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Licensing Issues in the Life Sciences Industry: Negotiating University License Agreements

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Overview

- Main Goals of Licensing Agreements
  - For-profit Perspective
  - Non-profit Perspective
- Practical Considerations, Due Diligence & Relationship
- Various Agreements in Life Sciences
  - Research Agreements
  - University License Agreements
  - Material Transfer Agreement
  - Clinical Trial Agreement
- Negotiating University License Agreements
  - Key Provisions

The main goals of a for-profit or a non-profit entity in any licensing arrangement

- For-Profit Perspective
  - Generating value for investors and patients
  - Identifying, protecting, managing and commercializing intellectual property
  - Developing new products and treatment to benefit patients
  - Using value generated for future research
  - Supporting corporate social responsibility initiatives

The main goals of a non-profit or a for-profit entity in any licensing arrangement

- Non-Profit/University Perspective
  - A goal (but not the primary goal?) of universities and research institutions is to identify, protect, manage and commercialize for the public good, their intellectual property
    - Funding for research and education
    - Patenting and development(?) of breakthroughs into products, methods and modalities of treatment
    - Furthers science when published in respected journals and presented at scientific meetings
    - BUT… what are the researchers' goals? And do they align with those of the University and/or tech transfer office?
  - Technology transfer offices have been created to help accomplish these goals (at least in theory)
    - What's their approach – passive or proactive? IP management or technology development?
    - What drives them? Do they have business experience?

Practical Considerations before working with Universities

- University researchers and administrators may have limited business experience – and few corporate style bosses
- Academic goals and incentives differ from those in industry
  - Publications, grants, tenure
- Research timetables are often slower
- Like any big organization, there's bureaucracy and few incentives to be flexible or take risks
- So – what to do? Stop there? ... Maybe

Due Diligence

- Due Diligence – similar (but different) to what you'd do prior to forming a business venture
  - Must go beyond the level of interesting research, an eminent researcher and sparkly facilities
  - Researcher(s):
    - Can you work with this researcher?
    - Are they passionate about and committed to working with you? Why?
    - Do they have experience working with industry?
    - Are they well-funded and staffed? Tenured?
  - Facility:
    - Who "owns" the facility? Are their competing demands?
    - Do you need personnel or resources from multiple departments or labs?
  - Administrators: Policies? Flexibility? Successes? Priorities?

Relationship Building

- Researcher Relationships are Critical
  - Without their commitment, you're likely done
  - With their commitment, amazing things can be done
  - Define the deliverables
- Facility Owner(s): Important (+,- or ?)
- Tech Transfer/Corporate Sponsored Research Offices: Help or Hindrance?
- Legal:
  - Help get to 'yes' or only say 'no'?
  - Are they experienced, flexible?

Different types of agreements in the life sciences industry

- Research Agreements
  - Sponsored Research Agreement (SRA)
  - Collaborative Research Agreement (CRA)
- University License Agreements
- Material Transfer Agreement (MTA)
- Clinical Trial Agreement (CTA)

Research Agreements

- A research contract is one in which a researcher seeks to obtain the rights to use some knowledge (patented or trade secret) to advance his or her research project
- Most common goal of research agreement: to develop new technology that can be commercialized
- Ensure that party executing is authorized signatory
- Additional signatory: “I, the undersigned Principal Investigator, will use reasonable efforts to uphold my obligations and responsibilities set forth in this Agreement”
- New technology usually leads to a license agreement
- Potential licensee:

    1) existing company (for ex. corporate sponsor); or

    2) new start-up/spin-out company

Sponsored Research Agreement (SRA)

- Research for hire
- When the researcher or research organization being hired is in the public sector, the agreement typically also creates knowledge for that organization and/or the research community in general
- Under an SRA, sponsor pays for research and retains certain IP rights in the outcome of that research
- More often than not, higher amount of cumulative research expenditures = higher number of licenses and options executed (*see* AUTM U.S. Licensing Survey: FY2012 Data Appendix)
- Greater funding = greater pressure to execute research agreement

Sponsored Research Agreement (SRA)

Key Provisions

Statement of Work

- Defines scope of research project

Inventions

- "Invention means any invention or discovery which is conceived *and/or* reduced to practice during the performance of the Project, which is or may be patentable or otherwise protectable under Title 35 of the United States Code."
- "Inventorship with respect to any Inventions will be determined according to United States patent law, as administered by the United States Patent & Trademark Office."
- Conceived and/or reduced to practice *during/after* performance of research project
- Solely by Institution ("Project Inventions"); solely by Sponsor ("Sponsor Inventions"); jointly by both Institution and Sponsor ("Joint Inventions")
- Assignment

Licensing

- Exclusive License
- Right to negotiate license
- Right of first refusal/Option for license
- Non-exclusive royalty-free license (NERF)
- Internal use only license
- Right of first refusal/Option to negotiate a license

Sponsored Research Agreement (SRA)

Key Provisions (continued)

Warranties

- Deliverables provided on an “as is” basis
- NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, MERCHANTABILITY

Indemnification & Liability

- A number of state institutions (NY) are prohibited from indemnifying other parties - limit indemnification to extent permitted by NY law
- In NY, indemnities construed very strictly: only cover claims by 3rd parties, not claims between parties, absent express and unambiguous language

Patent Prosecution/Expenses

- Institution files and prosecutes, Sponsor reimburses patent costs

Rights in Research Results

Publication

Publicity

- Written authorization prior to public use of name

Publicity & Publications

- Both parties are concerned about their reputations
- Consider the small vs. large company dynamic
- Be specific as to who controls, who edits, who decides when publication is appropriate
- Consider what happens if results are not successful- should there still be an obligation to publish?

Collaborative Research Agreement (CRA)

- Beyond Research Contract
- Working together on a particular research project
- Sharing
  - Monetary investment
  - Skilled talent
  - Technology
- Ownership of IP is a key issue

Collaborative Research Agreement (CRA)

Key Provisions

Statement of Objectives

Statement of Work

- Who Does What
- Milestone and Benchmarks

General Provisions

- Publication
- Confidentiality
- Amendments
- Termination

Budget

- Capital expenditures as well as staff, space, equipment

List of materials

Intellectual Property

- IP developed solely by one party
- IP jointly developed
- Options

University License Agreements

Key Provisions / Sample Provisions

- Limitations on License Grants
- Retained Rights
- Government Rights
- Consideration
- IP Enforcement Rights
- IP Ownership Rights
- Sublicensing Rights

University License Agreements: Sample Provisions

Limitations on License Grants

"Subject to the limitations set forth in this Agreement, including, without limitation, the rights reserved in Section X.X [research and government rights], the University hereby grants to Licensee an exclusive license under Patent Rights, in the Licensed Field of Use in the Licensed Territory, (a) to make, use, offer for sale, import, and sell Licensed Products and Licensed Services, and (b) to practice Licensed Methods."

University License Agreements: Sample Provisions

Retained Rights

"The University reserves the right to do any one or more of the following: (a) publish any technical data resulting from research performed by the University relating to the Invention; (b) make, use and import the Invention and associated technology for educational and research purposes; (c) practice Patent Rights for educational and research purposes, including in order to make, use and import products, and in order to use and practice methods; and (d) allow other educational and non-profit institutions to do any one or more of the activities described above, for educational and research purposes."

University License Agreements: Sample Provisions

Government Rights

> "Licensee understands that Licensed Subject Matter may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. This Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation . . . Licensee shall assure that, to the extent required by U.S. laws and regulations, Licensed Products used or sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government."

University License Agreements: Sample Provisions

Consideration

Royalties: "Licensee will pay to the University earned royalties at the rate of ten percent (10%) of the Net Sales of all Licensed Products and Licensed Services."

Sublicensee revenue: "Licensee will pay to the University twenty-five percent (25%) of any cash consideration, and of the cash equivalent of all other consideration, which is due to Licensee for the grant of rights under a Sublicense, excluding payments due to Licensee as a royalty based on Sales by the Sublicensee."

University License Agreements: Sample Provisions

Consideration

Equity: "In lieu of cash, other up front licensing fees and milestone payments, Licensee will issue to the University such number of share of common stock of the capital stock of Licensee as will cause the University to own shares of common stock representing ten percent (10%) of the outstanding shares of the capital stock of Licensee on a nondilutable basis."

University License Agreements: Sample Provisions

IP Enforcement Rights

"Licensee shall enforce the Patent Rights against any infringement by a third party in the Field . . . Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by the University in providing cooperation or joining as a party."

"If Licensee does not file suit within six months after a written request by the University to initiate an infringement action against an infringer in the Field, then the University shall have the right, in its sole discretion, to bring suit to enforce any Patent Right licensed hereunder against the infringing activities, with the University retaining all recoveries from such enforcement."

University License Agreements: Sample Provisions

IP Ownership Rights

University-Owned IP: "All patent applications and patents will be in the name of the University and owned by the University. No payments due under this Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party."

Licensee-Owned IP: "Any and all intellectual property rights, whether or not related to any Licensed Subject Matter, created or developed solely by Licensee without the assistance (including any funding, development, and/or facilities) of the University will, as between Licensee and the University, be exclusively owned by the Licensee, and the University will have no rights in or to any such intellectual property rights or any proceeds thereof."

University License Agreements: Sample Provisions

Sublicensing Rights

"The license granted by this Agreement includes the right of Licensee to grant Sublicenses. With respect to Sublicenses granted pursuant to this Agreement, Licensee will:

(a) provide the University with at least thirty (30) days prior written notice of any Sublicense and provide the University with documentation to verify that the Sublicense includes all the rights and obligations due to the University under the Agreement, in each case, subject to applicable confidentiality obligations, provided, however, that in the event that thirty days prior written notice is not feasible, Licensee will provide the University with such notice as soon as practicable;

(b) promptly provide to the University a copy of each executed Sublicense Agreement;

(c) not receive, or agree to receive, anything of value in lieu of cash as consideration from a third party under a Sublicense without the express written consent of the University; and

(d) make all Payments Due and deliver all reports due to the University whether owed by Licensee, Affiliates, or Sublicensees, and use commercially reasonable efforts to collect all payments due, directly or indirectly, to the University from Sublicensees."

Government Rights: Bayh-Dole Act

Bayh-Dole Act

- In the United States, much of the research performed at universities is funded by U.S. government agencies
- The Bayh-Dole Act permits grantee/contractor organizations to elect to pursue ownership of an invention in preference to the government
- Provides ownership and title to any invention made in *whole or in part* with federal funding
- Government reserves for itself an irrevocable, non-exclusive, royalty free license to practice invention for government purposes
- Invention is defined as intellectual property that is either conceived or actually reduced to practice in performance of a government funded project
- Good for U.S. economy

Government Rights: Bayh-Dole Act

Obligations of grantee/contractor organization:

- Invention reporting policy
- Report inventions to the federal funding agency within 60 days
- Elect title (or waive title) within two years
- File for a patent within one year of electing title
- Acknowledge federal government support in the patent application
- Notify federal agency of any decision not to pursue patent rights (or licensing)
- Submit annual utilization report for all patented and licensed inventions
- Submit final invention statement and certification within 90 days of the end of the project period
- Products developed with federal funds and used and sold in the U.S. should be substantially manufactured in U.S.
- No assignment of inventions without federal agency approval
- Royalties should be shared with the inventors
- Reasonable efforts to attract small business licensees
- Agree to allow government to “march-in”
- iEdison : http://www.iedison.gov

Clinical Trial Agreement (CTA)

- Clinical (human) trial/study
- Prerequisite to regulatory approval
- Contract Research Organization (CRO)
- Benefit from investigator expertise and patient access

Clinical Trial Agreement (CTA)

Key Provisions

Scope of Work

- Consistent with Protocol

Principal Investigator

Performance Period

- Consistent with Protocol, IRB requirements

Record Keeping

- Consistent with Protocol, IRB requirements, and in accordance with all applicable local, state and federal laws and regulations
- CRO/Investigator make available to Sponsor, regulatory authorities
- Case reports as per Protocol property of Sponsor

Costs and Payment

Clinical Trial Agreement (CTA)

Key Provisions (continued)

Confidential Information

- Sponsor should only provide what is necessary to complete study
- Mark confidential information
- CRO/Investigator must treat as confidential
- Term X years unless
  - Information known to CRO/Investigator before Agreement
  - Information disclosed to CRO/Investigator by Third Party not subject to confidentiality
  - Information publically available through no fault of CRO/Investigator
  - Information independently developed by CRO/Investigator without knowledge of Sponsor
  - Information disclosed as per Agreement
- Results or data considered confidential until published

Clinical Trial Agreement (CTA)

Key Provisions (continued)

Ownership of Data

Ownership of Intellectual Property

Use of CRO/Investigator's name

- ClinicalTrials.gov

Statement on Disbarment or Disqualification

- Onus on CRO/Investigator to comply and provide notice

Publication – who decides what and when to publish

Material Transfer Agreement (MTA)

- MTAs are legal instruments that define terms for the transfer of tangible biological materials, chemical materials, software programs & tools, human subject data, etc., between or among two or more parties
- MTAs are bailments that transfer possession but not title

Material Transfer Agreement (MTA)

- MTA-In or MTA-Out
- An MTA, regardless of its length or complexity, may incorporate many, if not all, of the following:

Preamble	Definitions
Purpose/Use of Materials	Confidential information
IP rights	Warranties
Publication	Liability and/or indemnification
Governing law	Termination
Signatures	Exhibits or appendices

- UBMTA (Uniform Biological Material Transfer Agreement)
- UBMTA Master and list of signatories: http://www.autm.net/index

Material Transfer Agreement (MTA)

Intellectual Property Rights

- Unmodified Derivatives vs. Modifications
- IP rights such as disclosing of inventions, patent prosecution, options and licenses
- Rights to past or future inventions

Publication

- Unrestricted right to publish research results
- Publication restrictions: editorial rights, what is “confidential”?

Public Benefit of University Research

- Publically available innovations
- Compromised if MTA requires grant of NERF

Rights in Research Results

- Must preserve researcher’s right to use his/her own research results
- Compromised if provider insists on owning research results