per license-year is $0.93 million, similar to MIT's $0.98 million.

Table 11 Scale Factors of Penn Study and MIT Study For each Portfolio of Licenses

		Physical Sciences Licenses	Biotech Licenses	All Licenses
Induced Investment per License-Year	Penn	$0.36M	$1.47M	$0.93M
	MIT	$0.68M	$1.22M	$0.98M
Induced Investment per License-Revenue	Penn	17	43	33
	MIT	18	29	24

CONCLUSION

Companies that license technology from the University of Pennsylvania invest significant resources in efforts leading to product commercialization. We have determined that current licensees of Penn's technologies have invested $151 million, which has led to the creation of 242 full-time jobs.

The approach developed by Pressman et al. and applied to the licenses from MIT is supported by this analysis, which gives similar results based on the licenses from the University of Pennsylvania. We found that there is on average $0.93 million

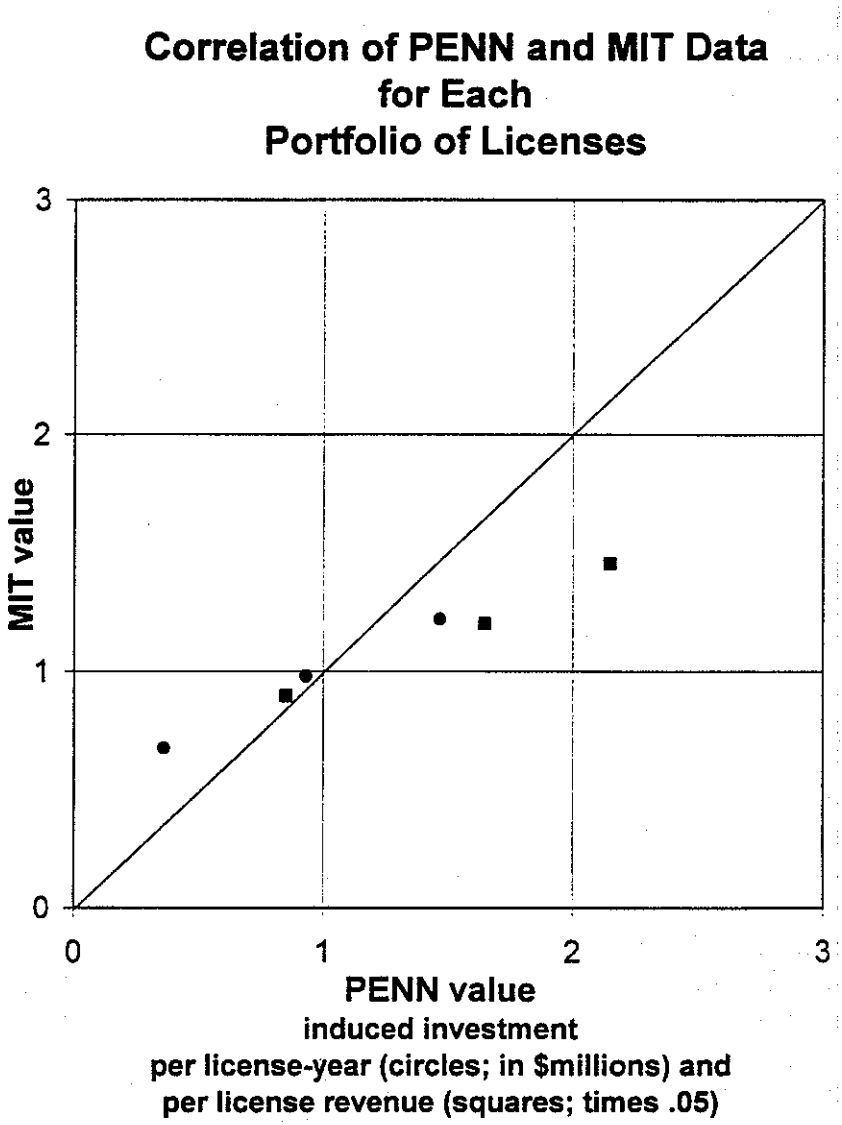

Figure 4. Correlation of PENN and MIT Data for Each Portfolio of Licenses. The Penn ratio of induced investment per license-year and per license-revenue for the physical sciences, biotech, and combined portfolios is compared to the corresponding MIT ratio. The points fall along the line of equality indicating correlation.

in induced investment for every year of every license compared to $0.98 million from the MIT study. A substantial portion of that induced investment comes from biotech start-up companies that invest approximately three times more per year in every license (i.e., $2.75 million from the Penn study, $3.16 million from the MIT study). We also found that there is a factor of 33 times more induced investment than license revenue, comparable to the MIT study's factor of 24. These scale factors that we have determined provide the means of deriving corresponding results from the licensing portfolios of other universities without the need to survey their licensees.

From these numbers we can attempt to calculate the total induced investment pre-commercialization in any one year from all of the licenses from U.S. universities, hospitals, research institutes, and patent management firms. Using a weighted factor of 20.2 (see Appendix for calculation of this weighted factor) for the ratio of induced investment to license revenue and the AUTM 1995 estimate of $413 million for license revenue (excludes Canadian Institutions) yields an induced investment of $8.3 billion. This overly large estimate, however, does not properly account for the fraction of the $413 million in license revenue that is post-commercialization, product royalty revenue. Alternately, using the Penn portfolio average factor of $0.93 million per license-year, and the AUTM 1995 estimate of 11,037 licenses, and assuming according to Pressman et al. that 45% of these licenses are exclusive and pre-commercialization, yields an induced investment of $4.6 billion. The number of full-time research and development jobs created by this induced investment can be estimated using the portfolio average of $168,000 per FTE-year to yield 27,000 full-time jobs in research and development.

Additional confirmatory studies validating the Pressman et al. induced investment methodology would be useful. Nevertheless, similarity of the results from Penn and MIT supports the general concept of induced investments and its value as a

measure of economic impact. The goals of the Bayh-Dole Act of 1980 include promoting the commercialization of inventions made under federally supported research and encouraging maximum participation of small business firms. The results of our study indicate that university licenses are meeting the goals of the Bayh-Dole Act and that licensing to start-up ventures plays a substantial role in economic growth.

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APPENDIX:

Calculation of a weighted average ratio of induced investment to license revenue:

Because of the wide disparity in induced investment per license-revenue between start-up companies and other companies, it is more accurate to use a weighted average ratio of induced investment to license revenue to determine total induced investment from total license revenue. In Table 8 we found that the induced investment per license-revenue for start-ups is 67. Furthermore, from Table 8, summing the induced investment from small and large companies (i.e., $7M plus $28M) and comparing that to the sum of the corresponding license revenue (i.e., $1.56M plus $1.33M) yields an induced investment per license-revenue for non-start-ups of 12.1. Following Pressman et al., we assume that 45% of the 11,037 licenses (i.e., 4,967 licenses) reported in the AUTM 1995 survey are exclusive and pre-commercialization. Furthermore, the AUTM 1995 survey reports that 734 licenses (i.e., 592 before 1995 and 142 in 1995) involved equity. Assuming that the fraction of licenses that involve equity represents the fraction of license revenue coming from start-up companies, implies that 14.8% (i.e., 734/4,967) of license revenue is from start-up companies. Therefore, the weighted average ratio of induced investment to license revenue is (14.8% times 67) plus (85.2% times 12.1), which is 20.2. This weighted average ratio can be compared to the corresponding weighted average ratio of 14.4 determined in the MIT study.

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