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University Licensing: Turning Academic Innovation into Useful Products

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Universities Become Economic Players

- "Universities around the world have expanded their mission beyond that of basic research and teaching to become places where knowledge fuels patent development, business collaborations and incubators for startups,"*

* *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization, Milken Institute* September,2006

Commercializing Innovation: U.S. University Contribution to World Economies (2006)

- 553 new companies formed
- 697 new products reached the global marketplace
- More Detail
  - 18,800+ Invention Disclosures submitted
  - 11,622 U.S. patents filed - approx. ¼ utility patents
  - 4,192 Licenses/options signed
  - 29,000 active licenses indicates pool of intellectualized knowledge working its way into the value chain
  - $1.8 Billion in royalty income (2005 figures) = 2-4% of the economic value realized by private industry from university-licensed IP
- Estimated: 4,300 products introduced into the market in the last 9 years through U.S. university licensing

* Source: AUTM Annual Licensing Survey, 2005 & 2006 based on 189 universities reporting

Academia + Innovation = Knowledge Assets

- "University intellectual assets" derive from a wide range of academic activity
  - New Knowledge (know-how usually learned from conducting research)
  - Innovation in science/new discoveries
  - Curriculum/course content/teaching methodology
  - More recently - new systems of knowledge delivery e.g. distance learning
  - The Arts
  - Administrative systems (software)

Commercializing University Assets: Two Points of View

- The current "tug of war" in evaluating academic knowledge distribution strategies
  - One point of view: Recognizing *Value* in the "commons"
    - Free distribution advances science and relies on natural market forces to capitalize on publicly available information
  - Pushing knowledge and new discoveries along the freely accessible continuum has indisputable value but . . .

Commercializing University Assets: Two Points of View

- Another point of view:
  - Societal value also found in turning academic innovation into products for the public marketplace and public benefit.
  - But, this is the job of the private sector, not the university, and requires universities to find new methods of interaction with the private sector
- Incentive for the private sector to "productize" requires finding *sufficient commercial value to recoup investment and make a profit*

Establishing *Commercial Value* for University Assets

- An asset finds commercial value in what it is worth, i.e. what someone is willing to pay for it to acquire a benefit
  - If everyone can use it, no benefit is available, hence no one pays for it – its commercial value = 0
  - If only some can use it, may be some benefit - commercial value = ~
  - If only one/few can use it and benefit from it - commercial value = +
- *Commercial value* + *user/consumer demand* = a candidate for commercialization

Intellectual Property: The Commercialization Launching Pad

- Applying lawfully acquired intellectual property rights creates commercial value
  - Exclusive rights period of protection permits the owner to maximize value by determining who uses the rights and how
- Matching university assets with IP rights
  - General Ideas/knowledge = trade secrets
  - Research Discoveries = patents/tangible research property
  - Computer software = patents/copyrights/trademarks
  - Teaching/curriculum/course content/methodology = copyrights
  - New systems of knowledge delivery = copyrights for software; patents for other; possibly trademarks

Licensing vs. Assignment: (Why the University Preference for Licensing)

- Two overriding Legal Reasons for University Preference for Licensing
  1. Federal Statute: Bayh-Dole (35 USC 200 et seq.)
     - Prohibits assignment of federally-funded inventions except in limited circumstances
       - Can assign to patent management firm
       - Can assign to the federal government
       - Assignment to inventors - *if* title waived by university & federal agency

Bayh-Dole: Encouraging Commercialization while Protecting the Public Interest

- Inducements to patent and commercialize research
  - Exclusive licensing permitted
  - Small business, universities can retain all revenues earned from licensing
  - Reporting requirements minimal
  - No government intrusion into commercialization process
  - University-industry working relationships encouraged

Bayh-Dole: Encouraging Commercialization while Protecting the Public Interest

- Protecting the public interest
  - Universities to license on a “non-discriminatory” basis
  - No selling or assigning patents to industry
  - Must ensure licensee utilization or government can “march in”
  - Exclusive licensees must “substantially manufacture” in the U.S. to encourage job growth
  - Royalties must be used for education and research
  - Inventors incentivized by receiving share of royalties

Licensing vs. Assignment: (Why the University Preference for Licensing)

2. <u>Other federal laws and regulations applicable to all commercially funded research</u>

   - ***The IRS***: §512(b)(2), 1986 IRC protects royalties from being taxable as "unrelated business income" – ***but*** assignment may be considered a "sale" by the IRS -likely to result in taxable transaction.
     - Selling of "services" not generally protected from UBIT
     - Industrially-funded research resulting in assignment of inventions cannot be conducted in facilities built with tax exempt bonds without impairing tax exemption of bonds (+/- 5% safe harbor available)

Licensing vs. Assignment: (Why the University Preference for Licensing)

2. Other federal laws and regulations applicable to all research regardless of funding source

- ***Export Controls***: The question of whether export licenses are needed (i) to send research results to foreign sponsor or (ii) to employ foreign national on a research project, depends upon whether the research is "fundamental".
  - Fundamental research requirements
    a. University must own it; and
    b. Must be publishable (without approval)

The University's Ultimate Commercialization Tool: The IP License

- Licensing: the preferential transactional mechanism used by universities to transfer (commercialize) IP-protected Innovation
- Benefits of IP Licensing
  - Owner's exclusive rights are transferable to the licensee without transferring ownership of the IP
  - Licensing permits the university to retain some control by imposing limitations, obligations through the terms of the license agreement
    - Of major importance are terms that promote diligent commercial development by the licensee

Commercializing University Assets: More Complicated Than Meets the Eye

- University IP assets come with a variety of "wrinkles" not always visible to the negotiating licensee
  - The "Ownership" Issues
  - Requirements imposed by funding sponsors
  - Non-profit Tax Considerations
  - University mission (policies)
  - The University "environment" – open campus

First Wrinkle: Sorting out Ownership

- Potential Owners to consider
  - **Inventors/authors**
    - University faculty, students, employed staff
    - Visitors
  - **University**
    - By employment or assignment agreement; as work for hire; by policy
  - **Joint owners**
    - Co-inventorship/co-authorship, agreement

First Wrinkle: Sorting out Ownership

- Potential Owners to consider
  - **3rd Party**
    - Under agreement as provider of funding for research
    - As owner of underlying IP such as software, materials used by university and its personnel under agreement
  - **No one owns**
    - In the public domain by regulation or agreement or failure to provide protection

First Wrinkle: Sorting out Ownership

- In the University, IP ownership determinations depend upon a number of factors but in the U.S. often driven by the University's IP Policy
- Structure of Policy (norm)
  - Generally starts with inventor/author ownership (no "hired to invent" or "work for hire") . . . . but
  - University acquires ownership through obligation to assign due to:
    - An employment agreement; or
    - Policy that requires assignment due to use of university funds/facilities (assuming policy is strong enough to create an implied contract between university and the people the policy is presumed to cover) . . . .

First Wrinkle: Sorting out Ownership

- More ownership wrinkles: Once inventors/ authors determined, are they subject to the policy?
  - Faculty
  - Staff
  - Students
  - Joint Appointees (common for hospitals)
  - Visitors (industry, other university, government)

First Wrinkle: Sorting out Ownership

- And one more ownership wrinkle: Whether there is an applicable external agreement that dictates ownership
  - Government as source of funds – generally university owns by federal law; government has default position
  - Industry research sponsor – generally university owns through contract negotiation, but not always
  - Use of 3rd party-owned IP – university may not own because of terms of agreement of use/license

Second Wrinkle: Licensing "Spoilers"

- Reviewing potential spoilers
  - Limitations imposed on licensing/ commercialization by pre-existing external funding agreements
    - Federally funded (Bayh-Dole requirements)
    - Industrially funded (terms of agreement)
    - Foundation/state funded (terms of agreement)

Second Wrinkle: Licensing "Spoilers"

- Limitations imposed by other pre-existing factors/agreement
  - Existing licenses granting licensee rights to future improvements
  - Applicable material transfer agreements w/rights clauses for materials provider
  - Licenses for electronic products/software with restrictions on use
  - Joint development agreements w/universities
  - Visiting scientist agreements
  - Background rights agreements

Universities as Licensors: Looking at "University Practice"

- Six licensing terms universities consider important and how they negotiate them
  - Scope of the license
  - Diligence requirements
  - Sublicensing
  - Royalties
  - Rights to Improvements
  - Assignment

1. Scope of License: Choosing the Best Licensing Strategy

- Alternative strategies to consider (scope of rights granted)
  - Exclusive vs. non-exclusive grants based on a number of factors including:
    - Type “technology” and its purpose
    - Value
    - Nature of licensee
    - Incidence of pre-existing rights
    - Government sponsorship
    - University & public interest

1. Scope of License: Choosing the Best Licensing Strategy

- Alternative licensing strategies (rights granted)
  - Licensing by Field of Use
    - Multiple applications
  - Licensing Geographically
    - Role of regional economic development
  - Time-limited Licensing (not life of the patent)
    - Licensee needs lead-time only
    - If not sure of licensee's staying power
- Universities generally in good position to maximize commercial applications

.2 Due Diligence: Ensuring Performance

- Diligence requirements universities favor
  - Performance:
    - Time to development; time to market
  - Sales volume
    - By units sold
    - By sales revenues
  - R&D commitments
  - Annual minimum payments
  - For start-ups – measured by ramp-up/acquisition of capital

2. Due Diligence: Flexible Terms Provide Useful Options

- Commonly-applied penalties for diligence failures
  - Downgrade of license from exclusive to non-exclusive
  - Financial penalties
  - Restructuring “scope of license”
  - Renegotiation of diligence requirements
  - Termination

3 Sublicensing: Adding Value

- When does granting sublicensing rights make good sense
  - Standard under an exclusive license grant
  - Under non-exclusive license, decide whether best returns will result from the licensee's sublicensing or from institution's direct licensing of 3rd parties. Major issue: avoiding competition from your own licensee
- Sublicensing royalty alternatives
  - Same royalty rate for licensee/sublicensee revenues
  - Percentage (50%) of licensee's sublicensing revenue

4. Negotiating Royalties: Pie in the Sky or Recognizing Realities

- Reality: the “royalty bargain” is based on hypothetical forecasts
- Reality: the “value” is the price a licensee is willing to pay

4. Negotiating Royalties: Pie in the Sky or Recognizing Realities

- What's important in the licensor's assessment
  - The number/kind of IP assets licensed (or bundled)
  - The scope of the license rights
    - Exclusive or non-exclusive
    - Geographical area covered
    - Field of use
    - License term
  - Commercial potential (size of market)
  - R&D to be carried out by the licensee
  - Barriers to the marketplace
  - Institutional goals

4. Negotiating Royalties: Pie in the Sky or Recognizing Realities

- What's important to the licensee
  - Value of licensed product to end customer
  - Cost of development
  - Dynamics of the marketplace (how robust is it)
  - Competition
  - Its own financial forecasts

4. Negotiating Royalties: Pie in the Sky or Recognizing Realities

- Factors that may make a difference in “price”
  - Importance of licensed technology to final product
  - Type of product and how unique it is
  - Typical profitability of the type of product
  - Strength and “reach” of the IP
  - Whether blocking IP requires additional licenses
  - Development cost & time to market
- Overall “business” expertise needed to negotiate royalties
  - Knowledge of product development, manufacturing process
  - Knowledge of markets
  - Knowledge of pricing for comparable technologies

5. Licensing Improvements: A Risky Business

- May result in financial gain . . . but is risky business for universities
  - Encumbers future research
  - Limits future funding sponsors
    - Industry and government impacted
  - May mortgage IP of unwilling inventor
  - A question of adequate consideration
- Licensing improvements means thinking twice before doing it!

5. Licensing Improvements A Risky Business

- If you must license improvements . . .
  - "improvement patents dominated by the claims of the licensed patent to the extent the licensor has the right to grant the license"
  - Non-exclusive license to improvements is less risky but ensure obligation to grant license is time-limited
  - Licensing of improvements should be a royalty-bearing event. To what extent is value of initially licensed patent enhanced by the improvement

6. Right of Assignment: Considerations for Universities

- A licensee assigning the license means university is gaining a new business partner
- Weighing pros/cons of assignment clause
  - Large company – transfers to subsidiaries, successor of part of the business to which the license relates; joint venture; w/all company assets may be OK.
  - Small company – permitting assignment risky w/out right of approval
  - Assignability of license a potential problem in bankruptcy proceedings – difficult to get license back
  - Obligation to get approval for assignment also creates an "all substantial rights" problem that may require licensors to be joined in patent infringement suits

University as Licensor:
. . . . . Wrapping Up



Content Licensing: A Different Challenge for Universities and Licensees

- Content licensing means dealing with copyright
- Content licensing means dealing with publishers
- Successful content licensing means working with faculty authors on ownership
- Successful content licensing means understanding different royalty structures
- Successful content licensing means understanding the importance of “retained rights”
- Content-based licensing is a matter for copyright and contract lawyers

A Challenge for University Licensees: Recognizing and Managing the "Spoilers"

- Ownership
- Encumbered rights
- Background rights
- Paying for patent costs
- Dealing with due diligence
- Rights to know how/improvements
- Indemnification against infringement
- Representations and warranties/limitations of liability

U.S. Universities: Protecting the Public Interest

- Licensing principles being adopted by universities include:
  - Negotiating licenses with retained rights to practice and permit other non-profits/government to practice
  - Structuring licenses to require maximum technology development and use. Non-exclusive licensing may be preferable pathway to promoting broad use
  - Attention to managing conflicts of interest
  - Managing licensing strategies to permit broad access to research tools
  - Considering the addition of humanitarian clauses to licenses to address unmet needs of neglected populations especially in the developing world