THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

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THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

OVERCOMING LICENSING ISSUES FOR UNIVERSITIES

THURSDAY, FEBRUARY 15, 2018 @ 1:00PM (CT)

MEET THE PRESENTER

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- **Former Corporate Counsel of IBM**

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AGENDA

- UNIVERSITY LICENSING ISSUES

- A WATERSHED YEAR IN UNIVERSITY LICENSING: 1980
  1) *Diamond v. Chakrabarty,* Human-made micro-organisms are patentable
  2) Cohen-Boyer patent on recombinant DNA issues
  3) Bayh-Dole Act

- STREAMLINING UNIVERSITY LICENSING
  1) University of Minnesota
  2) Pennsylvania State University

- LICENSE AGREEMENT SECTIONS PARTICULARLY RELEVANT TO UNIVERSITY LICENSING

- EXAMPLES OF RELEVANT PROVISIONS OF A UNIVERSITY LICENSE

Biotech costly, risky, and with extremely long development time – Universities goals do not always align with business' goals:

I. ISSUES:

A. Pharma, biotech, and medical devices have the longest development period from conception to actual marketability of any other industry

1) Costly – astronomical expense in some cases taking research to marketable product
2) Risky – vast majority of inventions in these fields never become marketable products
3) FDA regulations, clinical trials, most need to be proven safe and effective before they can be sold
4) All of the above create valuation difficulties that are most intense when money is needed the most – when the product is in beginning stages with few metrics to measure value

B. Universities have interests/responsibilities/cultural differences which can compete with a conventional business strategy for IP

1) Duty to taxpayers as public non-profit institutes of learning
2) Interest in retaining use of their IP for research/education and the ability to grant rights to other universities
3) Faculty inventors have the primary goal of publication of their work – this can sometimes be adverse to maintaining trade secrets and even patentable subject matter
4) There can be a cultural difference between University faculty inventors and business investors/developers that can cause problems if not carefully considered – the most important aspect is to make sure all parties understand communications
5) Governmental rights in IP generated from publicly funded research [Bayh-Dole Act]

Brief History – 1980 Three significant events

1) **June 1980 – *Diamond v. Chakrabarty* allowed patenting of living things**

2) **December 2, 1980 method patent issues: Process for producing biologically functional molecular chimeras US 4237224**

3) **December 12, 1980 Passing of Bayh-Dole Act**

Brief History – 1980 *Diamond v. Chakrabarty*

1. June 1980 – *Diamond v. Chakrabarty* Supreme Court allowed patenting of living things

June 1980 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) Chief Justice Warren E. Burger (St. Paul) wrote the decision, and was joined by Potter Stewart, Harry Blackmun, William Rehnquist, and John Paul Stevens. Burger wrote that the question before the court was a narrow one—the interpretation of 35 U.S.C. 101 (patentable subject matter).

Held: A live, human-made micro-organism is patentable subject matter under § 101. The micro-organism constitutes an "article of manufacture" or a "composition of matter" within the statute. 447 U. S. 308-318.

"The key discovery in Chakrabarty's research was that "plasmids" control the oil degradation abilities of certain bacteria. Plasmids are transmittable, non-nuclear segments of DNA. Chakrabarty developed a process by which multiple plasmids capable of degrading different hydrocarbon components could be incorporated within a particularly "hardy" single bacterium. This genetically engineered bacterium was capable of breaking down oil spills at a much faster rate than naturally occurring bacteria. As importantly, it was not affected by varying environmental conditions."[1]

[1]*Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents* By Douglas Robinson and Nina Medlock, Intellectual Property & Technology Law Journal Volume 17 • Number 10 • October 2005

Brief History – 1980 Cohen-Boyer

2. December 2, 1980 method patent: Process for producing biologically functional molecular chimeras US 4237224

Cohen – Boyer method patent issues Dec 2, 1980: Process for producing biologically functional molecular chimeras US 4237224, US 4468464 (8/28/1984) and US 4740470 (4/26/1988).

"Recombinant DNA molecules are sometimes called **chimeric DNA**, because they can be made of material from two different species, like the mythical chimera." (Wikipedia)

Recombinant DNA is used to identify, map and sequence genes, and to determine their function.

Collaboration – Stanley N. Cohen was faculty at Stanford, Herbert W. Boyer was faculty at University of California San Francisco (UCSF) – Stanford took the lead and the patents were wisely assigned to one entity.

Licensing problems can develop from joint ownership, for example – it can be impossible to provide an exclusive license when a joint owner has ability to license independently.

"No one was interested in patenting in 1974 until Niels Reimers, director of the Stanford Office of Technology Licensing took charge. He had to be very persuasive with Professor Cohen and reportedly convinced him to agree to patenting only after speaking to him like a 'Dutch Uncle'"[1].

[1]*Hughes SS, Making dollars out of DNA: the first major patent in biotechnology and the commercialization of molecular biology 1974-1980. Isis 2001; 92(3):541-75.*

Brief History – 1980 Cohen-Boyer

2. December 2, 1980 method patent: Process for producing biologically functional molecular chimeras US 4237224.

The three patents were recognized as huge innovations and created an industry around genetic engineering.

Stanford Licensing Program for the Cohen-Boyer has been called the Gold Standard of University Licensing programs.

Stanford University had four goals that guided the development of the Cohen-Boyer license:

- to be consistent with the public-service ideals of the university
- to provide the appropriate incentives in order that genetic engineering technology could be commercialized for public benefit in an adequate and timely manner
- to manage the technology in order to minimize the potential for biohazard
- to provide income for educational and research purposes[1]

While income was not top of the list, the three Cohen-Boyer patents generated over $100 Million in royalty.

[1]Feldman MP, A Colaianni and C Liu, Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A.; p. 1798; Available online at www.ipHandbook.org (2007).

Brief History – 1980 Bayh-Dole Act

3. Passing of Bayh-Dole Act in 1980 allowed universities, nonprofit research institutions, and small businesses to retain patent and licensing rights to inventions developed and supported by federal research funding. Before Bayh-Dole, the federal government kept ownership of federally funded inventions.

35 U.S. Code § 202 - Disposition of rights

…

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel …

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: …

Who owns an elected invention, the contractor or the inventor?

***Stanford v Roche Molecular Systems*, 563 U.S. 776 (2011)**

US Supreme Court addressed ownership issue regarding Bayh-Dole:

Ownership – Bayh-Dole does not vest ownership in contractor. Ownership is in the inventor.

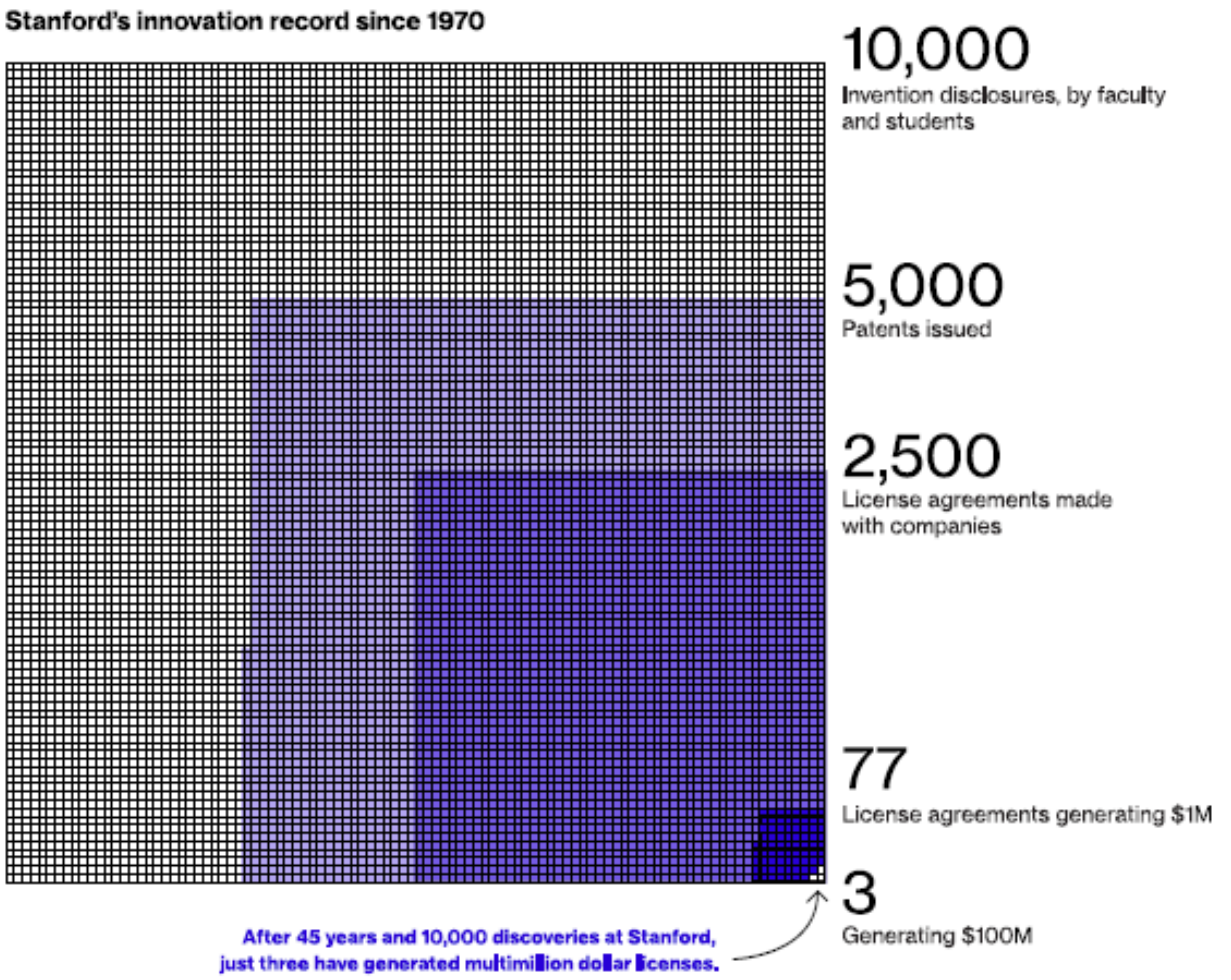
Held: US patent rights have always (since 1790) initially vested in "the inventor" and that the non-specific language of the Bayh-Dole Act does nothing to change the original setup.

For University Tech transfer offices to be successful – it is imperative that they still acquire an assignment from inventors for each application.

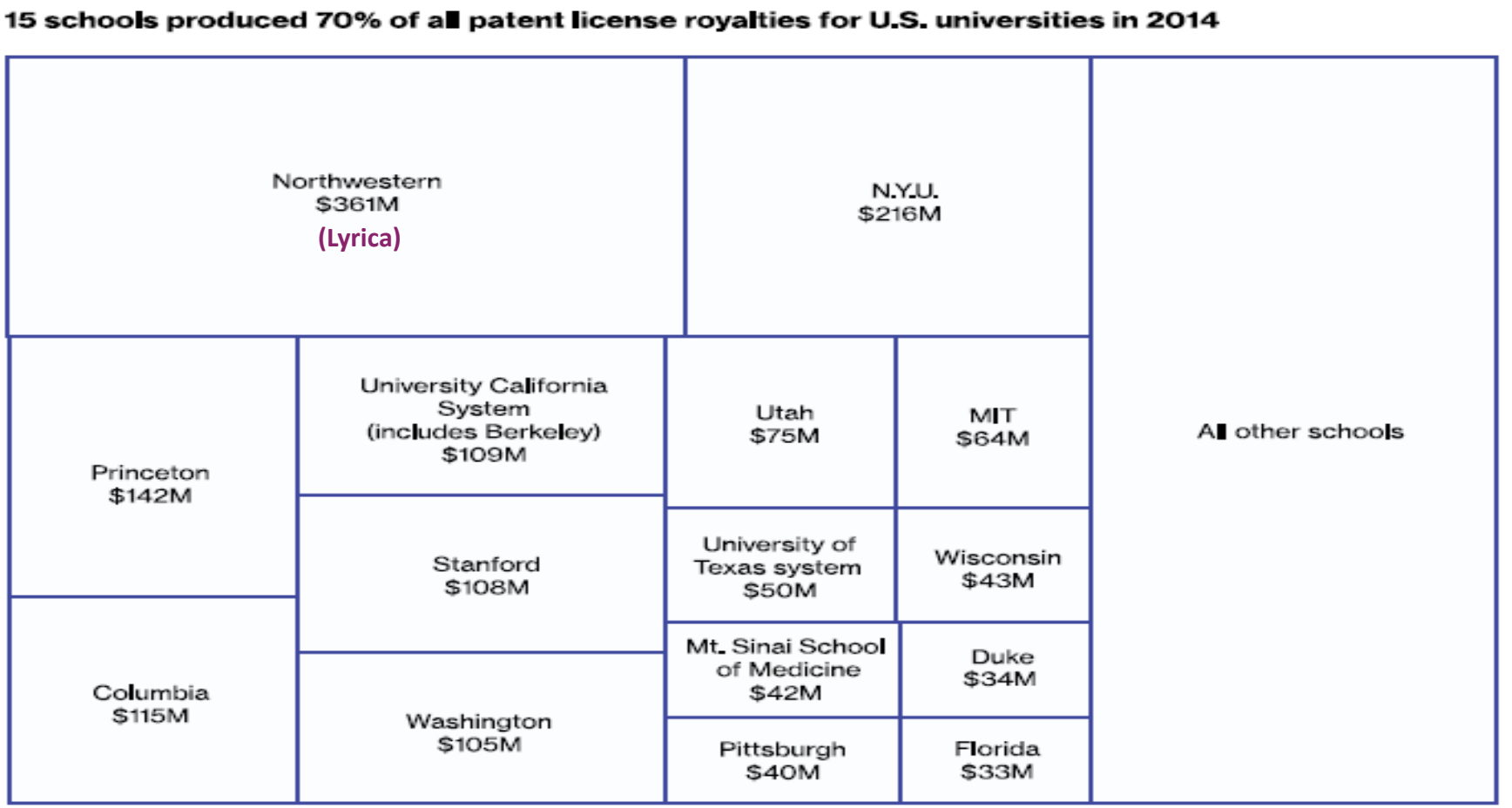
"Inventor agrees to assign, **and hereby does assign**…"
Stanford Roche

University Royalties

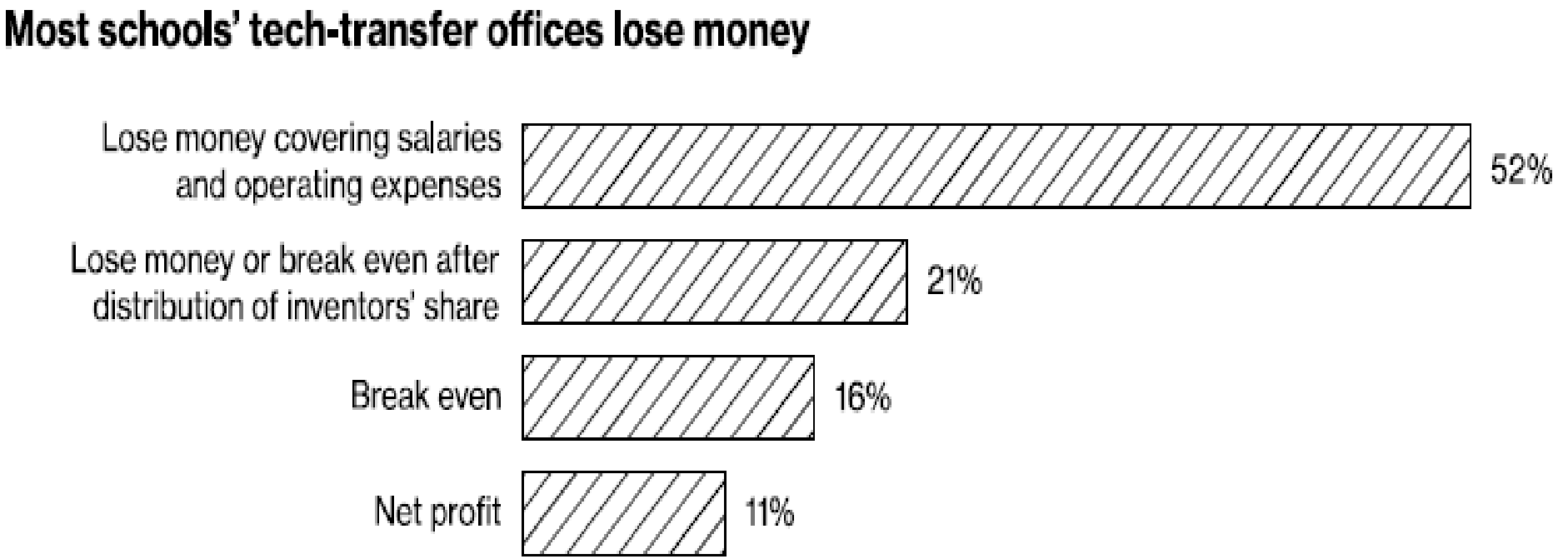
The following chart of Stanford's innovation history shows how rare it is to receive high royalties.



Graph of University Royalties



University Royalties



New Approaches at Streamlining Licensing

University of Minnesota has had recent success with the Sleeping Beauty gene editing patent licensing 2015 - $18M 2016 - $45M

(U.S. Patent 7160682—Nucleic Acid Transfer Vector for the Introduction of Nucleic Acid into the DNA of a Cell)

Sleeping Beauty is a DNA transposon designed to introduce precisely defined DNA sequences into the chromosomes of vertebrate animals for the purposes of introducing new traits and to discover new genes and their functions. Wikipedia

WO 2001081565 A3 (Maxwell, Delbrueck Centrum (Germany))

ABSTRACT

The invention relates to the use of the gene transfer system Sleeping Beauty for the somatic gene transfer for the purpose of stably inserting DNA in the chromosomes of living vertebrates, comprising the two components of the transfer system Sleeping Beauty that are injected into the somatic cells of an animal for the purpose of gene therapy.

New Approaches at Streamlining Licensing

University of Minnesota investigation into its licensing programs:

Around 2014 the University of Minnesota spent a year meeting with faculty and industry members in hopes of increasing industry sponsored research. They found that industry complained of: 1) lack of certainty of whether they would be able to get exclusive licenses to IP resulting from the research they sponsored; 2) complex licensing negotiations for unproven IP 3) lack of certainty of future costs.

U of M revamped their IP licensing program to include two main categories:

1) *Minnesota Innovation Parnerships* includes industry sponsored research

2) A *Try and Buy* program for IP that has already been generated from federally sponsored research

See Youtube video at https://www.youtube.com/watch?v=PHX3YijGchY

Under the MN Create program, the sponsor can choose one of three options: Option A: paying up front for exclusive licenses to IP resulting from the sponsored research; Option B paying lesser amount up front for non-exclusive licenses to IP resulting from the sponsored research;. or Option C where research sponsor can wait and see what IP results from the research and negotiate a license then. Option A allows the sponsor to control the patenting process, sublicensing and cross licensing. Option A includes a bonanza clause that allows the U of M to participate in a very successful product. For example a 1% royalty on annual sales of over $20 million. Also a royalty cap of $5 million if the resulting IP is an improvement to the sponsors own IP.

Try and Buy program allows the licensee to have low starting costs, only pay for IP that actually issues as patents and Royalty-free product revenue for the first $1 million. Because Minnesota is a land grant U – there are royalty discounts given to MN companies.

Simplifying University licensing programs appears to be a trend with other Universities also having revamped programs include Georgia Tech, Iowa state, North Carolina State, Purdue, University of Michigan, University of Oregon

New Approaches at Streamlining Licensing

Pennsylvania State University investigations into licensing program:

In 2011, Ronal Huss of the Technology Transfer Office at Penn State decided to study their IP licensing program from the years 2000-2006. Huss found that although Penn State had spent considerable time and money negotiating IP license relating to sponsored research, the revenue generated from the licenses was less than $100,000.

Huss interested the university administration in revamping the sponsored research IP program. **A major change was to allow assignment of Sponsored Research IP to the Sponsor.** Penn State included a *bonanza royalty clause* for IP that became very profitable. This gave Sponsors the certainty that they could own IP resulting from their sponsorship and gave the University an assurance that they would be not be left out from profits from their own discoveries. The program has appeared to increase sponsored research and dollar value of each agreement.

The License Agreement

License Agreement Sections Particularly Relevant to University Licensee

Grant of License

- Reservation to the university the right to use the technology for research and academic purposes – care must be taken here – see *Madey* case on next slide
- If relevant, reservation of rights to the sponsoring government agency

The License Agreement

From AUTM 9 points to consider:

https://www.autm.net/advocacy-topics/government-issues/principles-and-guidelines/nine-points-to-consider-when-licensing-university/

Definitions of non-commercial uses should be considered in light of *John M.J. Madey v. Duke University*. 307 F.3d 1351; 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002), cert. denied, 123 S. Ct. 2639; 156 L. Ed. 2d 656; 71 U.S.L.W. 3799.

In *Madey*, the Court of Appeals of the Federal Circuit narrowly interpreted the so-called "experimental use" exception to patent infringement. **The decision effectively limits permitted uses of unlicensed technology to aimless tinkering with patented technologies, and sets the stage for infringement suits even against non-commercial researchers.**

"In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, *so long as the act is in furtherance of the alleged infringer's legitimate business* and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, *the act does not qualify for the very narrow and strictly limited experimental use defense*. Moreover, the profit or non-profit status of the user is not determinative. … The correct focus should not be on the non-profit status of Duke but on the **legitimate business Duke is involved [teaching]** in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[1]

To address the *Madey* issue in recent license agreements, universities have attempted to make clear that they are reserving rights broader than those of a mere unlicensed party, and that activities held under *Madey* to be the "business" activities of universities are within the scope of the university's *contractually* reserved rights. Example discussed below.

[1]*Madey v. Duke University*, 307 F.3D 1351, 1362 (Fed. Cir. 2002).

The License Agreement

Consideration

- Initial License fee
- Equity for liquidation payment at exit if licensee is a start-up
- Milestone/diligence payments - can be used to ensure incentive of licensee – can be linked to termination
- Bonanza royalty – if commercialization is wildly successful, the University can participate

Patent Prosecution and Payment

- Typically the university will control patent prosecution and provide the licensee the opportunity to make comments, decisions about the prosecution strategy, which countries to file in, etc. In an exclusive license, the licensee reimburses the university for all its costs associated with preparing, filing, prosecuting and maintaining the licensed patents. Some Universities are allowing a sponsor that totally funds research to have more control over patenting and prosecution.

The License Agreement

Diligence Terms

- The license will provide for certain diligence milestones to be met by the licensee to ensure that the technology is being diligently developed and commercialized. For pharmaceuticals, these often are clinical trials milestones, for other products diligence terms might include first prototype, first sale, etc. Sometimes diligence terms or milestone terms include financing milestones (typically with startup companies) or issuance of first patent, etc.

- Licensor does not want licensee to be able to sit on a product

Indemnification

- The university position will commonly require the licensee to indemnify the university, its employees, regents, trustees, etc. against all claims, proceedings, demands and liabilities of any kind whatsoever. Universities may also require that the licensee obtain certain amounts of product liability insurance prior to commercial sale or use of a product.

The License Agreement

Improvements (Prospective rights to future technology improvements)

- This is an important area for consideration. Licensee may push for broad rights, but tying up all improvements with the licensee may restrict researchers. Focus of improvements may not even be apparent in early stages of development. Common framework can include licensor and licensee both obtaining non-exclusive rights to any newly developed IP for internal R&D and research. Options for broader rights (such as commercial right to sell or market products) can include an option to negotiate in good faith for an exclusive license and be negotiated when the future IP is developed.
- Grant back clauses can ensure that that licensor or licensee gets non-exclusive license to improvements.

University Licensing Takeaways

- BIOTECH IS EXPENSIVE TO BRING TO MARKET, AND UNIVERSITY GOALS DO NOT ALWAYS LINE UP WITH LICENSING GOALS
- 1980 CHANGED THE NATURE OF UNIVERSITY LICENSING
- UNIVERSITIES ARE STREAMLINING LICENSING AND ARE TRYING NEW LICENSING MODELS, WITH SUCCESS
- WHILE UNIVERSITY LICENSE AGREEMENTS ARE ESSENTIALLY THE SAME AS BUSINESS LICENSE AGREEMENTS, THERE ARE LICENSE PROVISIONS THAT ARE PARTICULARLY RELEVANT TO UNIVERSITY LICENSES

QUESTIONS & DISCUSSION

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