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Negotiating IP Rights in Industry Sponsored Research Agreements

Structuring Ownership, Licensing, Assignment, Confidentiality, Publication, and Use Provisions

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Negotiating IP Rights in Industry Sponsored Research Agreements

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Overview

- I. Sponsored Research Agreements
 - A. Considerations
 - B. Key Provisions
- II. Ownership of IP
- III. Rights to future IP
- IV. Licensing
- V. Enforcement

Sponsored Research Agreements - Considerations

What is a Sponsored Research Agreement?

- A Sponsored Research Agreement (SRA) typically governs scientific research conducted by a **Recipient** “public” institution and paid for by a **Sponsor** public (government, foundation) or private institution.
- An SRA can be distinguished from funding provided through a **gift** or a **Collaborative Research Agreement**.
- Sponsor **can** obtain intellectual property rights.

SRA Goals – University

- Access to private or public funding
 - Supplement NIH or other grants
- Access to unique resources
 - Proprietary compounds, cell lines
- Publishing opportunity
 - Publish results from work with unique resources
- Further University research mission

SRA Goals – Company

- Conduct research at relatively low cost
 - Important for start up companies
- Validation by leading scientists and institutions in the field
 - Can help with fund raising
- Intellectual property rights
 - Validate and extend existing IP

SRA Concerns – University

- Publishing rights
 - Academic freedom
- Appearing as “fee for service”
 - Intellectual property rights in advance
 - Secure University IP and licensing revenue
- Private control over research direction

SRA Concerns – Company

- Confidentiality
 - Concern regarding publications, posters, talks
 - Securing IP rights in advance
 - Avoid being blocked by downstream IP
- Liability
 - Speed
 - Meet internal deadlines, fundraising goals

Public vs. Private University

University

- Public University
 - Governed by federal, state, local law
 - Safety, human use, animal use (IRB), ethics, publishing
 - Charter, Legislative and Executive branch control
- Private University
 - Must comply with law, but may have more flexibility and fewer disclosure requirements.

Sponsored Research Agreements – Key Provisions

Statement of Work (SOW)

- This is probably the most important (and often the most neglected) part of the SRA
- Flexibility vs. Specificity
 - Remember: specificity needed for determining deliverables, IP ownership rights.
- SOW Scope = IP Scope
- Enforcement Scope

Key Provisions - Confidentiality

Confidentiality

- Definition and exclusions
 - Note: watch for "marking" requirements.
- Time Period
 - e.g., short (university) vs. long (company)
- Freedom of Information (FOIA)
 - public vs. private universities
- Publication

Key Provisions – Intellectual Property

Intellectual Property (IP)

- Background rights
 - e.g., company may already have background rights in a compound that will be tested by University.
- Trade Secrets
- Scope under SOW
 - e.g., control over patent prosecution
- Licensing
 - e.g., option vs. Pre-negotiation of licensing terms
- Bayh-Dole: April 2018 amendments

Key Provisions – Liability

Liability

- University Limitations
 - e.g., unable to provide indemnification
- Insurance
- IRB/Ethics

Key Provisions – Representations and Warranties

- **Infringement**
 - Note: Universities want to avoid liability when carrying out SRA activities (may be covered by research exception).
- **Negligence**
- **Warranties and Deliverables**
 - Note: Universities usually provide only limited warranties (if at all).

Key Provisions – Enforcement

Enforcement

- Dispute resolution mechanisms
- Choice of Law - e.g., "home" court advantage
- Forum

Ownership of IP

Forms of IP and Ownership

- Patent
 - Utility, design
- Trade Secret
 - Elevated importance - scope of patentable subject matter limited
- Copyright
- Subject to assignment provisions
 - IP is initially owned by the individual who creates/invents the IP
- Inventorship and Collaborations
 - Informed by SOW

Initial IP Ownership Positions - 1

- Consider the starting IP ownership positions for each contracting party
- Background IP rights
 - License to background IP required?
- Audit existing IP ownership position
- Audit chain of title in IP

Initial IP Ownership Positions - 2

- Determine scope of IP to be developed; define with particularity
- For inventions: do not overlook the importance of claim language

Rights to Future IP

Future IP

- Consider the scope of future IP; again we return to the importance of the SOW
 - Patentable inventions
 - Trade secrets
 - Copyright-protected content
 - Data rights (*e.g.*, for proof of principle or enablement)
 - Privacy rights - *e.g.*, *focus* on what type of data and where is the data being stored
 - HIPAA

Future IP Ownership and Rights

- Typically, the University is the initial owner of the future IP developed under a SRA.
 - Future IP can then be the subject of a right to license from the University to the private entity.
- Be careful with situations with work that will also be done by the sponsoring company (this work and its future IP should not be owned by the University).
- Be mindful of potential government rights (e.g., from NIH funding).

Future IP Ownership

- Contractually - determining future IP ownership often is based on:
 - IP subject matter at issue
 - Who created/invented

Inventorship

- “The definition for inventorship can be simply stated: “The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor.” MPEP at 2137.01
- More complicated in practice:
 - *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976 (Fed. Cir. 1997)
 - *Ethicon Inc. v. United States Surgical Corporation*, 135 F.3d 1456 (Fed. Cir. 1998)

Ownership vs. Licensed Rights

- Benefits of ownership = owner of title and interest
- Benefits of being a license holder = owner of interest only
 - Note: this is usually where you end up for IP that is generated by the University under the SRA.

Licensing

Nature of the license

- Define the IP to be licensed
- Option
 - Option period
 - Cost
- Anything else?
 - Know-how
 - Related services for future revenue streams

Key licensing negotiation issues

- Exclusive/non-exclusive
 - Cost, royalty structure
 - Control of patent prosecution
- Background IP rights
 - SOW, materials, data
- Sublicensing
 - Important to smaller companies
 - Approval by University
- Milestones (specificity)
 - Lack of specificity could make enforcement difficult
 - Can tie to regulatory process

Enforcement

Enforcement

- Dispute Resolution Mechanisms
- Choice of Law
- Forum Selection

Dispute Resolution Mechanisms

- Arbitration
 - Pros: rapid, private
 - Cons: expensive, non-appealable, subject-matter expertise
- Mediation
 - Pros: rapid, inexpensive, subject-matter expertise
 - Cons: non-binding
- Federal/State Court
 - Pros: appealable and more predictable
 - Cons: slow, subject-matter expertise

Enforcement

Choice of Law can be broken down further to:

- **Substantive Law**
 - Substantive law determines how the facts of a dispute will be determined.
- **Procedural Law**
 - Procedural law determines how a proceeding will occur.

Forum Selection

- "Home Court" Advantage
 - Note: this is very often a significant factor for universities.
- Requirements for state entities
 - Note: many state entities will be mandated to use their local forum - *i.e.*, this point will be non-negotiable.
- International considerations
 - As SRAs become more international in nature, be aware of local laws as you negotiate forum selection - *i.e.*, work with local counsel.

Thank you

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