

Bringing University Research to Market: An IP Perspective

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Agenda

- **Who owns the University's IP?**
- **How best to obtain rights to University IP?**
 - Assignment
 - License
 - Trade Secrets
- **Who controls prosecution of University IP?**
- **Should University employees manage startups?**
- **What is the Bayh-Dole Act, and how does this law impact the transfer of IP rights?**
- **Must a university be involved in enforcing IP rights?**

Who Owns the University's IP?

- Before you can obtain rights to University IP, you must first confirm who owns the IP
 - Make sure all assignments are clear and recorded at the USPTO
- *Board of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011)
- Supreme Court that held that **inventors own title in a patented invention**, even if the inventor is a researcher at a federally funded lab subject to the Bayh–Dole Act
- Case affirmed the US Constitutional law that inventors automatically own their inventions, and contractual obligations to assign those rights to third parties are secondary.
- **An obligation/agreement to assign is not sufficient**
- There must be an executed assignment to the university
- **Beware of vague transfers of rights back to inventors**

Who Owns the University's IP?

- ***Stanford v Roche*** - A Stanford employee, who was under **obligation to assign** inventions to Stanford, worked at a biotech company to learn a new PCR technique, and “**do hereby assign**” inventions to the company, but then went back to Stanford
- The company was later purchased by Roche
- Stanford filed patents on work the employee did after returning, and the company (and later Roche) introduced products based on the work the Stanford employee did at the company.
- Stanford sued Roche for infringing its patents; Roche countered it had an ownership in the patents due to the agreement it had with the Stanford employee
- District Court and Federal Circuit held that Roche had true assignment, as obligation to assign to Stanford was insufficient (and claims were invalid for obviousness)

How Best to Obtain Rights to University IP?

- **Assignment** – best if you can get this complete transfer of all rights, title, and interest
- **License**
 - Exclusive
 - **Field-of-Use**
 - **Geographic Restrictions**
 - Non-Exclusive
- **Trade Secrets/Know How**
 - Difficult in the university setting, because faculty need to publish and submit grant proposals
- **License Agreement may cover a mix of rights and include patents and “know how”**
- **Bottom line – make sure your agreement is clear, especially with respect to future inventions**

Who Controls Prosecution of University IP?

- **It depends entirely on the University**
 - Typically universities prefer to retain control over prosecution of IP that they have licensed
 - **However, most license agreements require the licensee to pay for prosecution costs**
 - Some universities are willing to allow the company to control prosecution, but with certain restrictions
 - **E.g., the licensee cannot abandon an application without notifying the university**
 - Some universities will assign rights to the startup company, which then has no restraints on patent prosecution
- **Bottom line – try to get control of prosecution if you can**

Should University Employees Manage Startups?

- **Are university employees permitted to become officers or have management level positions at startups?**
 - Up to university policy and employment agreement
 - **MIT does not permit officer/management roles – consulting/ advising roles only, for up to 20% of their time**
 - **Purdue encourages startups and permits faculty to have management roles**
- **Is it a good idea for university employees to run their own companies?**
 - Can work if has prior business experience, but dual role at both the university and the company can be very tricky
 - If research continues at both the university and the company, **conflicts of interest and breach of confidentiality issues** may arise
 - Investors may be wary of sufficient time and loyalty to the company
 - **Double patenting issues may arise if the employee leaves the university to work at the company and others continue research at the university**

Bayh-Dole Act's Impact on University IP rights?

- **What is the Bayh-Dole Act?**
 - Bayh–Dole Act or Patent and Trademark Law Amendments Act (Pub. L. 96-517, December 12, 1980)
 - The Bayh-Dole Act has been said to be responsible for over 10,000 startup companies, at least 200 drugs and vaccines, and contributed \$500 billion - \$1 trillion to the economy
- **Bayh–Dole permits universities to retain ownership of inventions made under Federal grants, as long as they:**
 - In each patent include a statement that identifies the contract under which the invention was made and notice of the government's rights in the invention
 - Report inventions to the sponsoring agency within 2 months of disclosure
 - Elect in writing whether or not to retain title within two years of reporting
 - Grant to the government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the US the subject invention throughout the world

Bayh-Dole Act's Impact on University IP rights?

- The **Bayh-Dole Act** requires in exclusive licenses to sell/use in the US **that products be manufactured substantially in the US**
 - This requirement can impact a startup's ability to freely decide where to manufacture a patented product
 - This requirement can impact foreign investments in the company
- The **Bayh-Dole Act** also requires that the university agree to allow the **government to "march in" and require licenses** to be granted, in certain circumstances, such as if the organization has not taken effective steps to achieve practical application of the invention
 - However, to this date, the government has not utilized these "march in" rights, though there have been several petitions to make this request

Bayh-Dole Act's Impact on University IP rights?

- **Other university obligations include:**
 - File initial patent application within one year upon election to retain title
 - Notify government if application/patent will be abandoned/lapse
 - Convey to the Federal agency, upon written request, title to any invention if the organization fails to file, does not continue prosecution, or will allow a patent to lapse
 - Report on the utilization of inventions
 - Certain additional requirements apply to nonprofit organizations only. Nonprofits must also:
 - **Assign rights to invention only to an organization having as a primary function the management of inventions, unless approved by the Federal agency**
 - **Share royalties with the inventor**
 - **Use balance of royalties for scientific research or education**
 - **Make efforts to attract, and give preference to, small business licensees**

Bayh-Dole Act's Impact on University IP rights?

- The government's **march-in right** is one of the most contentious provisions in **Bayh-Dole Act**
- Allows funding agency, on its own initiative or at the request of a third party, to ignore the exclusivity of a patent awarded under the act and force university to grant, or itself can grant, additional licenses to other "reasonable applicants."
- This right is strictly limited and can only be exercised if the agency determines, following an investigation, that one of four criteria is met, key of which is:
 - Failure by the contractor to take "effective steps to achieve practical application of the subject invention" or a failure to satisfy "health and safety needs" of consumers.
- Though this right is quite powerful in theory, **it has never been applied in practice**
 - But might this change in the current health crisis?

Bayh-Dole Act's Impact on University IP rights?

- *Stanford v. Roche*
- **Stanford** had argued that the **Bayh–Dole Act** gave grant recipients like **Stanford** a "right of second refusal" subject to the **Government's** right of first refusal, based on the following language of the statute:
 - "If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder"
 - Therefore **Stanford** should have earlier IP rights than **Roche**
 - Federal Circuit and Supreme Court disagreed
- **Bottom line - the Bayh-Dole Act did not change the basic law of inventorship**

Bayh-Dole Act's Impact on University IP rights?

- **Rule changes of May 14, 2018**
 - if a provisional application is the “initial” filing for patent protection for a Subject Invention, the grant awardee must convert the provisional application to a non-provisional (or PCT) patent application within **10 months** rather than the typical 12 months allowed for non-federally funded inventions. (See 37 CFR 401.14(c)(3))
 - funding agencies will “automatically” grant one year extensions of time to convert provisional applications, unless the agency objects in writing within 60 days of a request
 - one option is to revise docketing to note the 10-month deadline for conversion of provisionals, then after filing the provisional, file a request for extension of time, then after 60 days, the university (and its patent counsel) should move the 10-month deadline to a 12-month deadline
 - Federal government now also has an indefinite time period to request title after a university fails to meet a reporting or election deadline

Must University be Involved in Enforcing IP rights?

- In general, the **university patent owner is a necessary and indispensable party** where an exclusive licensee acquired less than **all substantial rights**
 - right to sue for infringement,
 - right to indulge infringement by choosing not to sue, and
 - right to assign the rights it received under the patent
- **Without at least the following two rights a party does not have all substantial rights to bring a suit in its own name:**
 - Receiving party must have full, unrestricted rights to practice the patent or patents being transferred and must be able to make, use, offer to sell, sell, and import the claimed invention in all fields of use for the entirety of the life of the patent; and
 - If the receiving party does have the full right to practice the patent, then it must also have the unfettered right to enforce the patent
- **Bottom line – make sure your license agreement contains full rights so university need not be involved in bringing suit**

Must University be Involved in enforcing IP rights?

- When patent owner is a state university, the situation is more complex
- The Eleventh Amendment to the U.S. Constitution grants state universities immunity from suit in Federal Court
 - This immunity may prevent an accused infringer from filing an action for patent invalidity when the patent is owned by a state university - even where the exclusive licensee of that patent has made an explicit infringement allegations against it
- ***A123 Systems, Inc. v. Hydro-Quebec*, No. 2010-1059 (Fed. Cir. Nov. 20, 2010)**
 - Federal Circuit decided that the University of Texas (“UT”) was a necessary and indispensable party to an action to declare a patent invalid that it owned, but had exclusively licensed to a private party
 - UT could not be joined as a party - entitled to sovereign immunity
 - The court dismissed the action to invalidate the patent, because all necessary and indispensable parties could not be joined

Must University be Involved in enforcing IP rights?

- **The Federal Circuit addressed three major issues in its decision**
 - The court held that “because Hydro-Quebec had acquired less than all substantial rights in the patents in suit, [the University of Texas (“UT”)] is a necessary party to A123’s declaratory judgment action”
 - the court upheld UT’s sovereign immunity rights, despite the fact that UT had waived those rights in a related litigation in Texas
 - the court found that UT was both a necessary and an indispensable party to the action under Fed. R. Civ. P. 19, and that the district court properly dismissed the action due to UT’s absence in the litigation
- **However, if a state university files a patent infringement lawsuit, then it waives its sovereign immunity**

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With well over 30 years of experience, Peter's practice emphasizes client counseling and patent prosecution in a wide variety of technologies, with an emphasis on healthcare, medical devices, and other biological and medical fields as well as various "green" technologies.

Peter helps clients from start-ups to multinationals to develop competitive worldwide patent strategies and to establish solid and defensible patent portfolios. He performs competitive patent analyses, identifies third-party patent risks, and provides patentability and freedom-to-operate opinions. Peter also has experience in opposing and defending patents before the European Patent Office and in U.S. litigation and post-grant proceedings.

Peter has experience in medical therapeutics, diagnostics, devices, and imaging, microfluidic systems, liquid biopsy, nucleic acid sequence analysis systems and software, cell culturing and bioprocessing, molecular biology, complex biomedical systems, optics, machine tools, and lasers.

Specific applications include, e.g., cancer antibodies, RNAi and CRISPR therapeutics, engineered AAV systems, microfluidic analysis of circulating tumor and fetal cells, cell-free DNA analysis, next generation sequence analysis, dendritic cell- and DNA- based vaccines, nanoparticle and vector-based delivery of therapeutic agents, automated blood analysis systems, nucleic acid probes, tissue engineering, infusion pumps, biochips, laser systems, cellulose processing for ethanol production, implantable drug delivery devices and microcapsules, ultrasound probes, wind and solar power, and diagnostic and therapeutic methods for, e.g., AIDS, cancer, autism, diabetes, psoriasis, and arthritis.

Thank you!

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