

AUTM 2011 Eastern Region Meeting

Click Through Licenses, Pre-Negotiated Deals: How to Communicate with Industry to Speed Transactions

May 23, 2011

The Two Cultures

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Societal Responsibility

- Societal Mission Dominates

Open Ended Goals

Research

- Unpredictable
- Need freedom to change direction based on outcomes
- No promises

Long Term Oriented

Individualistic

- Individuals Control (“Member of the Faculty”)

Proprietary Responsibility

(stockholders)

- Profit and Loss Driven

Specific Objectives

Development

- Specific objectives
- Specific Tasks
- Specific Measures of Completion

Shorter Term Oriented

Hierarchical

- Institution Controls (“Employees”)

Operating Environment: Academia/Non-profit

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- Internal Revenue Code/Tax Exempt Status
 - Charitable Mission
 - No Private Benefit
 - No Private Use (tax exempt bond covenants)
 - Avoid Unrelated Business Taxable Income
- Export Controls
 - Fundamental Research Exemption
- Academic Freedom/Integrity
 - Avoid appearance of conflict of interest
- Conflict of Interest
- Bayh Dole Act
 - Transfer federally funded inventions to benefit society

Operating Environment: Industry/For-profit

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- Profitability
 - Avoid bankruptcy
 - Increase shareholder value
- Internal Revenue Code
 - Taxable Income
- SEC/Accounting
- Export Controls
 - Formal compliance; limited exemptions

Academic Medical Centers and Health Care Companies

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Additional Restraints:

- Anti-Kickback Statute
- Stark Law
- Corporate Integrity Agreement
- PhRMA Code of Ethics
- AdvaMed Code of Ethics

Industry FAQs: 7 Key Questions

- Why can't my **company buy the invention and own it** outright?
- Why can't my company get a **free (or nearly free) license?** Even if we paid for the research?
- Why won't the non-profit entity make **IP representations and warranties?**
- Why won't the non-profit entity provide **product liability or infringement indemnification?**
- Why can't my company **control publication** of information about the invention and the resulting product?
- Why won't the non-profit entity assist with **marketing and promotion** of the resulting product?
- Why is it so difficult to reach a mutually **acceptable business deal?**

Why can't my company buy the invention and own it outright?

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- Internal Revenue Code:
 - License royalties are not taxable
- Bayh Dole Act:
 - Federally funded invention: non-profit has first right to own
 - “federally funded” = 1 penny rule
 - If non-profit chooses not to own, must notify U.S. funding agency and allow U.S. government right to own
 - If U.S. funding agency passes, then, and only then, can the invention be assigned to a third party
 - *Subject to the requirements and restrictions of the Bayh Dole Act*

Why can't my company get a **free (or nearly free) license?** Even if we paid for the research?

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- **Tax Exempt Status**

- Avoid Private Use: Must receive fair market value
- Avoid Private Benefit: Tax Exempt Bond covenants
 - Safe harbor
 - Research payment is for the services
 - Additional payment is for rights to the results, which can't be known until the results have been made and the invention known

- **Bayh Dole Act**

- Royalty sharing incentive for inventors
- Royalties used for research and education

Why won't the non-profit entity make IP representations and warranties?

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- Sole Ownership:
 - Requires that non-profit have control over how inventions are conceived, reduced to practice or created
 - No control over researcher's collaborative efforts
 - Faculty and researchers are not restricted in the way company employees are
- Noninfringement:
 - Licensee/company controls the information necessary for the assertion
 - Requires knowledge of *how* and *where* the patented invention will be practiced, manufactured and sold

Why won't the non-profit entity provide **product liability or infringement indemnification?**

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- Nonprofits are research and educational institutions
- Licensees/companies are responsible for commercial activities
- Nonprofits can not accept liability associated with commercialization activities
 - Need to protect endowment

Why can't my company **control publication** of information about the invention and the resulting product?

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- To maintain tax exempt status of revenue:
 - Control the research and control content of publication
- **Export Control/Fundamental Research Exemption**
 - Must intend to publish
 - Without for-profit oversight
- Company confidential information ok to keep confidential
- “Academic Trade Secrets” not ok: no intent to publish

Why won't the nonprofit entity assist with **marketing and promotion** of the resulting product?

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- UBTI:
 - Any revenues received for services unrelated to charitable mission are subject to taxation
- Academic Integrity:
 - Appearance of conflict

Why is it so difficult to reach a mutually acceptable business deal?

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Non Profit Value Perspective Includes

- Brick and mortar infrastructure
- Historical research and educational culture culminating in invention
- Reimbursement of allocated expenditures
- Importance to company's ability to move forward, but payment made based on company's later success
- Likely revenue stream directly or indirectly from the invention

For Profit Value Perspective Includes

- Reimbursement of actual expenditures
- Actual value of invention at time of licensing measured by ability of company to pay
- Value of invention to the company after the company has become successful
- Likely increase in revenue or profit from use or sale of invention

Thank you.

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