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LEGAL ISSUES WHEN LICENSING UNIVERSITY TECHNOLOGY

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The Other View of University Licensing

- ▶ PART I: Why be a University Licensee?
 - A Little History
 - Overview of Technology Transfer
- ▶ PART II: Licensing and IP Issues
 - Key Licensing Provisions
 - Prior Art Problems
- ▶ PART III: Conflicts of Interest
 - Relationship with University
 - Managing Conflicts
- ▶ PART IV: Conclusions

PART I

Why be a University Licensee?

▶ Roots of University Licensing

- Bayh Dole Act (1980) enabled universities to retain title to inventions made under federally-funded research programs

▶ Sponsorship to Partnership

- Same mentality began to apply in corporate sponsored research programs
- 1970's and early 80's saw IP being assigned to corporation and subordinated rights to publish

PART I

Why be a University Licensee?

- ▶ “Technology Transfer” to “Technology Partnership”
 - Tech Transfer offices have begun to move from legal area to business area
 - Occasionally will even establish separate entity
- ▶ University Interest in Commercialization
 - Opportunity for increasing revenues
 - More active role in commercialization make universities more like business partners (equity)
 - Insisting on more advantageous terms
 - Universities *and* inventors share in royalty

PART I

Why be a University Licensee?

- ▶ Result has been dramatic increase in university commercialization
- ▶ Tech transfer has contributed \$40B to economy*
 - Annual issued patents to universities have gone from 250 to 2,000
 - Over 200 universities in some form of technology licensing (8-fold increase)
 - 1991-1999: 200% increase in patent applications and 133% increase in royalties

PART I

Why be a University Licensee?

- ▶ Typical University Agreements
 - Exclusive/Nonexclusive License Agreements
 - Computer Software License Agreement
 - Sponsored Research Contract
 - Clinical Trial Agreements
 - Material Transfer Agreements
 - Confidential Disclosure Agreement
 - Agreement of Joint Commercialization

PART I

Why be a University Licensee?

▶ Advantages

- Leverage millions of dollars of government and private research dollars
- Instant credibility by forming relationship with prestigious university
- Frequently good path to starting venture backed company

▶ Precautions

- Sophistication in universities ranges widely
- Commercial viability of technology can be difficult to evaluate

PART II

Licensing and IP Issues

- ▶ IP Rights usually obtained through exclusive patent license
 - Could be non-exclusive license
- ▶ Scope of Rights
 - Usually includes licensed patents but consider including related patents, CIPs, etc.
- ▶ Exclusive license
 - Most common way of starting venture backed company
 - Frequently limited to a certain “field of use”
- ▶ Exclusivity is usually tied to milestones
 - Breach could result in non-exclusivity
 - Milestones useful to negotiate broader field of use

PART II

Licensing and IP Issues

▶ What Exclusivity Doesn't Include

- University Retained Rights
 - Right to do R&D
- Government Rights
 - Usually retains rights under Bayh Dole
- Third Party Rights
 - Any third party equipment or dollars involved?
 - Company needs to do own diligence because there is usually no warranty
- Right to Limit Publishing

PART II

Licensing and IP Issues

▶ Royalties

- Royalties are usually % of Net Sales
 - Can also get % of gross margins
- Combination Products
 - Net Sales calculated on portion covered by licensed patents (A/A+B)
- Anti-Royalty Stacking
 - Can get up to 50%
 - Q: must TP IP be “necessary” or “useful”
- Royalty Buyout
 - Attractive for acquiror because it provides certainty

PART II

Licensing and IP Issues

▶ Royalties

■ Milestone Payments

- More common in drugs and medical devices
- Can be 6 figures for FDA approval

■ Sublicensee Payments

- What to share in corporate partnering deals?
- Limit payment to license fees, and not R&D

■ Practice tip: focus on definition of “licensed product” not % number

PART II

Licensing and IP Issues

▶ Royalty vs. Equity

- Difficult to calculate early
- For companies and VCs, equity:
 - Eliminates royalty burden on profitability
 - Eliminates “gaming” royalty
 - Aligns the parties interests
- For Universities, equity:
 - Provides greater upside potential
 - Hedges against deviation from original technology
 - Is longer time to revenue/liquidity
 - More difficult to manage and distribute

PART II

Licensing and IP Issues

▶ Term

- Licensee wants as long as possible and licensor wants as short as possible
- Perpetual is “string of infinite length” and irrevocable is “string that cannot be cut”
- Term usually limited to life of patent but some Universities are pushing for shorter period of time where FDA approval is not required

PART II

Licensing and IP Issues

▶ Field of Use

- License can either grant unrestrained rights to use or have a “field of use” restriction
- Ex: description by product, by function, physical characteristics, markets, combinations with other technology or other technical or use aspects
- University will try to limit; but company should realize that ultimate “field of use” is probably unknown

PART II

Licensing and IP Issues

- ▶ Improvements
 - Option on obtaining improvements to patents and technology
- ▶ Technology as Important as Patents
 - Technology and know-how is often the “secret sauce”; but could be non-exclusive
- ▶ Non-exclusive Rights
 - Focus is usually on exclusive rights but could be valuable non-exclusive rights

PART II

Licensing and IP Issues

- ▶ Prosecution
 - Conflict of interest in direction of patent portfolio is inevitable so control of prosecution is essential
- ▶ Assignability
 - Important to have license assignable in acquisition
- ▶ 3 Most Important Provisions
 - Renegotiation, renegotiation, renegotiation