

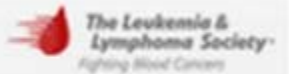
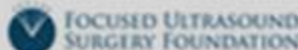
*FasterCures Webinar Series*  
**Unlocking IP: A Legal Roadmap for  
Non-Profit Disease Funders**

April 20, 2011  
1:00 pm (Eastern)

# About *FasterCures*

- *FasterCures* is not just our name – **it's our mission.**
- We are an “action tank” that works to improve the medical research system – so that we can **speed up the time** it takes to get important new medicines from discovery to patients.
- Our mission is to **accelerate the process of discovery and development of new medical solutions** for deadly and debilitating diseases

# TRAIN: The Research Acceleration and Innovation Network



# TRAIN

## THE RESEARCH ACCELERATION AND INNOVATION NETWORK

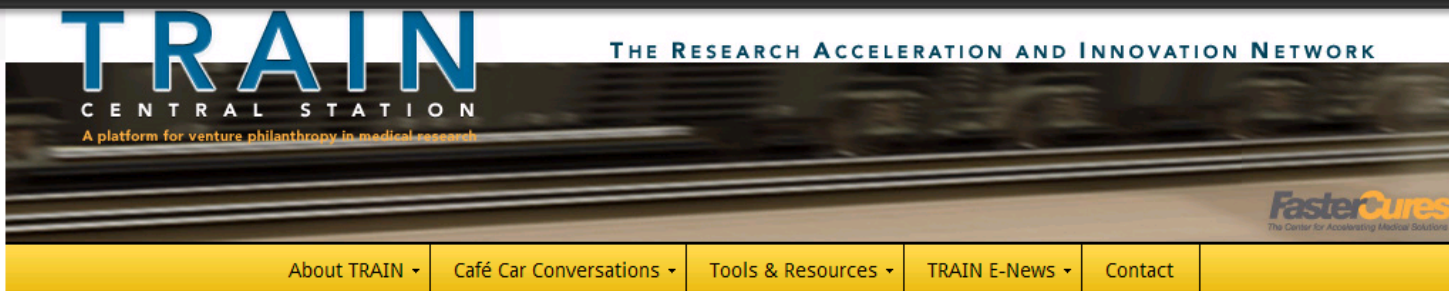
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CATALYZING INNOVATION IN MEDICAL RESEARCH

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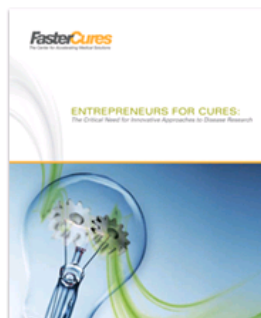
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What Metrics Matter Most in Nonprofit Medical Research?

# **Unlocking IP: A Legal Roadmap for Non-Profit Disease Funders**

*FasterCures* Webinar

April 20, 2011

# Who We Are

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Schaner & Lubitz, PLLC is a law firm dedicated to representing nonprofit entities with a particular specialty in representation of disease foundations. We are attorneys with over 80 years of legal experience who on a daily basis confront the problem of how on behalf of non-profit disease funders to unlock IP in ways that most effectively accomplish the missions of our clients. For more information, see [www.schanerlaw.com](http://www.schanerlaw.com).

# Who We Are

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Linda Johnson serves as the National Director of Strategic Alliances for JDRF. Prior to JDRF, she worked in the biotechnology, pharmaceutical and healthcare technology industries on a wide range of collaborations on disease therapeutics and has managed intellectual property portfolios. Ms. Johnson established the technology transfer office at University of Nebraska Medical Center and was a Board member on several university start-up companies. She began her career as a laboratory researcher. She is a registered U.S. Patent Agent.

# Statement of the Problem

- Unrealized IP
  - IP at academic institutions and for-profit companies can become ‘locked’ in the sense that it is not readily available to the scientific research community and the potential unrealized unless the IP can be ‘unlocked,’ i.e. made readily available to the scientific research community
  - IP at academic institutions not being put to use in advancing scientific research
    - This was a topic of robust discussion during Faster Cures annual conference last December
  - For-profit companies can lock their IP when they change research priorities or go out of business
    - This is an issue for non-profit organizations that fund for-profit IP

# Unlocking the IP

- Some have framed the problem in catastrophic terms for academics
  - For example, one journalist has said: “Universities have evolved from public trusts into something closer to venture capital firms. What used to be a scientific community of free and open debate now often seems like a litigious scrum of data-hoarding and suspicion.” Clifton Leaf, “The Law of Unintended Consequences,” Fortune (Sept. 19, 2005)
- Universities are incentivized to promote their interests through monetizing their IP to promote their interests
  - Emory University reaped hundreds of millions of dollars, which presumably has been used to further the academic missions of Emory
- Non-profit disease funders can use incentives to ensure effective employment of the IP they fund.

# Unlocking the IP: The Solution

- The solution to the problem of locked IP: Before awarding research funds, funders may obtain certain promises from awardees in return for funding.
- These promises are memorialized in research funding awards, which are contracts between the parties.
- Careful advance planning as to what terms are desired by a funder of scientific research will help make awardees more likely to agree and make the negotiation shorter and easier.
- We focus on obtaining “licenses” for our clients which mean that funders obtain certain rights to the results of the research they are funding.
- When appropriate, we also work with our clients and awardees to obtain alternative rights, such as commitments to sharing research results among awardees of the same funder or commitments from grantees not to obtain seek any proprietary rights to research results.

# The Bayh-Dole Act

- Federal legislation passed by Congress in 1980
  - Has become a principle force in defining IP rights at academic institutions – it created new rules for ownership of federally funded IP
  - Allowed universities and other grantees to retain rights to IP created with federal funds, subject to certain government interests
- Government rights
  - License to practice the invention for non-commercial purposes
  - March-in rights to take control of the invention if the owner fails to commercialize it or if public health and safety require it

# The Bayh-Dole Act (cont'd)

- Commercialization of inventions
  - Prior to Bayh-Dole, only 5% of federally funded inventions were commercialized
- Post Bayh-Dole
  - Has allowed universities to create revenue to carry out their missions
  - Contributed to US economy
    - Between 1980 and 2003, over 4,000 companies were created through federally funded research\*

\*AUTM FY 2003 Licensing Survey

# Restatement of the Problem

- Bayh-Dole has incentivized academic institutions to promote their economic interests through retaining control over IP.
- For-profit companies can lock their IP when they change research priorities or go out of business
- We will discuss the locking problem with respect to academic institutions and for-profit companies

# Stanford v. Roche

## The Fight for Control of IP

- The Case:
  - Assertion by Stanford and the federal government that pursuant to Bayh-Dole the academic institution's IP rights to federally funded research cannot be usurped by a company that obtained rights to an invention from the individual scientist who made the invention.
  - Roche used skillful drafting of its agreement with the individual scientist to arguably obtain a legal right to the inventions of the individual scientist superior to Stanford's rights under Bayh-Dole and its agreement with the scientist
- Status
  - Currently before the U.S. Supreme Court – a decision will be rendered this Spring
  - A lower court, the U.S. Court of Appeals for the Federal Circuit, the court charged with interpreting the rights of patent holders throughout the United States, agreed that the company's skillfully drafted agreement, gave the company superior rights.

# Stanford v. Roche

## The Fight for Control of IP (Cont'd)

- The case is an example of the way in which careful use of legal tools can affect IP rights
- Attention to drafting details with respect to those rights that are appropriate to non-profit disease funders can unlock IP for research, to which we now turn.
- Stanford v. Roche involves a legal concept called “assignment” which means that all rights to IP are given to a new party, and disease funders do not generally seek assignments of IP, but the same careful attention to legal drafting should be applied to “licenses”, which disease funders typically do seek.
- Licenses give a new party some, but not all rights to the IP.

# How We Unlock IP

- In exchange for funding from non-profit disease funders, academic institutions and companies must agree to pledge certain rights to funders. For example:
  - Research only license
  - No IP ownership
  - Interruption license / march-in rights
- Non-profit funders obtain rights through various terms in the agreements governing the research funding that they provide
- Our focus in this discussion is on non-profit disease funders' interest in pushing research to researchers, not in retaining rights to money (like the company in *Stanford v. Roche*).

# The Sublicensable Research Only License

- By “research only” the funder pledges not to use the IP as a source of revenue. It also means non-commercial.
- The license is “non-exclusive,” meaning that the owner may give or sell it to others
- At no additional cost to the licensee means that the disease funder can make available the funded technology to new researchers at no cost or only the cost of transferring the material.
- When it does so, the disease funder may exact similar research only no additional cost pledges to the results of down-stream technologies created with the licensed technology.
  - i.e. when a funder sublicenses its research only license to researchers, in the license agreement the funder may provide that the sublicensee will make its research results available to other researchers on a similar no additional cost basis.

# The Sublicensable Research Only License (Cont'd)

- Example from JDRF:
  - Artificial Pancreas Consortium
    - Created by JDRF to bring together medical and mathematical scientists to develop an artificial pancreas
    - All consortium institutions must execute the APP IP Policy in order to participate in the consortium
  - IP generated using JDRF funds is owned by the academic institution
  - JDRF retains a research only license, with right to sublicense, any research results for use in its artificial pancreas consortium
  - Continues the use/development of the IP and allows JDRF to further its mission related to the artificial pancreas

# Research Only License: Available to Company Researchers?

- Research licenses are subject to negotiation on a number of key points.
- A big issue is whether these licenses may be sublicensed to researchers working at for-profit companies.
- We have had success with this, but some academic institutions and companies say that companies should be charged a fee, some times a very high one, for using their research, or not receive such sublicenses at all since the research will be used in some way for a commercially viable product from which the company will profit.

# Research Only License: Field of Use and Other Limitations

- Field of use - academic institutions may want to limit the free or low-cost use of their research to research in “the field” in which the disease funder is working.
- Theory is that the funder is providing money for progress toward eradicating the disease(s) at which the funder is aimed and that funder has no mission-driven interest in other research fields.
- Disease funders usually are amenable to this because they are mission-focused and willing to limit their sublicensable license to the disease at which they are aimed.
- Sometimes academic institutions and companies that are on the other side of a research only license request will try to limit the license to a particular number of users or only other grantees of the disease funder

# Expansion of Sublicensable Research Only License

- Some of our clients have expanded the sublicensable research only license in novel ways.
- For example, clients have required grantees to share on a real-time basis interim inventions and data with colleagues in consortia formed by the funder.
- IP is protected by confidentiality agreements which include pledges by recipients not to further divulge the research information and materials they may receive outside the consortium.
- The confidentiality agreements give the academic institution comfort that shared inventions may be protected through the patent process and sold to others not within the consortium.

# Explosion of Research Only Licenses: No One Owns IP

- No one owns IP
- Some non-profit disease funders are requiring grantees to pledge up-front not to seek IP from their funded research
- The disease funders also pledge not to seek IP
- The effect – no one owns any IP
- The theory – the research will be freely available to all researchers
- In this situation, the funder also funds third party data and materials repositories to facilitate distribution to researchers

# Funding No-Ownership

- An example from the public literature is the ADNI (Alzheimer's Disease Neuroimaging Initiative):
  - “No one would own the data. No one could submit patent applications, though private companies would ultimately profit from any drugs or imaging tests developed as a result of their effort.” - Gina Kolata, “Rare Sharing of Data Leads To Progress on Alzheimer's,” The New York Times (Aug. 12, 2010).
- The Michael J. Fox Foundation's Parkinson's Progressive Markers Initiative is another example of the no-ownership model in action.

# Limitation of No-Ownership Model

- May work well in promoting innovation among a large number of scientists working on the same project, but it will not produce therapies for sale in the marketplace.
- An inability to claim IP rights means no company will invest the resources to take a product to market
- Without the period of exclusivity that patents afford the owner, a company will not risk its capital to commercialize a product
- The no-ownership model therefore may work well for diseases or particular projects that do not yet have a target at which commercial products may be aimed, but once a target is identified, disease funders will want to take a funding approach that permits assertion of exclusive intellectual property rights.

# Interruption License: Academic Institutions

- An interruption license is a march in right.
  - Permits the funder to “march in” and take control of the intellectual property if the grantee does not develop it.
  - Most often is an issue in providing research funding to private companies
- It is an “exclusive” right – in contrast to the research only license.
- May be recommended if the academic institution project to be funded has clear pathway toward development, i.e. academic grantee has established a company partnership for commercialization
  
- How is an interruption license effected?
  - if an institution fails to meet a pre-defined goal, i.e. fails to obtain company to buy the results of the research within a period of time, say 2 years or, if company fails to commercialize the product, then the funder obtains a period of exclusivity within which to find a buyer.
- The funder incentivizes the academic institution to agree by sharing in the proceeds of the sale to a willing buyer.

# Interruption License: Academic Institutions – JDRF Example

- Patent Protection
  - If grantee not diligently pursuing patent protection or chooses not to file patent protection, JDRF can step in and take over filing / prosecution
- Commercialization by Grantee
  - Diligence obligations to commercialize any JDRF-funded IP
  - Cannot enter into exclusive licensing arrangements without JDRF's written approval
  - Failure to meet diligence obligations = JDRF march-in right
- Royalties on JDRF-funded IP
  - Paid to JDRF if grantee successfully commercializes
  - Under JDRF march-in, JDRF will share in any commercial proceeds obtained from commercialization

# Interruption License: For-Profit Companies

- Interruption licenses more common when providing funding to for-profit companies.
  - Funding technologies that are expected to have commercial value
  - Funders want to ensure that technologies they fund will not be shelved due to reprioritization or failure of a company (i.e. bankruptcy)
- Terms
  - Funder obtains rights to underlying technology if company ceases commercially reasonable efforts to commercialize for a continuous period
  - If funder obtains license and commercializes, funder agrees to share in any resulting proceeds with the originator company

# Interruption License: For-Profit Companies

- Challenges – companies resist
  - Large pharma vs. biotech vs. start-up
    - Each negotiation is different with separate arguments
    - Pharma and biotech often resist if project IP relates to franchise IP or flagship products
    - Start-ups worry about ability to obtain venture funding
  - Rights to project IP vs. background/umbrella IP
    - Ability of funder to commercialize project IP under an interruption license
  - In cases where an interruption license cannot be obtained, a financial remedy should be negotiated
  
- In several cases the existence of an interruption license has prevented the loss of technology worthy of further development by the funder

# The Value of the Interruption License

- In one recent situation, a company that was funded by a non-profit went bankrupt
- The non-profit marched in and took the technology pursuant to its interruption license rights
- The non-profit then found a willing licensee to develop the technology, thereby saving the technology
- The interruption license right also ultimately resulted in a substantial payment to the non-profit by the buyer
- The company that purchased the assets of the bankrupt company also shared in a portion of the payment
- Had the interruption license not been available the technology could have been lost for a very long time.

# Mitigating Risk of Funding Technology Development

- Disease funders should approach each funding opportunity with its risk-mitigation interests in mind
- Academics
  - What happens if the institution fails to protect IP?
  - What commercialization diligence should be required?
  - What level of approval right does the funder want with respect to exclusive licensing by the institution?
- For-profit companies
  - What happens if the company changes strategy or decides not to further develop the product?
  - What is the background IP that would be required to commercialize technology under an interruption license?
  - What is the alternative risk-mitigator to an interruption license?
- Review terms carefully to mitigate risk (termination provisions, indemnification, royalties, etc.)

# Conclusion

- To unlock IP, non-profit disease funders must carefully plan for it at the time of awarding funds
- The sublicensable research license, including forced sharing and the no-ownership variations, and the interruption license can be powerful keys for unlocking IP
- These keys are versions of what the federal government requires in return for federal funding (pursuant to the Bayh-Dole act)
- Careful advance thought as to what goals the non-profit funder seeks in return for awarding funds is critical to any successful unlocking plan
- Academic institutions have long experience with federal funding and while they may wish to monopolize these rights they should readily understand why non-profit disease funders seek to employ the tools discussed herein

# Unlocking IP: A Legal Roadmap for Non-Profit Disease Funders

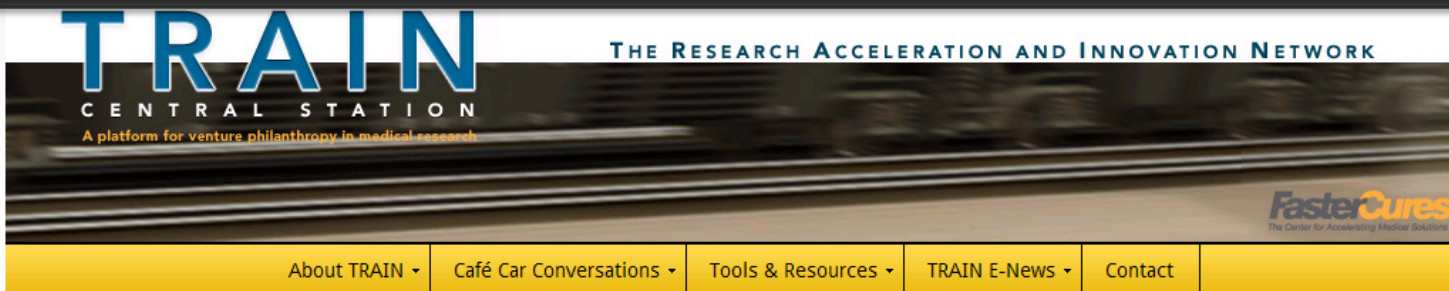


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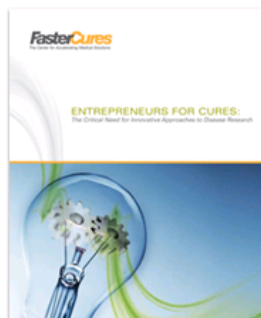
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