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Licensing in Global Markets
Industry/University Interactions

1. Introduction

This is a "golden age" for Intellectual Property Rights (IPRs). Bill Gates speaks of a new "Gold Rush." More than ever companies are built around patented technology. "Innovate or perish" is the motto. Patent filings and issuances are skyrocketing, so much so that there is talk of a patent "revolution," "explosion," "frenzy". In 2002 the USPTO issued almost 200,000 patents. Trademarks experience a similar boom.

The courts are pro-IPRs as is legislation; even the Antitrust Division of the U.S. Justice Department is pro-IPRs. In fact, courts read the riot act to infringers. Billion dollar damages have been awarded. Treble damages, once rare, are now the order of the day. Injunctions are normal and not even stayed during appeals. Thus, patents now are more enforceable and it no longer pays to infringe as in the 60's and 70's when, in the unlikely event the patent in suit was upheld, only reasonably-royalty damages were assessed.

"Everything under the sun made by man" is patentable according to our Supreme Court. As of 1998, formerly unpatentable business methods and computer programs (algorithms) are now also patentable. General Electric filed over 400 patent applications on business methods in 2000. Banks are establishing patent departments.

Royalties obtained for licensing IPRs have exceeded the billion dollar mark for companies such as TI, IBM ($1.8 billion) and over $100 billion for all U.S. industries. Hence, IPR rights are most valuable corporate assets or crown jewels.

And universities, not to be left out, have jumped on the bandwagon and by now are living in a "golden age" of their own for technology transfer.

2. The Bayh-Dole Act

The Bayh-Dole Act — "The Patent and Trademark Amendment Acts of 1980," which amended Title 35 of the U.S. Code by adding Chapter 18, Sections 200-212— represented a big step into a new relationship between the government, as represented by its agencies, and the universities. It also presaged a new and closer relationship with industry. The certainty of title in the universities to inventions made with government funds afforded by the Bayh-Dole Act provided the major impetus to new and expanding university-industry relationships. Inasmuch as the government always receives an irrevocable royalty-free license to such

inventions, and because of other provisions of the Bayh-Dole Act and the ensuing regulations under that Act, the relationship is, in reality, a university-industry-government relationship.

Before the enactment of the Bayh-Dole Act, no uniform regulations governed ownership rights between a sponsoring government agency and the university contractor receiving the funds. The Bayh-Dole Act envisages that in the eventuality of an invention flowing from the research sponsored by a government agency, the university elects title to the invention while the government acquires a non-exclusive, nontransferable, irrevocable, paid-up license. If the university does not elect to take title, the government may claim title. If the government does not claim title, then the inventor may petition the government agency for ownership, which is usually granted. The law applies to all federal agencies and virtually to all federal funding agreements with universities.

So-called "march-in rights" may be exercised by the government agency if (1) the agency determines that commercialization of the inventions is not being effectively pursued; (2) the license is necessary to satisfy health or safety needs; (3) the patent holder has not met the public use requirements specified by federal regulations; or (4) the patent holder has failed to agree that products incorporating the patent invention will be manufactured substantially within the U.S.

Other key provisions of Bayh-Dole, which turned out to be a truly trailblazing, landmark piece of legislation, are that the university

- generally may not assign an invention to a third party,
- generally must give priority in licensing to small businesses,
- must ensure that any exclusive licensee manufactures substantially in the U.S. and
- must share a portion of royalties with inventors and use the balance for scientific research or education.

As regards the royalty-sharing provision, a recent survey reveals inventors' shares of 25 to 50% of licensing income.

In Japan and Germany and elsewhere their educational ministries seek to emulate the U.S. university technology transfer system. Indeed, in Japan the "Law on Special Measures for Industrial Revitalization," a law that is comparable to the American Bayh-Dole Act and commonly referred to as the Japanese Bayh-Dole, went into effect on October 1, 1999. And Japan universities have begun to collect significant royalties.

3. Bayh-Dole's Impact

According to the most recent Annual Survey of the Association of University Technology Managers (AUTM), U.S. and Canadian universities, teaching hospitals and research institutes (hereinafter referred to as "universities" or "institutions") reported for 2001 receiving 13,569 invention disclosures, filing 6,812 new U.S. patent applications and obtaining 3,721 U.S. patents. The top ten American universities receiving the most

patents in 2002 were: University of California (431), Massachusetts Institute of Technology (135), California Institute of Technology (109), Stanford University (104), University of Texas (93), Johns Hopkins University (81), University of Wisconsin (81), State University of New York (55), Pennsylvania State University (50) and Michigan State University (49).

Furthermore, 4,058 new licenses and options were executed and 22,937 licenses and options were active in 2001. Product sales were reported from 22% of these active agreements and 9,707 licenses and options yielded income, amounting to $1.071 billion. Ninety-five institutions indicated that no fewer than 358 new products were commercialized under license agreements with corporate partners and since 1998 a total of 1,507 new products were introduced to the market place by 164 universities. Examples of significant licenses are: Gene Splicing — Cohen-Boyer (Stanford), Cisplatin (Michigan State), Gatorade (University of Florida), Synthetic Vitamin D and Warfarin (Wisconsin), Synthetic Penicillin and Magnetic Core Memory (MIT), etc.

As regards start-up activities in 2001, at least 494 new companies were founded, with 84% of them being formed in the state or province of the institution where the technology was invented. Of the 3,870 new companies created since 1980, 2,514 were still in business as of the end of 2001. Also, universities obtained an equity interest in 70% of their startups in 2001.

Total 2001 research expenditures funded by the federal government and industry amounted to $31.7 billion, with $19.9 billion coming from the federal government and $2.78 billion, from industry. The rest came from private sources (foundations, etc.)

Another indicator of the growth and importance of university innovation and technology transfer: in 1980 SUPA (Society of University Patent Administrators) had 65 members, while currently AUTM (SUPA renamed in 1989) has over 3,200 members. And the number of universities with technology transfer programs increased from 30 in 1980 to more than 200 in 2002.

In recognition of this growth and importance, Franklin Pierce Law Center (Pierce Law) has featured a lecture on University Licensing in its annual Advanced Licensing Institute since its inception in 1992 and now includes in its curriculum a whole course styled "Nonprofit Technology Transfer" twice a year, taught by Karen Heresy, former MIT's Senior Counsel for Intellectual Property. The objectives of this course, according to its syllabus, are to "equip students with the background necessary to effectively perform as technology transfer professionals within the nonprofit sector or as outside professionals capable of advising the nonprofit sector, or those wishing to do business with nonprofits, on the legal and intellectual property licensing issues, strategies and customary business practices in commercializing nonprofit technology."

Interestingly, what is being used as course materials in the "Nonprofit Technology Transfer" course, there being as yet no textbook or casebook for such a course, is the *AUTM Technology Transfer Practice Manual*, Second Edition, 2003, which comes in

four volumes and is an indispensable veritable bible, covering all aspects of university innovation and technology transfer, including many policy statements and model agreements. See attached Table of Contents.

4. Patent Donations

In addition to the straightforward university licensing practice, three other types of industry-university interactions were discussed as growing in popularity at a LES Workshop on "Making the Most of Industry and University Relationships" in San Diego last September. These are industry-sponsored academic research, licensing by industry of research tools developed in university laboratories and patent donations to universities. The first of these practices has been going on for many years in conjunction with university licensing and even before there was any such licensing and the second one is but a logical extension of university licensing, now that patenting of research tools has become standard practice. But patent donations are a controversial subject, which merits a word of caution. An article, entitled "Patent Donations: a Win-Win Deal or a Tax Dodge," will appear shortly in the Summer/Fall 2003 issue of the *Germeshausen Center Newsletter* of Pierce Law. Its introduction reads as follows:

> In the past several years, corporations have increasingly approached universities and other nonprofit organizations with offers to donate patented technologies alleged to be worth millions of dollars. Several hundred million dollars are said to have been so donated in the last few years. Skepticism and suspicion seem to be the hallmark response to these inquiries. In the words of Gregory Aharonian, commentator for the *Internet Patent News Service*, IP donations are the next accounting scandal, being nothing more than large companies "donating bogus patents to universities and claiming tax deductions on their federal taxes." As regards one donation between SBC Communications and the University of Texas, valued at $7,300,000, Mr. Aharonian commented that, "The patent stinks like a dead cow in the Houston shipping channel on a hot summer day." (Gregory Aharonian, "Patent Donations Next Tax Accounting Scandal," *Internet Patent News Service*, March 2003.) In certain situations this may be a well-founded response.

Anent skepticism and suspicion, Ms. Lita Nelson, Director of the MIT Technology Licensing Office, has stated that corporations need not approach MIT, inasmuch as MIT has no use for donated patents because they do not mesh with their interests, except in the rarest of circumstances.

Nonetheless, the forthcoming article concludes:

> A patent donation can represent a win-win proposition for both the nonprofit donee and the corporate donor. Both parties, however, must work together to make it a winning proposition. At the center of a successful donation, there must be a commercially valuable technology. The technology must be compatible with the interests

> of the nonprofit donee. A thorough due diligence in respect to the strength of, and the market for the technology must be conducted. Complete cooperation, by both the donor and the donee, is essential to the seamless transfer of the donation. And there must be a willingness to provide, and to accept, post donation support to nurture the development of the donated technology.

Furthermore, since the IRS is facing growing problems with patent donations with exaggerated valuations, Congress is set to pass legislation that would curtail tax deductions for such donations. In fact, there is a provision in a must-pass trade bill in Congress now that would substantially reduce deductions for donated patents — donors could deduct only their tax basis instead of fair market value.

5. Due Diligence

Speaking of due diligence in patent donation practice, it is important to keep in mind that thorough due diligence is also required in the licensing/technology transfer process. Mark Bloom, Chief IP Counsel of the Cleveland Clinic, in his annual lectures at Pierce Law's Advanced Licensing Institute on "Non-Profit Organization Licensing," lists the following queries to be pursued:

- Are there other forms of available IP protection, e.g. copyright, trade secret, plant registration or plant patent?
- Has the inventor published the inventive concepts prior to filing?
- Has a patentability/validity study been conducted to determine whether valid patents will issue?
- Will the technology be practiced in combination with other technologies, which may require royalty stacking?
- What *quid pro quo* can be offered: royalties, equity stake, stock options, consulting arrangements?
- Are there any conflict of interest issues?
- Have all inventorship and ownership issues been resolved and requisite assignments executed?
- Are negotiations being conducted with a party authorized to bind the institution? Etc.
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6. Trade Secrets

It was conventional wisdom and general policy for a long time that universities in line with their "freedom-to-publish" and "no secrecy in research" principles, did not believe in trade secrets and did not keep trade secrets and consequently did not have trade secrets to license and transfer. And, in fact, the Bayh-Dole doctrine rests on patent rights not trade secrets. That had to change, if it is true, as I have maintained all along, that patents are but the tips of icebergs in an ocean of trade secrets, over 90% of all new technology is covered by trade secrets and over 80% of all license and technology transfer agreements cover proprietary know-how, i.e. trade secrets, or constitute hybrid agreements relating to patents and trade secrets. My experience tells me it is also true that as a practical matter

licenses under patents without access to associated or collateral know-how are often not good enough for commercial use of the patented technology. Hence trade secrets are the "work horse of technology transfer," according to Bob Sherwood.

In this regard, let me cite the following persuasive comments:

> "In many cases, particularly in chemical technology, the know-how is the most important part of a technology transfer agreement." (Homer Blair)
>
> "…some regard a patent as little more than an advertisement for the sale of accompanying know-how." (Peter Rosenberg)
>
> "Trade secrets are a component of almost every technology license…(and) can increase the value of a license up to 3 to 10 times the value of the deal if no trade secrets are involved." (Melvin Jager)

Academic neglect of trade secrets may be due in part to the fact that much of the university research is early-stage and the volumes of research results generated during later product development stages, do not yet exist. But even in an early stage there may be masses of research results that are not, cannot and need not be incorporated in patent specifications and this is true despite the enablement and best mode requirements.

And changes are afoot, albeit not in all institutions. Mark Bloom, as indicated above, shows cognizance of trade secrets when he refers to "trade secret(s)…(as) other forms of IP protection that would be more appropriate (for university technology transfer)." Most importantly in Chapter 2.5, Part IV of the *AUTM Manual*, there is ample recognition that "know how can be valuable and the technology transfer manager must be familiar and skilled in licensing it" and that "(l)icensing ancillary know how as part of a package of licensing one or more existing patents can be a most effective strategy and can create an imposing hurdle for an exclusive licensee's competitors."

7. Problem Areas

a) Conflict of Interest

First and foremost, conflict-of-interest problems can raise their ugly heads. Universities want faculty and researchers to conduct research objectively without influence by personal financial gain, their primary professional allegiance being to the university and their primary commitment of time and intellectual energies, to the education, research, and scholarship programs of the institution.

For technology transfer reasons, it is often desirable that the faculty works closely with the licensee. But this closeness sometimes presents a concern. Most universities have a process to review conflicts of interest and are able to find ways to balance the interests of the university with the licensee's interests.

Start-up companies harbor a specially challenging conflict-of-interest problem, according to Katharine Ku, Director, Office of Technology Licensing, Stanford University. Universities are often willing to take equity as partial compensation for a license agreement since start-up companies are typically cash-poor.

For example, MIT takes a small percentage of equity in start-ups "in partial lieu of royalties," in addition to some licensing fees and some running royalties, but without playing any management role. Also MIT inventors can take equity in start-ups but may not accept sponsorship of research by that company. On this point, MIT's "Conflict Avoidance Statement," to be signed by faculty members, is of interest. It reads in pertinent part:

> Because of the M.I.T. license granted to the above company and my equity position and continuing relationship with this company, I acknowledge the potential for a possible conflict of interest between the performance of research at M.I.T. and my contractual or other obligations to this company. Therefore, I will not:
> 1) use students at M.I.T. for research and development projects for the company;
> 2) restrict or delay access to information from my M.I.T. research;
> 3) take direct or indirect research support from the company in order to support my activities at M.I.T.; or
> 4) employ students at the company except in accordance with Section 2.12.2, "Relations of Faculty and Students," in the Policies and Procedures guide.

b) Publication

Furthermore, there are potentially serious publication problems and impasses. On the one hand, since dissemination of research findings is at the core of academic life, the university position is fairly straightforward: the investigator must be able to report the results of his/her research without undue delay and without censorship by the sponsor. The sponsor, on the other hand, may be concerned about a potential loss of intellectual property rights and thus may want the right to delay publication until patent applications are filed or may even want to preclude publication in order to main the results as a trade secret.

Still in this area, there is considerable variation among universities, with Harvard being at one of the extremes allowing no delay in publication. They will not even guarantee that the sponsor will receive copies of publications prior to their submission for publication.

In Harvard's view even if there is no communication and the copy of the submitted publication is the first time the company learns that a patentable invention has been made, it usually takes about four to six months before the article is actually published. During that time period, it should be possible for the parties to decide whether a patent application is to be filed, and to get it filed. Even if the publication is on a "fast track," there are at least three weeks to get an application on file.

But it is not that simple in my opinion. I had situations in my previous career as corporate patent counsel where we had to file patent applications within a day for university professors whose inventions of interest to the corporation had been published and the one-year grace period was running out. The ready availability of the journal text made it possible to still file an application in the "final hour." However, foreign patent rights were lost. Also, submission of the manuscript to the editor and to peers for peer review may pose a risk to patentability.

c) Oral Disclosure

And then there is a related problem with oral disclosure. Presentations at scientific meetings can constitute a bar to patent filings in absolute novelty countries. However, Harvard feels that most major scientific meetings require the submission of abstracts well in advance of the meeting and those abstracts will enable the sponsor and the university to decide whether a patent application should be filed. If an abstract is not submitted in advance, a possible solution is to require that the investigator notify the sponsor when he/she accepts an invitation to present the results of the sponsored project. Then, the sponsor and the university can review the work in progress and prepare a patent application if appropriate.

d) Derivation Contests

A very troublesome problem can come to light in so-called derivation interference proceedings. An interference in the U.S. first-to-invent patent system is a contest where two or more patent applications pending in the U.S. Patent and Trademark Office (PTO) claim the same invention and a determination must be made as to who is entitled to the patent, inasmuch as only one patent can be issued on one invention. An interference can be either a contest to determine priority or originality. In the former, the respective dates of conception and reduction to practice of an invention are taken into consideration to decide who made the invention first. In the latter, a derivation contest, the issue to be decided is who made the invention.

For instance, in this author's professional experience, it happened several times that a university, to whom an inventive concept or invention was disclosed to enable it to carry out certain tests to complete reduction to practice or to confirm the utility, filed a patent application on such an invention incorporating their test results before they were communicated to the corporate sponsor and without informing it of such filing. Subsequently, when the corporate sponsor filed a patent application on the very same invention also including the university's test results, an interference was declared by the PTO since two applications on the same invention were pending.

In such a contest, it is not the earliest conception and reduction to practice dates that count; rather the question to be determined is whether the corporate sponsor disclosed the invention to the university fully and completely so that the university actually derived the knowledge from the corporation. In the derivation cases with which this author is familiar, it was the corporation that prevailed over the university. The lesson to be learned from these experiences is that whenever a corporation discloses inventive

concepts or research projects to universities to enable them to do certain desirable or necessary testing, all such disclosures and discussions should be clearly and fully documented.

Hopefully, this may no longer be a serious problem, in light of greater institutional sophistication about IPRs and technology licensing and the explosive rise of technology licensing offices.

8. Storm Clouds

First and foremost and the most recent ominous developments are the *Madey v. Duke University* (2002*)*, *Embrex v. Service Engineering* (2000) and *Integra Lifesciences et al v. Merck* (331 F. 3d 860, 2003) decisions from the Court of Appeals for the Federal Circuit regarding the experimental use exception or defense to patent infringement. These decisions in a nutshell essentially rule out experimentation as an exception and defense to infringement, even when conducted in universities. In the *Embrex* case, Judge Rader stressed that the Patent Act does not tolerate an experimental use doctrine because infringement does not depend on intent and the slightest commercial implication would render it inapplicable anyhow. And the *Madey* court held that while the experimental use defense exists, it is very narrow and strictly limited to amusement, idle curiosity or philosophical inquiry and does not apply to uses in furtherance of a legitimate business, even if the business is non-profit.

Interestingly, Judge Newman, in her dissent in the *Integra Lifesciences* decision, pointed out that "philosophical" as first used by Justice Story (in *Whittemore v. Cutter*, in 1813) referred to "natural philosophy," the term then used for what we today call "science." Judge Newman is also correct when she maintains:

> The majority's prohibition of all research into patented subject matter is as impractical as it is incorrect. The information contained in patents is a major source of scientific as well as technologic knowledge. Indeed, in many areas of technology, technical information is not published outside of patent documents. A rule that this information cannot be investigated without permission of the patentee is belied by the routine appearance of improvements on patented subject matter, as well as the rapid evolution of improvements on concepts that are patented.
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> The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology.

Clearly these cases will have a chilling effect on innovation everywhere, particularly at universities and spin off and startup companies and thus have been duly criticized as abominations. According to Mark Bloom *Madey v. Duke University* arguably eliminated the experimental use defense to patent infringement and thus has "forever altered the landscape for academic technology transfer."

At Harvard the assumption nowadays is that no reliance can be placed on the experimental use defense because everything they do is done for profit in some way and consequently they obtain a lot of licenses.

There is another concern or problem based on the "infamous" *Singer* case. In *Singer v. The Regents of the University of California* (1997), the California Court of Appeals held that the university gave overly favorable licensing terms to companies in return for sponsored research funds, depriving the inventors of substantial potential royalties. Thus, in licensing negotiations, trading-off of benefits to the university may conflict with the expectations of the researchers. As regards the impact of Singer, Mark Bloom, opined in his latest lecture at Pierce Law's Advanced Licensing Institute, that Singer will jeopardize the financial integrity of universities, there will be a corresponding reduction in corporate-sponsored research and open communication between a technology licensing office and other campus offices will be negatively affected.

9. Conclusion

As can be seen from the above survey, policies and practices regarding licensing and research contracts between universities and corporations have reached a stage of great complexity and sophistication. However, in light of the vast experience inside universities and corporations in the area, the extensive literature (including model agreements) and the many programs dealing with the issues, as well as the objectivity, realism and professionalism exhibited by the players and actors in this field, negotiation and preparation of license and research agreements between universities and corporations are greatly facilitated, albeit still challenging.

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