PIERCE LAW
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INTELLECTUAL PROPERTY RIGHTS IN THE COMPANY-UNIVERSITY RELATIONSHIP

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I. INTRODUCTION

Live in "Golden Age" for IPRs
Patent filings and issuances are skyrocketing
Talk of patent "revolution," "explosion," "frenzy"

"Anything under the sun that is made by man" is patentable, even business methods
Courts, Congress, Justice Department — pro IPRs
Corporations built on patented technologies
Motto: Innovate or perish

Value of IPRs for securing exclusivity — simply invaluable
Royalties for licensing IPRs in 2002: over $100 billion
Over $1 billion for some companies
Universities jumped on bandwagon
Getting patents, concluding licenses, collecting royalties

II. THE BAYH-DOLE ACT

"The Patent and Trademark Amendment Acts of 1980"

A trail blazing, landmark statute

A big step into a new relationship between the government and the universities

Major impetus to new and expanding university-industry relationships

Relationship is, in reality, a university-industry-government relationship

II. THE BAYH-DOLE ACT (cont'd)

The Bayh-Dole Act envisages

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

II. THE BAYH-DOLE ACT (cont'd)

March-in rights may be exercised by the government agency if

- commercialization of the inventions is not being effectively pursued
- the license is necessary to satisfy health or safety needs
- the patent holder has not met the public use requirements specified by federal regulations
- the patent holder has failed to agree that invention will be manufactured substantially within the U.S.

II. THE BAYH-DOLE ACT (cont'd)

Other key provisions of Bayh-Dole 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.

A recent survey reveals inventors' shares of 25 to 50% of licensing income

Japan, Germany, Italy and other countries seek to emulate the U.S. university technology transfer system

The "Japanese Bayh-Dole" went into effect on October 1, 1999

Japanese universities, e.g. Tokai University, have begun to collect significant royalties

III. THE BAYH-DOLE'S IMPACT

Most recent AUTM survey shows university activities for 2003:

- 16,792 invention disclosures received
- 8,346 new U.S. applications filed
- 4, 112 U.S. patents obtained
- 4,967 new licenses and options executed
- $1,345 million royalties received
- 432 new companies founded

IV. PATENT DONATIONS

A popular but controversial corporate IP monetization tactic.
Several hundred million dollars donated to universities.
Win-win deal or tax dodge?
Gregory Aharonian: donating bogus patents and claiming big tax deductions is next accounting scandal.
MIT does not accept donated patents.
Can be winning proposition for valuable technology if parties work together and there is post donation support.
New tax law severely limits tax deduction to lesser of donor's basis or fair market value.

V. DUE DILIGENCE

Thorough due diligence is also required in the licensing/technology transfer process. The following queries are 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.

VI. TRADE SECRETS

Conventional wisdom: because of “freedom-to-publish” and “no secrecy in research” principles, universities did not believe in trade secrets, did not keep trade secrets; hence, did not have trade secrets to license and transfer.

The Bayh-Dole doctrine rests on patent rights.

Academic neglect of trade secrets is due to fact much of the university research is embryonic, early-stage.

Volumes of research results generated during later product development stages do not yet exist.

Even in the early stage there may be masses of research results not incorporated in patent specifications true despite the enablement and best mode requirements.

VI. TRADE SECRETS (cont'd)

Trade secrets are the "crown jewels" of corporations — not the "cesspool of the patent system."

Mark Halligan and James Pooley proclamations.

Trade secret misappropriation cost Walt Disney $240 million and Cargill $300 million.

88% of responses in an IPO Survey indicate trade secrets to be the really important intellectual assets because patents have limits: patentability requirements, publication, invent-around feasibility.

VI. TRADE SECRETS (cont'd)

Trade secret protection operates without delay and undue cost against the world — unlike patents which are territorial and so expensive to obtain and maintain that only very selective foreign filing is done.

Patents are tips of icebergs in an ocean of trade secrets

- Trade secrets cover over 90% of new technology
- Over 80% of technology licenses cover trade secrets or are hybrid licenses

Trade Secrets are the "workhorse of tech transfer" (Bob Sherwood).

VI. TRADE SECRETS (cont'd)

Patent/Trade Secret Interface

Indeed, as a practical matter, licenses under patents without access to associated, collateral know-how are often not enough, because patents rarely disclose the ultimate scaled-up commercial embodiments of products and processes.

"In many cases, particularly in chemical technology, the know-how is the most important part of a technology transfer agreement." (Homer Blair).

"It is common practice in industry to seek and obtain patents on that part of a technology that is amenable to patent protection, while maintaining related technological data and other information in confidence. Some regard a patent as little more than an advertisement for the sale of accompanying know-how." (Peter Rosenberg).

VI. TRADE SECRETS (cont'd)

Patent/Trade Secret Interface (cont'd)

In technology licensing "(r)elated patent rights generally are mentioned late in the discussion and are perceived to have 'insignificant' value relative to the know-how." (Michael Ward, Honeywell VP Licensing).

"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).

Failed Brazilian tactic.

CIBA-GEIGY examples: Eastman Kodak & DuPont licenses.

VI. TRADE SECRETS (cont'd)

Patent/Trade Secret Complementariness

- Supreme Court (*Kewanee Oil*, 1974): perfectly viable alternatives.
- Not mutually exclusive but mutually reinforcing — dovetail, in harmony
- "Coexistence is well-established." (Don Chisum).
- Inextricably intertwined: Most R&D data and collateral know-how cannot and need not be included in patent applications — grist for trade secrets.
- Trade secrets precede, accompany and follow patents.

VI. TRADE SECRETS (cont'd)

Patent/Trade Secret Complementariness (Cont'd)

1. In the critical R&D state and before any applications are published or patents issued, trade secret law protection is all you have.
2. Assuming that a development has been enabled and the best mode described in an application, all collateral know-how not disclosed, whether or not inventive, can be retained as a trade secret.
3. All R&D data, including data pertaining to better modes, developed after filing, again whether or not inventive, can also be protected as trade secrets.
4. With respect to technologically complex developments consisting of many patentable inventions and volumes of associated know-how, complementary patenting and secreting is tantamount to having the best of both worlds. E.g. • GE's industrial diamond technology
   - Wyeth's Premarin Process
   - "PIZZA HUT Case"

The question is not whether to patent or to padlock but rather what to patent and what to keep a trade secret.

The best policy and strategy is to patent as well as to padlock.

VI. TRADE SECRETS (cont'd)

Exemplary Trade Secret Cases

1. GE's exclusive industrial diamond process technology
   - Holds patents (some expired) and trade secrets
   - Refused to grant licenses
   - Fast-track GE scientists stole trade secrets for Far Eastern interests for million dollar payments
   - In the end got caught, tried, jailed

2. Wyeth's exclusive Premarin manufacturing process
   - Has had market exclusivity since 1942
   - Patents expired decades ago
   - Closely guarded its trade secrets
   - Natural Biologics stole these trade secrets
   - Wyeth sued, got sweeping injunction

VI. TRADE SECRETS (cont'd)

Exemplary Trade Secret Cases (Cont'd)

3. Pizza Hut case
   - Pizza Hut supplier, C&F Packing, invented and patented a manufacturing process for pizza sausage toppings and kept improvements secret
   - Pizza Hut misappropriated trade secrets and got sued
   - Court decision:
     1) patents are invalid on on-sale bar grounds (on Summary Judgment)
     2) trade secrets are enforceable and Pizza Hut had to pay $10.9 million (after trial)

VI. TRADE SECRETS (cont'd)

The Best Mode Requirement

The "*best mode*" requirement applies

- only to the knowledge of the inventor,
- only at the time of filing and
- only to the claimed invention.

Hence best mode requirement is no impediment, because —

1. Patent applications are filed early in the R&D stage to get the earliest possible filing or priority date.
2. The specification normally describes in but a few pages only rudimentary lab experiments or prototypes.
3. The best mode for commercial manufacture and use remains to be developed later.
4. Patent claims tend to be narrow for distance from the prior art.
5. As shown by case law, manufacturing process details are, even if available, not a part of the statutorily-required best mode disclosure of a patent.

VI. TRADE SECRETS (cont'd)

The Best Mode Requirement

Tom Arnold: it's "flat wrong" to assume that "because the patent law requires a best mode requirement, patents necessarily disclose or preempt all the trade secrets that are useful in the practice of the invention."

VI. TRADE SECRETS (cont'd)

Integration Of IPRs

Prof. Dratler (1991)

- IPRs are now a "seamless web"
- Single field of law with much overlap
- Several IPRs available for same IP or different aspects of same IP
- Not taking advantage of overlap — malpractice

One IP category — center of gravity
Others are supplementary but very valuable to

- cover additional subject matter
- strengthen exclusivity
- invoke additional remedies in litigation
- standup if primary IPR becomes invalid

and thus provide synergy and optimize legal protection — dual or multiple protection

Most important management strategy: exploiting the overlap between patents and trade secrets

VI. TRADE SECRETS (cont'd)

Changes are afoot.

Mark Bloom recognizes trade secrets as other forms of IP protection that would be more appropriate (for university technology transfer).

AUTM Manual also shows 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."

VII. PROBLEM AREAS
a) Conflict of Interest

Conduct research objectively without influence by personal financial gain, primary professional allegiance to university and primary commitment to education, research, and scholarship programs.

It is often desirable that the faculty works closely with the licensee. Universities have a process to review conflicts of interest to find ways to balance the interests of the university with licensee's interests.

Start-up companies have specially challenging conflict-of-interest problem

MIT's "Conflict Avoidance Statement" to be signed by faculty members to the effect that they will not:

1) use students at M.I.T. for R&D projects for the company;
2) restrict or delay access to information from my 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.

VII. PROBLEM AREAS (cont'd)
b) Publication

Dissemination of research findings is at the core of academic life University position: the investigator must be able to report the results of his/her research without undue delay and without censorship by the sponsor.
The sponsors concerns:
Potential loss of IPRs
Hence they want us to delay publication until patent applications are filed or to maintain trade secrets.

Harvard allows no delay in publication.

Their position: as it usually takes about four to six months before a paper is actually published, there is time to decide whether a patent application is to be filed, and to get it filed.

VII.PROBLEM AREAS (cont'd)

b) Publication (cont'd)

In my experience patent applications for university professors had to be filed within a day had been published and the one-year grace period was running out.

Foreign patent rights lost.

Submission of the manuscript to the editor or to peers for review also poses a risk to patentability.

Oral disclosure during discussions at scientific meetings may bar patent filing in absolute novelty countries.

VII. PROBLEM AREAS (cont'd)

c) Derivation Contests

In my experience, it happened several times that a university, to whom an invention was disclosed to enable it to carry out tests, 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, the PTO declared an interference since two applications on the same invention were pending.

In such an interference, a derivation, rather than a priority, contest, the issue to be decided is who made the invention, not who made the invention first.

Question to be determined: whether corporate sponsor disclosed the invention to the university fully and completely so that the university actually derived the knowledge from the corporation

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

This my no longer be a serious problem, greater institutional sophistication about IPRs and technology licensing explosive rise of technology licenses offices.

VIII. STORM CLOUDS

Ominous developments: *Madey v. Duke University* (2002), *Embrex v. Service Engineering* (2000), *Integra* 2003 on experimental use exception or defense to patent infringement.

In the *Embrex* case, Judge Rader: the Patent Act does not tolerate an experimental use doctrine because infringement does not depend on intent and the slightest commercial implication kicks it out.

Madey court: experimental use defense is strictly limited to amusement, idle curiosity or philosophical inquiry. Does not apply, even if the business is non-profit.

A front page article of the *Wall Street Journal*, entitled "A Laser Case Sears Universities' Right to Ignore Patents" and dated October 11, 2004,points out

> Madey v. Duke is raising a central question: At a time when universities increasingly act like corporations, should they also be subject to the intellectual property laws that bind businesses and consumers?

VIII. STORM CLOUDS (cont'd)

> These days, big research universities use their formidable powers for far more than teaching and scholarly inquiry. They invest in top scientists, create big labs, team up with companies and spawn commercial spin offs. They and their scientists lure grants from foundations and federal agencies. The National Institutes of Health alone funded $20 billion of research at U.S. campuses last year.
>
> And big universities generate patents themselves.

Per Carl Gulbrandsen, managing director of WARF:

> We believe it's a mistake to say [to industry] you need to pay us for intellectual property but we aren't going to pay you, because we're a university.

Judge Newman dissent in the *Integra Lifesciences* decision: "philosophical" referred to "natural philosophy," i.e. "science."

Judge Newman is also correct when she maintains:

VIII. STORM CLOUDS (cont'd)

… 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.... 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.

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.

VIII. STORM CLOUDS (cont'd)

These cases have a chilling effect on innovation at universities and spin off and startup companies.

Duly criticized as abominations.

Mark Bloom: *Madey v. Duke University* arguably eliminated the experimental use defense to patent infringement — "forever altered the landscape for academic technology transfer."

Harvard places no reliance on experimental use defense because everything they do is done for profit obtain a lot of licenses.

MIT however takes contrary position: The *Madey* is an aberration involving a disgruntled professor; they will continue to ignore patents, inasmuch as they don't expect to be sued.

Another concern is the "infamous" *Singer* case.

In *Singer v. The Regents of the University of California* (1997), the university gave overly favorable licensing terms to companies in return for sponsored research funds, depriving the inventors of substantial potential royalties.

Per Mark Bloom, Singer will jeopardize the financial integrity of universities, communication between a TLO and other campus offices will be negatively affected.

IX. CONCLUSION

Policies and practices regarding licensing and research contracts between universities and corporations reached a stage of great complexity and sophistication.

Negotiation and preparation of license and research agreements between universities and corporations are greatly facilitated thanks to the trailblazing Bayh-Dole Act.

Thank you very much.