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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. Other federal laws and regulations applicable to all commercially funded research

- **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!

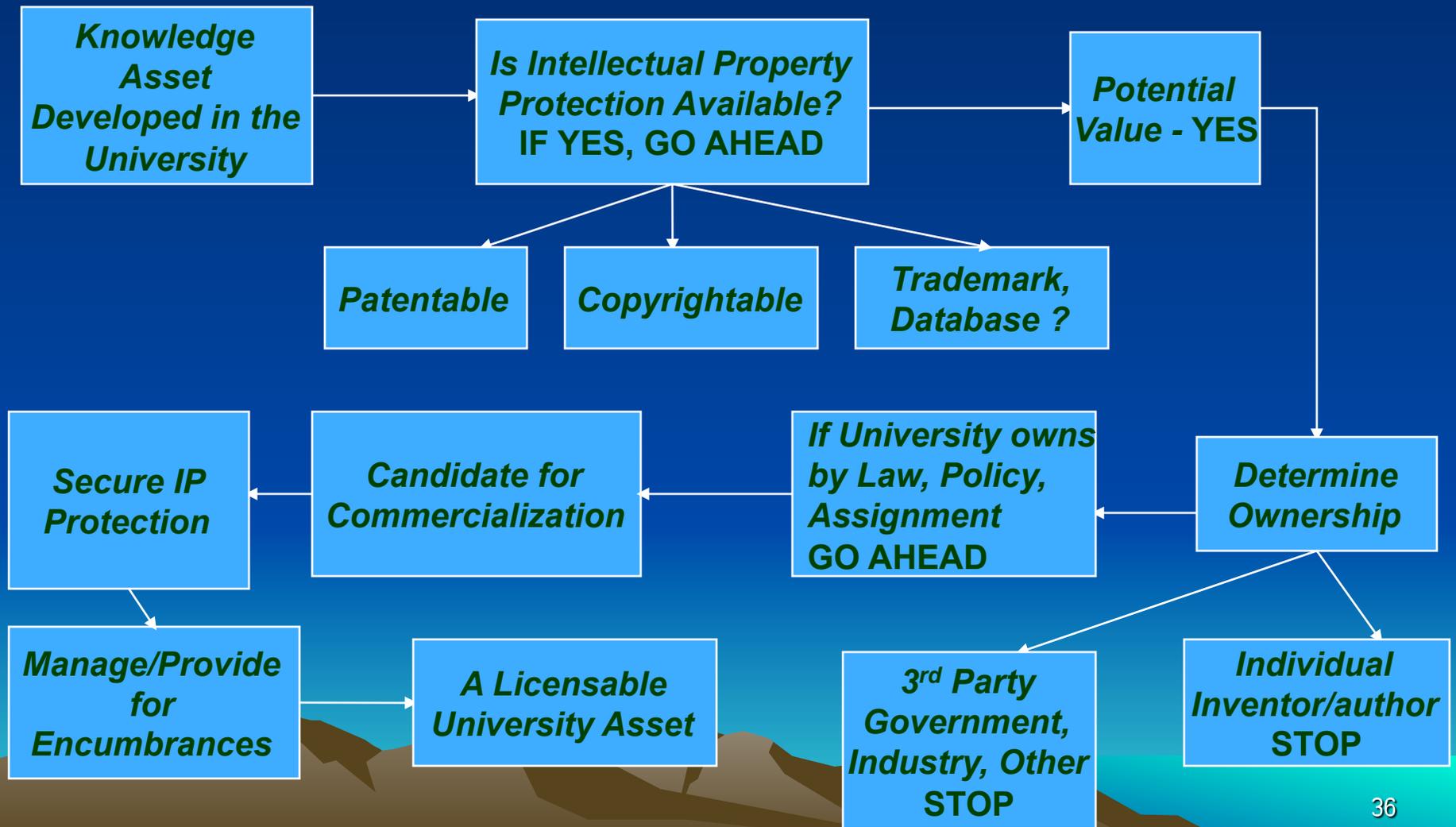
5. Licensing Improvements A Risky Business

- 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