

Intellectual Property

Technology Transfer and Intellectual Property
Principles in the Conduct of Biomedical Research

Frank Grassler, J.D.
VP For Technology Development
Office for Technology Development
UT Southwestern Medical Center

What is intellectual property?

- Intellectual property is the general term for intangible property rights which are a result of intellectual effort. Patents, copyrights, trademarks and trade secrets are the main categories of intellectual property rights.
- At universities, intellectual property most frequently refers to patentable inventions and copyrightable works created by faculty and staff in the course of their research or scholarly activities.

Who owns the IP?

- In the US, the inventor(s) own the IP they discover or create personally.
- Virtually all employment contracts, both in industry and at universities, stipulate that most forms of IP created by their employees, students, etc., must be assigned to the employer.
- In virtually all cases, a university will have the right to claim ownership of IP discovered or created by their faculty, staff and students.

Laboratory Notebooks

- Laboratory notebooks are the property of the employer and so is the data contained therein.
- Laboratory notebooks are critical documents in the pursuit of intellectual property rights. They serve as the best documentation of the “evidence of invention” and substantiate invention dates.

Bayh-Dole Act

- The passage of P.L. 96-517 in 1980 (as amended in P.L. 98-620) created a new framework for creating value in university intellectual property.
- Universities were enabled to exercise title to inventions developed under U.S. Government funding.
- By having title to such inventions, universities could safely make investments in technologies allowing them to capture the value of innovations developed on their campus.
- “Public good” was the driving goal.

Why protect an invention?

- Each protection strategy provides the owner with the ability to exclude others from accessing the technology for a specified time period.
- The ability to minimize competition protects a intellectual property owner's (or licensee's) investment in the technology.

Types of Protection

There are a number of different protection strategies:

- Patent (20 years from the application filing date)
- Copyright (life of the creator + 50 years)
- Trademark (20 years, but extendable)
- Trade Secret (forever? Maybe)

Patent Requirements

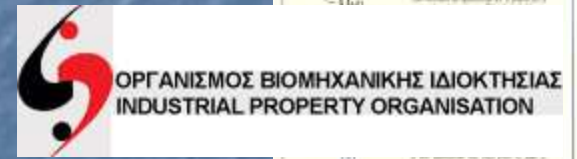
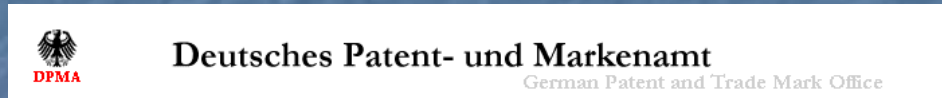
- The invention must be useful, novel and non-obvious. It cannot be a law of nature or naturally occurring substance or mathematical formula.
- In the US, the initial patent application must be filed within 1 year of an enabling public disclosure.
- In most foreign countries, a patent application must be filed prior to ANY enabling public disclosure.

Scope of Patent Coverage

- The scope (or coverage) of claims in an issued patent must provide adequate protection to the patent owner and potential licensees.
- An invention that describes the “best” way of achieving a commercial goal doesn’t mean it will always be preferred.



Typical Patent Timeline



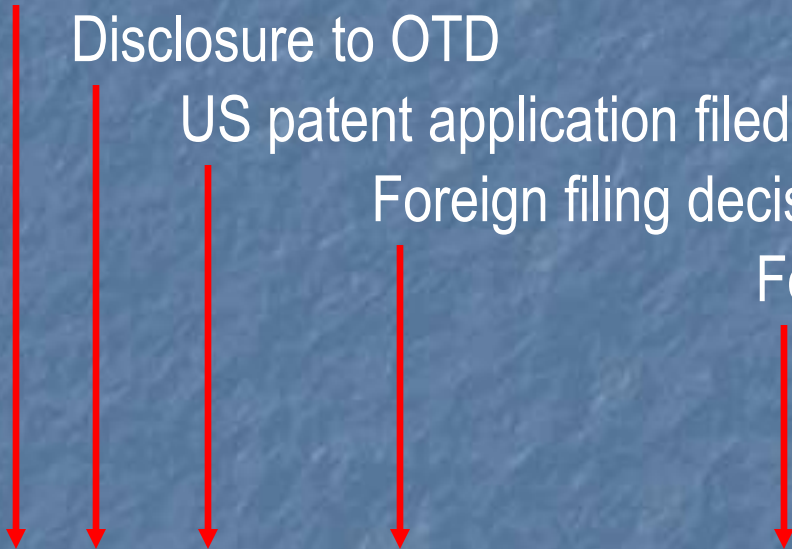
Inventive act

Disclosure to OTD

US patent application filed

Foreign filing decision

Foreign national/regional stage



1 year

US patent issues?

30 months

Foreign patents issue?

Inventorship

- Determining inventors on a patent application is not like naming authors on a publication; it has a strict legal meaning.
- Determined by patent counsel, not PI's department heads, etc.
- Only those individuals that have made independent, conceptual contributions to the claimed invention are entitled to be named as inventors.

Copyright Protection

- The exclusive right, granted by law, of the creator of a work (or his/her assignees or employers) to make or dispose of copies and otherwise to control the use of a literary, dramatic, musical, artistic, or other work.
- UT does not own all categories of copyrightable works created on campus.
- Cost is minimal.

Trademark

- Any word, name, symbol, device, slogan, package design or combination of these that serves to identify and distinguishes a specific product from others in the market place or in trade. Even a sound, color combination, smell or hologram can be a trademark under some circumstances.
- Cost can vary.

Trade Secret

- The key to maintaining a trade secret is the word “secret” - as long as the technology can be kept confidential, the owner can practice the technology and avoid competition.
- Third parties are not prevented from independently practicing and duplicating the technology once the trade secret is disclosed or discovered.
- Reverse engineering is acceptable.
- Is trade secret an ethical protection strategy for a university to enable?

Why seek IP protection?

- In industry, IP protection can be used to exclude others from practicing the technology, providing a business advantage. You can either practice it yourself, license the rights to others in exchange for financial return, trade it via cross-license to gain access to third party intellectual property or simply shelve the technology so others cannot use it.

Why seek IP protection?

- In universities, IP protection is used to preserve value in a technology (especially early stage technologies) that can be recouped via licensing to commercial entities in exchange for financial return. Universities do not operate directly in the marketplace, so cross-licensing is very rare and “technology shelving” is non-existent.

Costs

- Each protection strategy has associated costs, both financial and time resources.
- Costs can be significant.

Why technology transfer?

- Commercialize technologies for the public good.
- Help retain creative university faculty.
- Foster relationships with industrial partners.
- Promote faculty entrepreneurship.
- Provide increased funding for research and education.
- Support local economic development.
- Meet intellectual property-related sponsor obligations.
- Required by Bayh-Dole.

Types of Agreements

- Confidential Disclosure & Limited Use Agreements
- Material Transfer Agreements
- Consortium Agreements
- Collaborative Research Agreements
- Sponsored Research Agreements
- Option Agreements
- License Agreements
- Consulting Agreements

Effects of Agreements

- The existence of any one or any combination of agreements may create certain obligations that can significantly impact an institution's ability or willingness to develop meaningful IP protection and a flexible commercialization strategy.
- Ethical issues arise more frequently when there is a need to navigate a landscape filled with pre-existing agreements.

Typical Sources and Effects of Pre-existing Obligations

- Confidentiality Agreements – Restrict use of information obtained from third parties.
- Funding sources – Many have associated contractual obligations with conditions impacting commercialization, publication, dissemination of research data, sharing of research materials, retention of rights, ownership of IP, sharing of license revenues, etc.
- Material Transfer Agreements – Virtually all MTAs restrict use of the materials to a particular lab, for a particular project and for a particular time period. In addition, they usually require the recipient NOT to use the materials in projects with obligations to commercial entities. Most bar transfer to other labs, even within the same university.
- Consortium Agreements – May restrict commercialization opportunities or dedicate IP to the public.

Typical Sources and Effects of Pre-existing Obligations

- Sponsored Research/Collaborative Research – These agreements typically grant the commercial entity an option to negotiate an exclusive license to any IP resulting from the project.
- Option/License Agreements – Contractually, few pre-existing obligations are created in most licenses. However, if a laboratory discovers a technique that might be dominated by IP rights already licensed to an existing entity, then your ability to work with other potential licensees might be limited.
- Consulting agreement – Potential IP “leakage” via personal consulting obligations.

Confidential Disclosure Agreements

- A “Confidential Disclosure and Limited Use Agreement,” “Non-disclosure Agreement” or similar agreement is used to describe a relationship where only information is disclosed.
- Agreements can be for receiving information, sending information or for a 2-way exchange of information.
- Agreements cover transmission of information over a specified time period and stipulate that information disclosed from one party to another will be maintained in confidence for a specified time period and may not be used for any other purpose other than evaluating a potential relationship between the parties.

Material Transfer Agreements

- A “Material Transfer Agreement” is used to describe a relationship where one party wishes to share research materials with another entity.
- Terms in MTAs between universities and other non-profits are very standardized. MTAs between universities and industry are not and are heavily dependent on each party’s sensitivities.
- Use of materials is typically restricted to non-commercial use in a specific research program for a fixed length of time. Materials generally cannot be shared outside the receiving laboratory.

Material Transfer Agreements

Ethical Considerations

- The university executes several MTAs with other parties enabling an important research project.
- A company approaches the university investigator and presents an opportunity to sponsor research in the investigator's laboratory.
- What ethical dilemmas might arise?

Consortium Agreements

- A “Consortium Agreement” is typically used to describe a research collaboration involving many entities (universities and/or companies) with no exchange of money.
- Because of the number of different institutions/companies involved, these agreements can be very complicated.

Consortium Agreements

Ethical Considerations

- The university executes a consortium agreement involving 8 other universities and 2 companies to study ABC disease in a specific laboratory in the molecular genetics department.
- The university recruits a new professor in the molecular genetics department with expertise in ABC disease. This new professor is interested in maintaining an existing sponsored research and personal consulting relationship with a company that has previously denied interest in participating in the consortium.
- What ethical dilemmas might arise?

Collaborative Research Agreements

- A “Collaborative Research Agreement” is typically used to describe a research collaboration involving two entities with no exchange of money.
- Most simply attempt to detail the research obligations of the two parties and pre-plan how any resulting IP issues will be handled.

Collaborative Research Agreements

Ethical Considerations

- West Coast University executes a collaborative research agreement with East Coast University stating that the universities will work together to jointly license any new intellectual property developed under the collaboration.
- Eventually, valuable IP is jointly developed. WCU wants to license the IP to a start-up in San Francisco and ECU wants to license the IP to a start-up it recently formed in Boston.
- What ethical dilemmas might arise?

Sponsored Research Agreements

- A “Sponsored Research Agreement” is typically used to describe a research relationship where the university laboratory receives monetary support from industry for a research project.
- The industry sponsor typically receives an exclusive option to negotiate an exclusive license to any IP developed.

Sponsored Research Agreements

Ethical Considerations

- The university executes an SRA with XYZ Co. IP is developed naming two university investigators as inventors and the company wishes to exercise its rights to negotiate a license agreement. You draft financial terms for review by both investigators. One investigator informs you that they are desperate to conclude an extension of the SRA to maintain laboratory funding since his laboratory has no other financial support. The other investigator is no longer interested in working with XYZ Co. and wants to extract as much license revenue as possible.
- What ethical dilemmas might arise?

Option Agreements

- An “Option Agreement” is typically used to place a technology with a commercial entity on a temporary basis while the company evaluates the commercial attractiveness of a technology or develop enabling technologies.
- Usually have a short duration (<2 years).
- May be granted exclusively or non-exclusively and be restricted to specific fields of use.

Option Agreements

Ethical Considerations

- After years of searching, the university executes an option agreement with SmallCheapTech Co. and the company begins its due diligence. Half way through the term of the option agreement, the investigator submits a new IP disclosure describing a new technology significantly enhancing the value of the original technology. The investigator stops cooperating with the optionee and doesn't want to share the latest development with them, hoping they will terminate their option. The investigator also gives you the name and phone number of a VP of Business Development at BigBucksMultinational, Ltd. and asks you to call them.
- What do you do?

License Agreements

- A “License Agreement” is used to convey intellectual property rights from one party to another. They may include different technologies. Rights can be granted exclusively or non-exclusively. Rights can be granted for a broad scope of uses or only within a specific field. Licensees are usually also able to grant sublicenses to others to enable joint commercialization efforts with other parties.

License Agreements

Ethical Considerations

- Several years after completing the university's due diligence and exclusively licensing a patent application to a company, the investigator admits development of the technology was enabled by the receipt of certain materials received via an MTA signed directly by the investigator and not previously disclosed to you. The MTA restricts use of the materials to non-commercial projects and grants the company an exclusive option to negotiate an exclusive license to any IP developed through the use of the materials.
- What do you do?

Consulting Agreements

- Consulting agreements hold huge potential for ethical dilemmas.
- They are personal agreements.
- The university is not a party to the agreement. Most universities approve them for outside employment and require the inclusion of certain required IP language (e.g. UTSW).
- They are not a vehicle for sharing proprietary university information.

Consulting Agreements

- They are NOT a mechanism to share university-owned information or materials.
- No use of university time or resources.
- Limited time commitment permitted.
- Compliance is the responsibility of the consultant.
- No university indemnification.

Standard Paragraph

- "The Company acknowledges that Consultant is a full-time employee of UT Southwestern (and as such, an employee of the State of Texas), and is subject to UT Southwestern's policies, including policies concerning consulting, conflicts of interest, and intellectual property. If there is a conflict between Consultant's obligations under UT Southwestern policies and any of [Consultant's obligations to Company under this Agreement, Consultant's] obligations under UT Southwestern policies take priority over any obligations the Consultant may have to Company by reason of this Agreement. Company specifically recognizes that, under UT Southwestern's policy on intellectual property (<http://www.utsystem.edu/bor/rules/homepage.htm>), Consultant has an obligation to assign to UT Southwestern all intellectual property that is related to Consultant's employment responsibilities to UT Southwestern."

Consulting Agreements

Ethical Considerations

- During a consulting visit, an investigator is presented with documents and the company asks the investigator to sign them. The documents relate to a patent application filed by the company naming the investigator as an inventor resulting from discussions held during the last consulting visit.
- What should the investigator do?

Conflicts

- Conflicts often arise between an investigator's role as a university employee, existing pre-existing university contractual obligations and an investigator's personal situation (including, but not limited to, consulting agreements).

Types of Conflicts

- Conflict of Commitment
- Conflict of Interest

Conflict of Commitment

- Any situation in which an UT Southwestern employee's outside commitments may interfere with the primacy of their commitment as a UT Southwestern employee.

Conflict of Interest

- Any situation in which financial or other personal considerations may unduly influence a UT Southwestern employee's professional judgment in exercising UT Southwestern responsibilities, specifically the design , conduct, and reporting of research.

Managing Conflicts

- Disclose any potential conflict.
- Cooperate with the Conflict of Interest Committee in the development of a conflict management plan.
- Comply with the terms of conflict management plan.