University of Utah Technology Transfer Office Handout February 13th , 2004

Useful Links: **University of Utah** Policy and Procedures Manual (PPM) http://www.admin.utah.edu/ppmanual/ Particularly: Section 2-26 Remunerative Consultation and Other Employment Activities. http://www.admin.utah.edu/ppmanual/2/2-26.html Section 6-3 University Faculty Profit-Making Corporations http://www.admin.utah.edu/ppmanual/6/6-3.html Section 6-4 Patents and Inventions http://www.admin.utah.edu/ppmanual/6/6-4.html Section 6-7 Copyright Policy: Ownership http://www.admin.utah.edu/ppmanual/6/6-7.html Section 8-10 Code of Student Rights and Responsibilities http://www.admin.utah.edu/ppmanual/8/8-10.html Sections 8-12-1 to 8-12-8 Code of Faculty Rights and Responsibilities http://www.admin.utah.edu/ppmanual/8-tbl.html

Technology Transfer Office (TTO) <u>http://www.tto.utah.edu/</u> Technology Transfer Tutorial <u>http://www.tto.utah.edu/tutorial/index.html</u>

Office of Sponsored Projects (OSP) http://www.osp.utah.edu/

Office of the Vice President for Research http://www.research.utah.edu/

Patents

Legal

Bayh-Dole Act Overview <u>http://www.cimit.org/coi_part3.pdf</u> Patent Act (35 USC) <u>http://www.bitlaw.com/source/35usc/</u> Intellectual Property Regulations (37 CFR) <u>http://www.bitlaw.com/source/37cfr/</u>

Databases

United States Patent and Trademark Office (USPTO) <u>http://www.uspto.gov/</u> World Intellectual Property Organization (WIPO) <u>http://www.wipo.org/</u>

Copyrights http://lcweb.loc.gov/copyright/

Other

NIH Office of Technology Transfer http://ott.od.nih.gov/ ACS Handbook "What Every Chemist Should Know About Patents" http://chemistry.org/portal/resources?id=1b41692a6cf811d6f8dd6ed9fe800100

CONTACT INFORMATION

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INTELLECTUAL PROPERTY

What is Intellectual Property (IP)?

• Any form of knowledge or expression created with one's intellect -- i.e. an idea

What is protectable IP?

- An idea, when expressed or reduced to practice, may become protectable by law via:
 - o Patent -

A form of personal property that provides the owner with the right to exclude others from making, using, selling, offering for sale, or importing the invention described in the patent claims. This is the most common form of protection we deal with in the TTO.

o Copyright -

Provides the creator of a literary, dramatic, artistic, or musical work the sole right to reproduce that work (in whole or substantial part) or authorize someone else to reproduce it.

Copyright is restricted to the expression of an idea and not does not extend to the idea itself (which may instead be patentable), for example, software can be patented and/or copyrighted.

A copyright is generally much more easily circumvented than a patent.

o Trademark –

Distinguishes the goods or services of one person or company from those of another. Trademarks are not commonly disclosed to our office, but are sometimes registered in conjunction with a patented compound, piece of equipment or method.

o Trade Secret –

Information protected by keeping it secret. This is not common at universities but can apply to materials or information not yet made public or that have commercial value as research tools

Why protect IP?

- An important commodity of an institution/researcher
- Value enhanced when it can be protected
- Obligations to sponsors
 - Federal grants
 - o Commercial sponsors
 - o Foundations (e.g. Huntsman or HHMI)

What is patentable IP (a.k.a. an invention)?

- The discovery or creation of a new material, a new process, a new use for an existing material, or an improvement of any of these.
- Some IP is NOT patentable:
 - o Theories
 - o Ideas
 - o Plans of Action
 - o Laws of Nature or Scientific Principles
 - o Anything Immoral or Injurious to Society
 - Copyrightable Works
 - o Sexually Reproduced Plants (asexually reproduced plants CAN be patented)
- The inventive process can be broken down into two steps:
 - o Conception -

The first time the invention was imagined. Because the US follows a "first to invent" policy and because one may need to demonstrate diligence in reducing an invention to practice, it is important to document the date of conception.

• Reduction to Practice -

Demonstration that the concept works. Such demonstration for patent purposes is not nearly as rigorous as for publication of a result in a scientific journal and, in some cases, the reduction to practice requirement may be fulfilled by providing a compelling and logical conclusion or description of the invention in the patent application itself.

- To obtain a patent the IP must be:
 - o New or novel –

To maintain full patent rights in all parts of the world, the invention must not have been publicly disclosed in ANY manner (written, oral, electronic or through use), ANYWHERE. The US provides a one year grace period in which a patent can still be filed after public disclosure.

o Non-obvious or involve an inventive step -

It is often easy to feel that your invention is obvious, but this is likely not as rigorous a standard as you would apply to yourself, so it is probably preferable to err on the side of disclosing to the TTO, if you are not sure.

• Useful or capable of industrial application –

The US uses the "useful" standard which is generally broader than the foreign requirement of "capable of industrial application," e.g. this is why certain things such as surgical methods may be patentable in the US but not in other countries.

- Additionally, to be valid, a patent must reveal:
 - o Enablement -

Provide sufficient detail for a person of ordinary skill in the art to reproduce without requiring an inventive step (i.e. reduction to practice).

o Best Method -

The expected way in which the invention will work best.

o Non-Abandonment –

The inventor must diligently pursue the invention and prosecution of the patent or be able to explain any lapse.

o Correct Inventorship -

Each person named must have contributed an "inventive step." Inventorship can sometimes be difficult to determine, but claims of incorrect inventorship can be used to invalidate a patent. The standards for inventorship are very different than those for authorship, i.e. financial support does not qualify you as an inventor nor does following someone else's direction without contributing an inventive idea to the end product.

TECHNOLOGY TRANSFER

The Patent and Trademark Law Amendments Act (a.k.a. The Bayh-Dole Act)

- Although technology transfer has occurred at universities for many years (e.g. the University of Utah office was established in 1967 and MIT has been practicing forms of technology transfer since WWI), the Bayh-Dole act was enacted in 1980 to create a uniform patent policy for all organizations accepting federal monies.
- Provisions of the Bayh-Dole Act include:
 - Universities are permitted to retain title to inventions to help ensure commercialization.
 - Universities are required to share proceeds from commercialization with the inventors.
 - Small business is to be given a priority for receiving university licenses to commercialize technology.
 - Universities are encouraged to set up technology transfer offices to manage their intellectual property.

Responsibilities and Role of the Technology Transfer Office

- Assist the University in retaining creative faculty.
- Assist faculty and staff with understanding and implementation of the technology transfer process.
- Manage the commercialization of technology.
- Review invention disclosures for patentability and commercial appeal.
- Market intellectual property to private industry.
- Negotiate and enter into agreements for the commercialization of University technology.

University Policies Related to IP

- The University, through the University of Utah Research Foundation, owns any IP that was produced in the course of research or that required use of significant university resources as defined in the Policy and Procedures manual in Sections 6-4 (patents and inventions) and 6-7 (copyrights).
 - o Patents

<u>PPM 6-4 III.B.1.</u> "As a condition of the University's provision of employment, services, facilities, equipment or materials to faculty, staff and students, the University acquires and retains title to all inventions, discoveries and improvements made as the result of University employment or research, or created through the use of time, facilities, equipment or materials owned or paid for by or through the University, except when such facilities, equipment or material are available to the general public. Each full-time faculty and staff member is bound through this policy as is each part-time faculty and staff member and student employee or student participating in research (see also III.B.6, below), and any of the foregoing may be asked to execute an assignment of such inventions, discoveries, and improvements to the University and shall do so on request."

<u>PPM 6-4</u> III.B.4 "Each full or part-time faculty and staff member and student employee or student participating in research is expected also to inform promptly the director of the University Technology Transfer Office concerning all inventions, improvements, and discoveries made as a result of University employment, or created through the use of time, facilities, equipment, and/or materials owned or paid for by or through the University or as a result of University employment or participation in research at the University; to cooperate with and assist the director of the University Technology Transfer Office in the handling of such matters; to execute all rightful papers and do necessary and proper acts to assist the University in obtaining, utilizing and enforcing patent protection on such matters, and to abide by and benefit from the patent policy of the University in effect during the inventor's respective associations with the University."

Copyrights

<u>PPM 6-7 II.A</u> "Works created by University staff and student-employees within the scope of their University employment are considered to be works made for hire, and thus are Works as to which the University is the Owner and controls all legal rights in the Work. In contrast, Works created by University staff and student-employees <u>outside</u> the scope of their University employment are not covered by this policy and are considered to be owned by the Creators, <u>unless</u> such Works are created through "substantial use of University resources" (as described in Section III of this policy)." – See additional sections for definitions and additional exceptions.

<u>PPM 6-7 II.C</u> "Notwithstanding Section III, and except to the extent contrary to University agreements with third parties or other law, unless provision is made to the contrary in advance of the commencement of the Work, students are the Owners of the copyright of Works for which academic credit is received, including theses, dissertations, scholarly publications, texts, pedagogical materials or other materials."

• Revenue received from licensed inventions is shared with the inventors and their departments

<u>PPM 6-4 IV.B.1</u> "Inventors shall receive a share of royalty income or other revenue received by the University of Utah Research Foundation as a result of commercialization of an invention. The inventors' share of income shall be based on a percentage of such income or revenue remaining after reimbursement of the University for all direct costs of patent prosecution or maintenance and all development funds advanced pursuant to section III.C.3 ("net revenue"). The inventors' share (in the aggregate where there is more than one inventor) shall normally be forty percent of the first twenty-thousand dollars (\$20,000) of net revenue, thirty-five percent of the next twenty thousand dollars (\$20,000) of net revenue, and thirty percent of any additional net revenue received by the Research Foundation."

- The inventors' share of revenue is split evenly among the inventors unless an agreement to split the money differently is agreed to *in writing* by all parties involved (i.e. if one inventor is thought to have made a greater contribution, or if the inventors wish to recognize the contribution of another researcher whose contribution may have been important, but did not rise to the level of inventorship).
- The University may also share up to 25% of the revenue with the departments in which the inventions originated.

SERVICES OF THE TTO

Management of disclosures (see attached annotated disclosure form)

- What do you disclose?
 - Potentially patentable IP
 - o Commercially valuable research tools (e.g. plasmids, cell lines, antibodies, software, etc.)
 - Copyrighted materials made with significant use of University resources
- How do you disclose?
 - Use the disclosure form that can be obtained on our web site <u>http://www.tto.utah.edu/</u> or by contacting our office at 1-7792 (see attached annotated version for an example).
 - You may fax (1-7538) or e-mail (<u>Carla@tto.utah.edu</u>) the filled out version to our office, but the ORIGINAL, SIGNED version MUST follow by campus mail to the Technology Transfer Office, 615 Arapeen Drive, Suite 110.
- When do you disclose?
 - ASAP, but preferably two to three months prior to any public disclosure so that we can determine any sponsor obligations, evaluate the prior art, and provide time for a patent to be drafted if necessary.
 - Think about tech transfer when you are MAKING PLANS to attend a conference, give a talk, set up a collaboration (with a researcher outside the University of Utah) or when you BEGIN writing a paper, a grant proposal, your thesis or dissertation.
- What does the TTO do with a disclosure/invention?
 - 1. Both hard copy and electronic files are set up and the disclosure is assigned to a licensing manager. An acknowledgment letter is sent to each of the identified inventors.
 - 2. An initial evaluation of the disclosure form is done to determine:
 - a. Completeness of the disclosure form (signatures, correct inventorship, funding, adequate info. to evaluate the invention, etc.)
 - b. The existence of any sponsor obligations and fulfillment of any reporting requirements
 - c. The existence of any collaborating institutions that will need to be notified so that an appropriate inter-institutional agreement (IIA) can be put in place if no prior collaboration agreement exists
 - d. Upcoming public disclosure dates to determine if there are any time constraints on patenting
 - 3. Patentability analysis
 - a. Is the technology disclosed patentable? Is it desirable to patent it? (e.g. some materials, such as antibodies, although commercially valuable may not be likely to generate enough revenue to repay the patent costs, which are generally around \$15,000 to \$25,000 by the time a single patent issues. We can commercialize non-patented technologies.)
 - b. Our office, a search company or an attorney may perform a prior art search of patent databases to determine if patents covering the invention or limiting the scope of the invention already exist
 - c. We request that the inventors, as experts in the field, provide our office with literature references related to the disclosed technology.

- d. If needed, we may request a patentability opinion from an outside attorney (however, this can be quite expensive, e.g. \$5,000 to \$10,000, so this may only be done if there is a compelling reason or if it is very difficult to tell if a specific reference may wipe out the value of our own application).
- 4. Market Assessment
 - a. A Non-Confidential Summary (NCS) for the invention that summarizes the important concepts, advantages, and applications may be produced to help to assess interest and attract potential licensees.
 - b. If companies request additional information it is provided under a Confidential Disclosure Agreement (CDA).
 - c. The TTO may also place the company in contact with the researcher so that technical details can be discussed. Such discussions should only occur after a CDA has been signed.
- If the technology appears both patentable and marketable, the TTO will then undertake the patent process and begin searching for a commercial partner. Writing a patent requires the input of the inventors. You can expect to spend time on the phone and by e-mail passing on information and patent drafts (this is a bit like writing a manuscript, but with a somewhat different point of view).
- If the technology does not appear to be patentable and/or marketable, the TTO will notify the inventor and a decision on how to proceed can then be made.
 - 5. Licensing
 - a. As a public educational and research entity, the University is prohibited from engaging in commerce. Therefore, the University controls intellectual property through the University of Utah Research Foundation (UURF). The University transfers rights to make, use, sell and import intellectual property through license agreements whereby the University retains ownership and management of the intellectual property. **N.B.: You do not lose your right to practice your invention by licensing. LICENSES STATE THAT THE UNIVERSITY RETAINS RIGHTS FOR ACADEMIC USE.**
 - b. There are three basic types of license agreements although each may have a number of variations.
 - Option agreements For a smaller fee than a license, the option gives an interested company a short time (generally six months to two years) to evaluate (BUT *NOT* to make, use, sell or import) a technology.
 - Non-Exclusive License Gives rights to a company to make, use and/or sell the patented technology with the understanding that those rights can be extended to other parties by the UURF as well.
 - Exclusive License Gives rights to a company to make, use and/or sell the
 patented technology with the understanding that the UURF will not offer the same
 rights to any other parties. Multiple exclusive licenses may be executed for a
 single technology, however, if there are multiple uses for a technology (Fields of
 Use) or companies only want rights in certain parts of the world, etc. Exclusive
 licenses also generally allow the licensee to sublicense a technology to other
 parties.

- c. The University must ensure that each company to which it grants a license has the ability to develop the technology and make it available to the public. This obligation is one of the implied aspects of the Bayh-Dole Act.
- 6. Diligence
 - a. Disclosures As additional presentations or publications come out, we need to know so that we can report these to sponsors. The TTO also needs to know if improvements are made in a technology so that patents can be filed as needed. We need to be notified of address changes both for notification purposes and so that royalty distributions can be made.
 - b. Patents Once a patent is filed there are ongoing patent prosecution procedures to be addressed. The originally filed application is virtually guaranteed to be rejected in all or part. Each argument made must be rebutted (requiring legal and scientific input and generally additional paperwork). Once the patent is accepted all the figures must be correctly formatted, all the paperwork must be completed, and the issue fee and maintenance fees over the life of the patent (20 years) must be paid. This process is repeated in each country in which a patent is pursued.
 - c. Licenses Once a technology is licensed our office monitors the licensee to verify that fees and royalties are paid, that the licensee is using the technology and not just holding it away from others, and that we don't see other companies that are using our technology without permission (infringing). We may also be involved in arbitration or litigation for breach of contract or for infringement.
- 7. Other Services
 - a. Signature Authority The TTO can provide legally binding signatures for the University on contractual agreements related to IP and materials. Researchers and students cannot legally sign documents on behalf of the University nor should they sign documents that may obligate them to actions violating University policy or sponsor obligations. The TTO is happy to review such documents for you.
 - b. Notary Services The office has three notaries.
 - c. Confidential Disclosure Agreements (CDAs) Before disclosing the details of a technology to anyone outside the university (particularly any commercial or private group)
 - d. Review of Sponsored Research Agreements (SRAs) The TTO reviews clauses related to IP
 - e. Inter-institutional Agreements (IIAs) When you are planning to collaborate or have collaborated with researchers outside the university or you are leaving the U and plan to take any materials or practice any patented methods owned by the U.
 - f. Material Transfer Agreements (MTAs) for materials coming in or going out
 - g. Software Access
 - h. Copyright (as per the PPM)
 - i. Trademarks
 - j. Grants the TTO administers or offers services related to both Technology Commercialization Projects (TCPs) and Centers of Excellence (COE) grants.

ANNOTATED DISCLOSURE FORM v.965 - 01/28/04

Commercial entity Others (Please Specify)

Our office assigns each disclosure a "U number" which is used in all subsequent references to an invention. We recently passed U# 3700

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vention Related D	ates:							
	Date		Written record	If Yes , location o	f the wr	itten records.		
	(mm/dd/yea	r)	exists? (Yes/No)	If No, list names	with wh	om you had disc	cussions.	
Disclosure to TTO	These date	s refi	lect the dates of	^c conception and re	duction	ı to practice. T	They can be	
Conception of invention	<i>important</i>	in de	fending your st	atus as "first to inv	ent" ar	nd are also imp	ortant in	
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Experimental evidence								
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ventor Informatio	<u>n:</u>							
# Inventor's Legal Na	me, Suffix T	e, Suffix Title		epartment		Tel. Number	% Share*	
1 You should includ	le collaborato	rs at	other institution	ns, but please indi	ate wh	ere they are fr	om so that	
2 we can set up sha	ring agreemer	its w	ith their institut	tion and file correc	t assign	nments.		
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1. Brief Summary of Invention: (This is used in preparation of marketing materials. Please append complete descriptions (e.g. papers)

2. Advantages over State-of-the-art:

3. Practical and Commercial Applications:

Answers to questions 1, 2, and 3 are important for evaluating the patentability and marketability of an invention. The answers may also be used to help formulate a non-confidential summary used to market the invention to potential licensees.

4. Please list any companies you feel are/should be interested in your discovery. (specific contacts are most helpful)

For a majority of inventions that are successfully marketed, the inventors identified the licensee. The inventors may have contacts at companies working on similar research projects or been approached by a company representative for information at a meeting, based on publication of an article, or because of a general interest in the lab's work. BEFORE DISCLOSING ANY DETAILS ABOUT ANY WORK DONE IN THE COURSE OF RESEARCH ON CAMPUS RESEARCHER'S SHOULD CONTACT OUR OFFICE SO THAT A CONFIDENTIALITY AGREEMENT CAN BE PUT IN PLACE.

5. Have the essential elements of the invention been disclosed to anyone outside the University*, either orally or in writing? (* Both ARUP and HCI are within University of Utah confidentiality)
Yes
No
(Please type X) If Yes, please specify (e.g. date, name, circumstances).

As mentioned, public disclosure of an idea immediately forfeits foreign rights in the invention and starts a one-year clock on the time in which the invention may be patented in the US.

6. Do you intend to publicly disclose the essential elements of the invention in the future, either orally or in writing? (e.g. publication, thesis/dissertation, seminar, poster, meeting abstract, web page)
Yes
No
(Please type X) If Yes, please specify planned date of disclosure.

This is important for the same reasons as 5 above. It may also be possible to put confidentiality agreements in place for upcoming presentations (particularly to companies) to help protect your IP.

7. Did this invention utilize data or materials from any of the following? (Type X on all that apply)					
MTA (Material Transfer Agreement) CRADA/SBIR/S		CRADA/SBIR/STTR		High Risk Cancer Clinic	
	Biological materials		Population Database		Others (Please Specify)
	(e.g. Human blood, tissues, & cell lines)		(UPDB/Cancer Registries)		

Many company sponsored research agreements or funding from foundations (e.g. HCF or CBI) come with IP strings attached (e.g. the sponsor may be able to review any publications for IP before they are submitted or may have the first option to license a technology)

8. Please identify inventors who were students at the University of Utah at time of invention. (List Names)

Student rights differ in some ways from faculty rights and we also wish to be sensitive to the need for students whose graduation may depend in all or part on the work being disclosed.

The undersigned hereby declare(s) that they (he/she) are (is) the true and only originator(s) of the invention disclosed herein at the University of Utah and that the invention arose in the course of work at or on behalf of the University of Utah and will be handled according to University of Utah's Policies and Procedures Manual 6-4 for patents and 6-7 for copyright. Please call the Technology Transfer Office at 581-7792 with any questions.

For each University of Utah and ARUP Inventor, please TYPE in all fields, then sign and date.

The Disclosure Form is a leg needed to file a patent appli NOTIFY OUR OFFICE IF pay you your share of royalti	A legal document requiring your acknowledgement by signature. The additional information is pplication and fulfill reporting requirements to funding agencies. It is also important that you IF YOU MOVE (we may need additional information from you and we also want to be able to alties). Main Contact Inventor 1 Name: Citizenship: Home Add:							
	Phone: e-mail: Signature:	FAX: Date:						
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