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QuickLaunch University Webinar: Key Issues in University Licensing

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Webinar Guidelines

- Participants are in listen-only mode
- Submit questions via the Q&A box on the bottom right panel
- Questions will be answered as time permits
- WebEx customer support: +1 888 447 1119, press 2

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Agenda

- University licenses:
  - Why they differ from ‘commercial’ licenses
  - How they differ
- Government funding

Why University Licensing Is Different

- Goals of University
  - Education, public interest, faculty incentives, return
- Various constituencies
  - Licensing office, faculty/students, agencies, academic
- Concerns over conflicts of interest
  - Financial interests in research
  - Consulting days/privilege
- IP is often early-stage
- Requirements imposed by government funding

How University Licenses Differ

- Scope of rights
- Diligence obligations
- Financial, Equity terms
- Patent prosecution and enforcement
- Relationship with professors
- Liability allocation
- Bayh-Dole compliance

Scope of Licenses: Subject Matter

- Patents
  - Typical: Existing patent family, not new matter in CIPs
  - Sometimes: Dominated improvements, same inventors
    - Usually time-limited (within 3 years after license agreement)
    - Often subject to obligations to research sponsors
    - May require an option payment
  - Never: general improvements by University
- Know-how
  - Sometimes
  - Only if disclosed by inventor
  - Expect to pay a royalty

Scope of Licenses: Breadth of Rights

- Field
  - Biotech: often able to get rights in broad fields
  - In some industries, non-exclusive rights may be more common
- Retained Rights
  - Use for (internal) research, education, clinical treatment
  - May extend to use with third party research sponsors
  - Sometimes: right to license other academic/non-profit research institutions
- Sublicensing
  - Sometimes requires University consent
  - Often prohibit “naked” sublicensing
  - On termination, University typically can choose to assume sublicenses on terms of originally license vs. sublicense

Diligence

- Commercially reasonable efforts
- Plus: specific achievements by specific dates:
  - Fund-raising
  - Development funding
  - Development milestones
  - Sometimes: commercial milestones
- Reports of past/future development activities
- University remedies
  - Conversion to non-exclusive
  - Termination
- Mandatory sublicensing/march-in
  - “third party proposed products” provision

Financial Terms

- Up-fronts: option fee, license fee
- Equity; M&A Percentage; Dilution Protection
- Sublicense Income
- Milestones
- Annual maintenance fee and/or minimum annual royalty
  - Creditable against royalties in same year
- Royalties
  - Patent applications
  - Stacking
  - No deductions for generic/combination products
- Patent prosecution costs

Sublicense Income

- Pay % of income received from granting sublicense
  - Ideally, clarify how to allocate among multiple IP sources
- Key = what's excluded
  - Pass-through royalty
    - Licensee pays University fixed percentage of sublicensee net sales
  - R&D payments
  - Patent prosecution/enforcement reimbursements
  - Other R&D materials/equipment
  - FMV of equity
  - Reimbursements of patent and other costs
  - FMV of cross-licenses from "non-cash consideration"

Patent Prosecution and Enforcement

- University usually controls prosecution
  - But licensee can comment
  - University will let licensee step-in before abandonment
- Licensee reimburses University's prosecution costs
  - Can be pro rata if there are multiple non-exclusive licensees
  - Failure to pay → loss of license (by country/patent)
- Most universities have reluctantly come around to letting exclusive licensee have first right to enforce
  - Some still impose restrictions
  - Need right to name University as a party for standing
  - No settlement without University consent
- Recoveries are shared:
  - At a minimum, licensee pays an equivalent royalty

Relationship with Professors

- Universities are becoming more involved in reviewing/approving consulting arrangements
  - Perhaps driven by recent Stanford v. Roche case
- Now often requiring an ‘addendum’ applying University’s IP policy verbatim
- Read the IP policy ahead of time

Liability Allocation

- Representations
  - Minimal reps from University:
    - To knowledge, University has the right to grant the licenses
- Indemnification
  - University will give no indemnification
  - Licensee not responsible for University's negligence/misconduct
- Insurance
  - Licensee must carry insurance
  - Self-insurance must be approved by University's risk management organization
- Non-use of University name

Requirements Imposed by Government Funding

- Tax-exempt bond financing
- Bayh-Dole compliance

Tax-Exempt Bond Financing Limitations

- Tax-exempt government bonds may be used to construct public universities' facilities
- Tax exemption is subject to a "private business use test"
- IRS guidance: "[W]hen private entities or the federal government sponsor research at a facility financed with tax-exempt bonds, such research agreements may result in the bonds meeting the private business use test," but
  - Corporate-sponsored research is not private use if corporate sponsor must pay competitive pricing to use resulting technology
  - Research agreement is not private use if sponsors fund "governmentally performed basic research" and other conditions are met

Federal Funding of University Research

- Total annual U.S. R&D spending approximately $500B, with federal share around 30% in recent years
- Total U.S. federal government R&D $147B (FY 2016 est.)
- Concentrated within a few agencies (FY 2016 est.)
  - 48% Defense Department
  - 22% Health & Human Services (NIH)
  - 10% Energy Department
  - 9% NASA
  - 4% NSF
- Approx. 60% of university R&D is federally funded

Federal Funding Agreements

- Grants
  - Most common source of federal funding for university research
  - Federal funding for public purpose
  - Minimal government involvement in the work
- Cooperative agreements
  - Like a grant, but with more substantive involvement by the government funding source
- Contracts
  - Acquisition of specific goods and/or services for use by the federal government
  - May include research services

Patent Rights Under Federal Funding Agreements

- Historically, federal agencies took title to inventions made with government funds
- Bayh-Dole Act, 1980 (35 U.S.C. §201 et seq.)
  - Allowed small businesses and non-profits to retain title to "subject inventions" arising from federal funding agreements
  - Subject to conditions intended to promote commercialization and the U.S. economy
  - Government receives nonexclusive license rights, in lieu of title
- Policy extended to large businesses in 1983 by non-statutory Presidential Memorandum
  - Energy, NASA, and NRC still obtain title for large business inventions, subject to waiver procedures

Applicability of Bayh-Dole

- “Funding agreement” means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the TVA, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government

- “Subject invention” means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement

Scope of “Subject Invention”

- “Conceived” OR “first actually reduced to practice”
- “In the performance of”
  - Liberally construed by courts
  - Invention need only have a “close and umbilical relationship” to the government funded work
  - Temporal connection: During the period of performance?
  - Substantive connection: Encompassed within the statement of work?
- Universities and other recipients should tailor statements of work to avoid unduly broad assertion of government rights
- Licensees should inquire if an invention is not described as a subject invention, but seems related to a federal research program

Bayh-Dole Mechanics

- Disclosure: Recipient must disclose subject invention to the funding agency within 2 months after it becomes known to personnel responsible for patent administration
- Election of title: Recipient may elect to retain title in subject invention, generally within 2 years
  - But: Stanford v. Roche (2011) established that recipients' rights are subject to prior contractual assignment by the inventors to their employer
- Confirmatory license: Grants the government a worldwide, nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States
- Patent filing: Recipient must file patent application, generally within 1 year after election of title

Special Rules for Non-Profit Recipients

- Must offer to license subject inventions to industry, with a preference for small business licensees
- Net royalty income must be used for research or education
- Post-assignment income must be shared with the inventor(s)
- Assignment of the inventions is not permitted without agency approval, except to organizations primarily engaged in management of inventions
- Assignees shall be subject to the same conditions as the recipient

Government Title

- Does the university have title?
- Government can obtain title in certain cases
  - Recipient fails to timely disclose or elect title (or elects not to retain title), provided that the agency requests title within 60 days after learning of the failure
  - In countries in which the recipient fails to timely file patent applications, and has not filed prior to receipt of government's request for title
  - In countries in which the recipient decides not to continue steps to obtain or maintain patent

March-in Rights

- Compulsory grant (or direct grant by Government if contractor refuses) of a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances.
- Possible reasons for march-in:
  - Failure to make progress toward practical application
  - Necessary for health or safety
  - Necessary for public use per regulation
  - Failure to impose U.S. manufacturing terms
- Subject to review by Court of Federal Claims
- Occasionally threatened, but never actually used

Preference for U.S. Industry

- Licensees with exclusive right to use or sell any subject invention in the United States must agree that…
- Any products embodying the subject invention or produced through the use of the subject invention will be “manufactured substantially in the United States”
  - “Substantially” is not defined
- Case by case waiver:
  - Reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or
  - Domestic manufacture is not commercially feasible.
- Waivers must be requested by the funding recipient, so requests are generally joint efforts

Government Rights in Derivative Products

- "The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license."
- "[T]he government's rights attach only to the inventions created by federally funded research and do not necessarily extend to later inventions based on them. Thus, the government may have no rights in a next-generation invention that builds on federally funded technology if the new invention were not itself created by federally sponsored research." [GAO-03-536]
- License agreements might still prohibit licensees from charging royalties to the government, without distinguishing between the subject invention and derivative products

NIH Dissemination Policy

- NIH Policy promotes dissemination of the products of agency funding:
- “Unique research resources” or “research tools” developed with NIH funds should be readily available for research purposes to qualified individuals in the scientific community
- “[L]icenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product”
- “If the materials are patented or licensed to an exclusive provider, . . . commercialization option rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate” [64 FR 72093-94]

Licensing Directly From Federal Agencies

- Presumption that federally owned inventions are available for licensing (37 CFR Part 404)
- Agencies must notify the public of available inventions
- Agencies may grant nonexclusive, co-exclusive, partially exclusive, or exclusive licenses
- Licenses may be royalty-free or for royalties or other consideration
- Licensee must have a development and marketing plan
- License must provide for periodic reporting
- License must provide for termination for failure to make adequate progress toward practical application

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Questions?

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