

# Crown Jewels and War Chests: All About IP

#### **Summer Program on Bioentrepreneurship 2009**

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### **Two Important Questions**

# 1. Why does IP matter to you?

# 2. Do you have an IP strategy?

### What Is Intellectual Property?

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### Why IP Is Important

Do you want to commercialize your idea?

- Without an IP strategy in place, you may not have the right to commercialize any products or services – or do so in a cost-effective manner.
- Investors, management candidates, and customers care about your IP. So should you.

### Why IP Is Important

### Role of IP for Life Sciences Companies

- Core Asset -- Stock in trade
- Offensive use against competitors
- Defensive shield
- Revenue generating asset
- Enhance company value

## Why IP Is Important – Typical IP Due Diligence

### Investors will perform due diligence to assess:

Your rights to commercialize your IP (i.e. the scope of your IP rights, both owned and licensed)

The value of your IP

#### Your freedom to operate

- Can third parties prevent you from commercializing?
- Are there any actual or likely infringement disputes?
- Do contractual or other obligations limit your ability to commercialize?

### **Roadmap for an Intellectual Property Strategy**

Be prepared! Develop a strategy.











## Identify

## Identify Relevant IP – What is it?

### Identify "technology" vs. IP rights

 Determining the "stuff" of interest (e.g., info, ideas, compounds, devices, processes) and separately the IP rights in that "stuff"

### > Now existing vs. future developments/improvements

 Determining what exists now and what is likely to be developed in the future and where, and by whom, such future developments are likely to occur

# Identify

## Identify Relevant IP – Who Owns It?

### Your IP

 Created by you or your employees (e.g. in the university setting, this could mean the researcher, his or her research team and graduate students)

### Third Party IP

 Consultants, industry partners, sponsors of research, universities, third parties with whom you have no relationship

## Identify – Is It Your IP? Who owns it?

### Which hat are you wearing? Are you inventing for:





### Identify – Is It Your IP?: Employee Agreement

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provides that (a) Any provision in an employment agreement which provides that an employee shall assign, or offer to assign, any of his or her rights in an invention to his or her employer shall not apply to an invention that the employee developed entirely on his or her you him evithout using the employer's equipment, supplies facilities, or trade secret information except for those inventions that either; (1) Relate at the time of conception or reduction to practice of the invention to the employer's builting, and reduction and employee the entirely on his or her you may work performed by the employee the employer. (b) To the extent a provision in an employment agreement purports to require an employee to assign an invention otherwise excluded from bein required to be assigned under subdivision (a), the provision tagging the public policy of this state and is unenforceable. In any suit or action artising under this taw, the budgen of proof shall be on the individual claiming the benefits of its provisions.

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RETENTION: Accounting: 5 years after separation, except in cases of disability,	Employee/Guest Name (Please print):	
retirement or disciplinary action, in which cases retain until age 70. Other Copies; 0-5 years after separation.	Employee/Guest Signature:	Date:
Outer copies, the years area separation.	Witness Signature:	Date:

PLEASE SIGN STATE OATH AND PATENT ACKNOWLEDGMENT - ATTACH TO PAF, UPAY560.

"I acknowledge my obligation to assign inventions and patents that I conceive or develop while employed by University or during the course of my utilization of any University research facilities or any connection with my use of gift, grant, or contract research funds received through the University. I further acknowledge my obligation to promptly report and fully disclose the conception and/or reduction to practice of potentially patentable inventions to the Office of Technology Transfer or authorized licensing office. Such inventions shall be examined by University to determine rights and equities therein in accordance with the Policy. I shall promptly furnish University with complete information with respect to each."



## Identify – Is It Your IP?: Section 2870

#### CALIFORNIA LABOR CODE — Section 2870

(a) Any provision in an employment agreement which provides that an employee shall assign, or offer to assign, any of his or her rights in an invention to his or her employer shall not apply to an invention that the employee developed entirely on his or her own time without using the employer's equipment, supplies, facilities, or trade secret information except for those inventions that either:

(1) Relate at the time of conception or reduction to practice of the invention to the employer's business, or actual or demonstrably anticipated research or development of the employer; or

(2) Result from any work performed by the employee for the employer.

(b) To the extent a provision in an employment agreement purports to require an employee to assign an invention otherwise excluded from being required to be assigned under subdivision (a), the provision is against the public policy of this state and is unenforceable.

# Identify – Separating Your IP from the University

- It may be better for the University to own inventions for patentability reasons
- Keeping ownership separate from the University
  - Develop the inventions on your own time
  - Use your own equipment, supplies, and facilities
  - Do not use any confidential information or work of the University or sponsors
  - Make sure the subject matter is sufficiently different from your paid research
  - Keep notebooks and document your work
  - Don't use any grant money



# Identify – Introduction to Intellectual Property



Intangible property, i.e., property created by the human mind

> You need to protect and prepare a strategy for both:

- Your intellectual property (e.g., the know-how, the technology, the "stuff") AND
- The **rights** associated with it



## Identify – Types of IP

- Patents
- Copyrights
- Trademarks
- Trade Secrets
- Each type differs with respect to:
  - Protected subject matter
  - Rights conferred
  - How rights are acquired and enforced
  - Duration of rights
  - Registration and maintenance requirements



# Identify – Patents (1)

- <u>Utility patents</u> protect useful inventions: processes, machines, articles of manufacture, or compositions of matter
  - e.g. a process for producing ethanol
- <u>Design patents</u> protect novel, non-functional design elements
  - e.g. nonfunctional design of an electric car
- Plant patents protect asexually reproducible plants
  - e.g. distinct and new variety of switchgrass

## Identify – Patents (2)

- No right to do anything. Instead, right to exclude others from:
  - Making, selling, or using the patented invention
  - Importing the patented invention or an article made by a patented process into the U.S.
  - Note: Others may be excluded from practicing patented invention whether or not they copied the invention from the patentee

### Other benefits:

- Obtain royalties
- Create leverage (to obtain rights to other's IP or in business negotiations)
- Maintain freedom to operate (by stopping others from filing)

## **Identify – Patents (3)**

Must file patent to obtain protection.

Generally, patent is in force from the date that the application issues until 20 years after the filing date of the application

# Identify – Copyrights (1)

- Protects original expression of an idea fixed in a tangible medium of expression
  - E.g., poster for academic conference, carbon-tracking software, etc.
- Right to exclude others from:
  - Reproducing, creating derivative works of, publicly distributing, publicly displaying, or performing the copyrighted work
  - NOTE: If someone else independently comes up with the same way of expressing something, there is no infringement

# Identify – Copyrights (2)

No filing requirement. Copyright exists from the moment that a work is fixed in a tangible medium of expression (e.g. paper, computer disk, or DVD).

### Ownership

- Author is the original owner and can assign copyright (in whole or in part) to others
- For "works made for hire," employer or commissioning party is considered the author

### Duration

- New works: 70 years after the death of the author
- Work for hire, anonymous, or pseudonymous work: Protection for either 95 years after publication or 120 years after creation, whichever occurs first

# Identify – Trademarks (1)

- A distinctive word, phrase, logo or design that identifies the source of a product or service
- Trademarks can be "weak" or "strong" depending on the mark itself and how well known it is

### NANOBATTERIES v.



Trademark owner may exclude others from using that trademark or a confusingly similar trademark in connection with the same or related goods or services

# Identify – Trademarks (2)

#### Acquiring Protection

- In U.S., rights are acquired through use of the trademark in connection with goods or services. However, registration confers certain advantages.
- In many other countries, rights are acquired solely through registration

#### Ownership

 Owner is the party that uses the mark and controls the nature and quality of the goods or services offered under the mark

#### Duration

- Potentially perpetual, as long as owner continues to use mark
- Trademarks can be abandoned (and the trademark rights lost) if owner stops using the mark, allows the mark to become "generic," or engages in licensing without quality control

### **Identify – Trade Secrets (1)**

- Protects virtually anything that is not generally known and gives owner a competitive business advantage
- Owner can prevent use or disclosure by anyone who learned or derived the trade secret from the owner (and must do so to maintain trade secret status)
  - NOTE: Trade secret rights do not give you the ability to stop use or disclosure by someone who *independently* discovers the trade secret
- Rights are acquired by developing or formulating the valuable secret, and taking necessary precautions to maintain its secrecy. No need to register trade secrets

## Identify – Trade Secrets (2)

### **Key Differences Between Trade Secrets and Patents**

- Obtaining and securing rights
- Protecting and maintaining rights
- Duration of rights
- Enforceability of rights

### **Secure Rights**

# Secure Rights to IP.

### Your IP

- File for patents
- Register copyrights
- Register trademarks
- Adopt and implement trade secret policies

### Other's IP

- Obtain assignments from founders, employees, consultants, advisors, etc.
- Obtain licenses and assignments for third party IP

## **Secure Rights – University Setting**



#### **Patenting Process at University**

- Record of Invention form submitted to University for evaluation
- Patentability, commercial potential, etc. evaluated;
  marketing for potential licensees begins
- Case referred to patent attorney who may file for patent; inventor assigns patent to University at filing

Technology Transfer Office will usually proceed with patenting as long as sponsor has been secured

Meet with your office to discuss your goals

### File application with U.S. Patent and Trademark Office

- Does proposed invention meet statutory requirements of usefulness, novelty, and non-obviousness?
- Does application teach how to make and use invention?
- Cost to prepare an application is typically \$8,000 to \$15,000
- TIP: Due diligence is important, e.g. Google Patent Search, but exposure to other patents may increase risk of enhanced (up to 3x) damages for willful infringement

### Provisional filings

- Establish early filing date
- 12 mos. to file corresponding non-provisional application
- Risks of relying on provisional applications

### Parts of a Patent

### Abstract

Specification (35 U.S.C. Section 112, par. 1)

- describes the invention in a way that:
  - allows one of ordinary skill in the art to know that the inventor made the invention;
  - teaches how to make and use the invention, including the best way the inventor knows how to accomplish this.





### Claims

Sets the metes and bounds of the inventor's property right.

# **Types of Utility**

### Credible Utility

- Is it believable to one of ordinary skill in the art based on the totality of evidence and reasoning?
- Specific Utility
  - Is it specific to the claimed subject matter?
- Substantial Utility
  - Does it have a "real world" use?

# **Utility: Example**

### Claim:

- An isolated and purified polynucleotide *comprising* SEQ ID NO:1.
- Specification:
  - SEQ ID NO:1 a full length ORF cDNA sequence encoding an uncharacterized protein (SEQ ID NO:2) with unknown function
  - Only asserted utility is to use SEQ ID NO: 1 as a probe to identify other proteins like SEQ ID NO. 2

# **Utility: Example**

There is a Credible Utility

- There is a Specific Utility
  - Specific for DNAs that are similar to the DNAs that encode SEQ ID NO:2
- There is No Substantial Utility
  - Requires further research to determine the utility of SEQ ID NO: 2 and therefore SEQ ID NO:1



# Novelty

Prior art of others before invention

- Public use or knowledge in the US
- Patented or described in a printed publication anywhere
- Prior art by <u>self</u> (or others) 1 year before filing
  - In public use or "on sale"
  - Patented or described in a printed publication anywhere

# "Absolute" Novelty

- Most foreign jurisdictions follow "absolute" novelty
  - measured as of filing date
  - no 1 year grace period for own acts
- Test for lack of novelty (US):
  - All of the elements and limitations of the *claimed* subject matter <u>must</u> be in the single prior art reference.
  - Cannot combine references

## **Non-Obvious Subject Matter**

Analyze differences between the claimed subject matter and prior art

Would claimed subject matter as a whole been obvious?

- To one of ordinary skill in the art
- At the time the invention was made
- Hindsight not allowed

## **Written Description Requirement**

 $\succ$  Establish inventor(s) in possession of *claimed* invention.

 Standard: specification must "reasonably convey" to one skilled in the art that inventor in possession of the claimed invention
#### Written Description: Example

- Claim:
  - An isolated mammalian cDNA encoding insulin
- Specification:
  - Discloses rat cDNA sequences for rat proinsulin
  - State of art: proinsulins expected to be variable
  - No indication of known structural relationship
- Conclusion:
  - No written description for mammalian genus claim
- Rationale:
  - Neither specification nor state of art provides partial structure expected to be common
  - Rat insulin cDNA therefore not representative of claimed genus.

### Enablement

Teach how to make and use the invention

- one of ordinary skill in the art
- without "undue experimentation"
- determined as of filing date

### **Best Mode Requirement**

- Best mode contemplated by inventor(s) for carrying out invention
  - Subjective inquiry
  - Need not be right



# Inventorship

- An inventor must contribute to the conception of the claimed invention.
  - Must have contributed to the conception of the invention described in at least 1 of the claims in the patent (or application).
- Conception Defined:
  - "[T]he formation, in the mind of the inventor, of a definite and permanent idea of the *complete* and *operative* invention, as it is thereafter to be applied in practice...." *Merganthaler v. Scudder 11 App. D.C. 264,276, 1897*

### **Joint Inventorship**

- Each inventor must have made some inventive contribution to at least one of the claims.
  - Routine experimentation under the direction of an inventor is not an "inventive contribution".
- There must be at least some quantum of collaboration or connection between inventors.

# Ownership

- Each inventor has an undivided ownership interest in a patent.
  - Usually transferred by "assignment" to the inventor's employer.

Assignee owns the monopoly right of the inventor.

- Can prevent third parties from practicing the invention
- Can license the patent rights to third parties.

### **Secure Rights – Copyright Registration**

- Submit required materials to Copyright Office
  - Application
  - Filing fee
  - Non-returnable deposit of work being registered
  - Registration is effective on the date the Copyright Office receives all required materials
- Benefits of registration
  - Establishes public record of copyright claim
  - Required for filing of infringement suit in federal court
  - Allows for statutory damages, recovery of attorney's fee, etc.

#### **Secure Rights – Trademark Registration**

- File trademark application with USPTO
  - Use or intent to use
  - Drawing and specimen of the mark

Requirements for proposed mark

- Distinguishes goods and services from others
- Not merely descriptive
- Does not cause confusion or resemble other registered marks

**TIP:** Perform a full name search before choosing your trademark. Check for trademarks, business names, and URLs. It is much easier to switch the name at start-up.

### Secure Rights – Assignments & Licenses



- Invention assignment agreements from founders, employees, advisors, etc.
- Consulting agreements with consultants
- Assignments & licenses from third parties
- University technology transfer agreements

# Secure Rights – Technology Transfer Agreements with Universities

#### Consider licensing technology from the University

- Universities generally retain ownership of patents
- You may be able to obtain an exclusive license within a field of use (but note that you will be required to meet certain diligence requirements)
- Try to obtain an **option to negotiate or to license future IP**:
  - University preference to license only existing inventions
- License to "blocking patents" not likely to be granted because of desire to disseminate information

# Secure Rights – Technology Transfer Agreements with Universities

# **Basic Licensing Terms (1)**

- License grant
  - scope, fields, exclusivity, sublicenseability
- Payments
  - fees, milestones, royalties
  - amount and scope of coverage
  - reach through possibilities

# Secure Rights – Technology Transfer Agreements with Universities

# **Basic Licensing Terms (2)**

- Diligence requirements and minimum royalties
- Patent prosecution, enforcement and defense
- Improvements and future developments

#### **Protect Your IP**

#### Take initiative to protect your Intellectual Property!

- Keep trade secrets secret
- Enforce employee agreements
- Enforce confidentiality agreements
- Maintain IT security
- Beware of marketing documents and disclosures
- Maintain registrations
- Police trademarks

### **Protect Your IP – University Setting**



### **Protect Your IP – Patents and Confidentiality**

#### Patent bar in U.S.

- Grace period of <u>one year</u> to file application from time of:
  - Sale or Offer to sell
  - Public disclosure
- Note patent app. publication 18 months after filing
- Patent bar for foreign filings
  - <u>No grace period</u>: Any publication of invention before application will bar the right to a patent
- TIP: Beware of activities which could trigger bar
  - Even a poster you display at an academic conference could be considered a "public disclosure"
  - We can provide guidance on how to disclose— describe what something does instead of how it does it

### **Protect Your IP – Confidentiality Agreements**

#### **Confidentiality Agreements: Use Them.**

For Employees, Business Partners, Customers, etc.

- VCs may not sign them
- Customize them. Nondisclosure agreements are not "one size fit all."



#### Leverage Your IP.

#### What is the plan for commercialization?

Provide consulting to industry
Make and/or sell products

- License your IP
- Joint ventures or partnerships

### Leverage – Beware Exclusive Relationships

#### **Exclusivity = Reliance**

#### Beware exclusive relationship early in life of company:

- You may want to expand into different markets or sell to someone in different markets
- Exclusivity implies a right to exploit the technology, but consider being clear about research and development, milestones, marketing, sales, and other commitments.
- Will exclusivity be contingent on meeting performance requirements? Minimum royalties? Revenue share requirements?

# Office of Technology Licensing (OTL)

#### **Mission**

To promote the transfer of Stanford technology for society's use and benefit while generating unrestricted income to support research and education.

#### **Technology Transfer Portfolio**

Patents Copyrightable Material Software Biological Material Semiconductor Maskworks

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### **Stanford's Intellectual Property Policy**

Patentable Technology University takes title to all inventions created with more than incidental use of University resources <u>www.stanford.edu/dept/DoR/rph/5-1.html</u>

Copyrighted Works University takes title to copyrightable works created with significant University resources <u>www.stanford.edu/dept/DoR/rph/5-2.html</u>

SU-18 Patent and Copyright Agreement www.stanford.edu/dept/DoR/rph/su18.html



#### **Stanford's Royalty Distribution Policy**

- Cash Royalties from Issue, Minimums, Earneds
- Net Royalties = Cash Royalties
  - minus 15% for administrative expenses minus out-of-pocket expenses (e.g. patent costs)





### **OTL: Invention to License**



- Disclosure
- Evaluation
- Licensing Strategy
  - File patent?
  - Market to potential licensees
- The License
- Maintaining the Relationship
- 7 "Licensing Associate/Licensing Liaison" teams
  - Technical degrees and marketing focus
  - Responsibility for inventions from cradle-to-grave



### **Key License Terms**

# Financial terms

- License issue fee
- Annual minimum payments
- Earned royalties
  - % of Net Sales
  - \$ per product sold
- Reimbursement of patent costs
- Equity in start-up companies

# Non-financial terms

- Definitions
- Grant
- Development milestones & diligence provisions
  - Prototype
  - First Commercial Sale

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- Warranties and indemnities
- Infringement actions
- Dispute resolution

#### **Inventor's Role in the Process**

- Disclose inventions
- Identify potential licensing prospects
- Participate in patent preparation and prosecution
- Host visits and/or provide technical information to potential licensees
- Provide input into the licensing strategy
- Sometimes become consultant to licensee

#### Questions

# **THANK YOU!**

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