



CASE

CASE WESTERN RESERVE UNIVERSITY

Technology Transfer 101: Mechanisms and Opportunities for Commercializing Your Intellectual Property

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Objectives of this Presentation

Provoke thought and discussion about intellectual property and its role in your research.

- What do we have to protect?
- How can we protect it?
- How are we protecting it now?

Explain mechanisms for working to protect and develop intellectual property at Case or peer non-profit institutions.

Encourage you to explore commercial aspects of your research.

Why We Create IP Assets

Protect our research and establish ownership of an idea or concept

Create legal monopolies to favor our company or our licensees

Block our competitors or assure our own freedom to operate

Selecting Which Assets to Protect

How critical is an asset to your ongoing research?

What level of commercial outcome do you realistically expect?

What competitive advantage does this give you?

How easy and/or ethical is it to protect?

How easy would it be to design around it?

Intellectual Property

Separate from tangible items

Product of the mind

Types: Patents, Trade Secrets, Trademarks,
Copyrights, Mask Works

More abstract than other types of property

Courts will enforce your rights

- Must file a civil law suit to enforce

What is a Patent?

Deed or Title to an Invention Granted to the Applicant(s) by a Government In Exchange for Disclosing the Invention to the Public

For the Term of the Patent it Allows the Patentee to Exclude Others From:

- Making the Invention
- Using the Invention
- Selling the Invention

What does a Patent Allow You to do?

Prevent Others from Infringing or “Stealing Credit
and Ideas”

Prevent Others from Blocking Your Future Research

- "Defensive" Patenting

Generate Revenue through Licensing

What does a Patent NOT Allow You to do?

Practice your own invention

- May be required to obtain a license from owner of a dominating patent
- Owner of dominating patent has no obligation to grant license
- Universities are increasingly being required to comply with patent law → no more “research exemption”

The quid pro quo of Patenting

Government grants time-limited right to exclude others from making, using, selling/importing

- Limits Competition

Applicant/Patentee makes full, enabling disclosure of best mode -- teaches the invention to the public

- Eliminates trade secret option

The Parts of a Patent

Background of the invention

Sets the tone of the patent description and the environment of the patented invention

Description of the invention

Sufficient detail to enable one skilled in the art to practice the invention without undue experimentation -- must disclose best mode

Claims define what is patented

Definitions are in one-sentence paragraphs which define the legal boundary of what is protected

Requirements for Patentability

- Novel (i.e., New)
- Non-obvious to one of ordinary skill in the relevant art
- Useful
- Subject matter -- "anything under the sun made by man"

What Happens before Filing?

Interactions with Patent Counsel

- Identify Inventors/Owners
- Develop Disclosure
- Consider any Bars to Patentability
- Consider Relevant Information/Art

Inventorship

Inventor is one who conceives of the unique features that make the invention patentable -- definite and permanent concept

Inventor is not just anyone who works on a project

Important to identify only true inventors (legal question)

- Inventorship is dictated by the claims; cannot know for sure the identity of inventors absent consideration of the claims
- Not similar to “Authorship” determination!

What is an Adequate Disclosure?

Complete Written Description of the Invention

Enabling Description

- How to Make the Claimed Invention
- How to Use the Claimed Invention

Best Mode of the Invention Known to Inventor(s) at Time of Filing

What Can Lead to Denial/Loss of US Rights?

Statutory Bars

- Must file application < 1 year after:
 - Publication
 - Public Use
 - Sale or Offer for Sale

Patented by Others

- First to invent can lose rights if not diligent

What is Prosecution?

Process of "Negotiation" with Patent Examiner

- Examiner reviews application and issues "Office Action(s)"
 - Cites "prior art" that is deemed to defeat patentability
 - Identifies vague terms in claims; cites failure to adequately describe or enable the invention
- Attorney responds with Amendments/Arguments
- Examiner may issue additional actions or may allow case
- Attorney may respond, appeal, refile, or proceed with allowance

What is Prior Art?

"Prior Art," Refers to that portion of the Accumulated, Published Knowledge of All Humankind that is relevant to the subject matter of the claimed invention, and Includes:

- Prior Inventions of Others
- Prior Commercially Available Products;
- Prior Publications; and
- Any Other Prior Technical Information

What is a Publication?

- Journal Article, Thesis, Grant Application, Abstract
- Lecture/Presentation Open to Public
- Disclosure to Others Not Under Confidentiality
- Web-Page Posting
- Product
- Product Brochure
- also
- Public Use
- Sale or offer for sale

Provisional Patent Applications

Priority Document Only; Never Becomes a Patent
USPTO Does Not Search and Does Not Examine

PROS

- FAST!! Does Not Require Claims
- Does Not Require Signatures by Inventors
- The 12 Month Period Does Not Count Against the 20-year Term
- Cheaper (less \$\$ commitment upfront)

CONS

Must Meet All Other Patent Application Requirements, Including
Best Mode and Enablement -- if Early Date is Needed

Typical Application Timeline

Receive 1st Office Action 10 Months to 26 Months after Filing

Response Due within 3 Months (extensions available) -
Subsequent Office Actions may follow 2-4 months after response filed

Application published 18 Months after earliest priority date (e.g., provisionals may be published 6 months after utility application filed)

Receive Notice of Allowance/Refile case

For United States Patent Protection

Points to remember:

1. Best to file before public disclosure, publication, sale or offer for sale
2. Must file within one year of public disclosure, publication, sale, offer for sale or use by anyone (including the applicant)

Is there a "research exemption" that permits practice of the patent rights of another?

NO

See *Madey v. Duke*

Case/UHC Service to Researchers and Institution

Necessary

- Material Transfer Agreements (MTAs)**
- Confidentiality Agreements (CDAs)**
- Governmental Compliance (Bayh-Dole)**
- New NIH regulations**

Value-adds

- Patent Development**
- Sponsored Research Agreements**
- License Agreements**
- New Enterprise Development (Startups or Spinoffs)**

Benefits to Inventors

Convenience/necessity

Revenue

Education

Industrial access

Equity/Spinoff opportunities

Translational development opportunities (including sponsored research)

Benefits to Departments, University and Region

Revenue

Recruitment

Regional development (jobs, taxes)

Publicity

Shared resources

Translational culture

Costs: Time and Dollars

It costs Approximately \$30,000 and takes 3-4 years to obtain a US biomedical patent

Under Bayh-Dole, the owner (University) has a legal obligation to shepherd the technology – this takes time and money

In return, university tech transfer operations attempt to break even (3 of 4 do not)

Costs: COI and Constraints

Conflicts of Interest, perceived and actual are of crucial importance to individuals and universities

Industrially-sponsored research programs can impact academic inquiry and freedom

Biomedical world particularly exposed

Poor tech transfer contracts can strip school and faculty of \$\$\$ and even technology and publication rights

Non-patentable Does Not Equal Non-valuable

Research tools (transgenic models, assays, antibodies, prototypes, software code, etc.) can be very valuable – usually not patentable

Conversely, patent not always enforceable: legally or operationally

Clinical data and materials \$\$\$\$, but high risk (legality unclear)

Miscellaneous

Federal grant submission not a public disclosure (sans Abstract) until approved and money allocated

Federal for-profit development programs are wonderful source of translational funding (SBIR/STTR)

One invention disclosure should occur for each \$2 million of sponsored research

Industrial arrangements (MTAs, sponsored research, licenses) should not impact academic inquiry or publishing rights and cannot ignore federal requirements

The Process

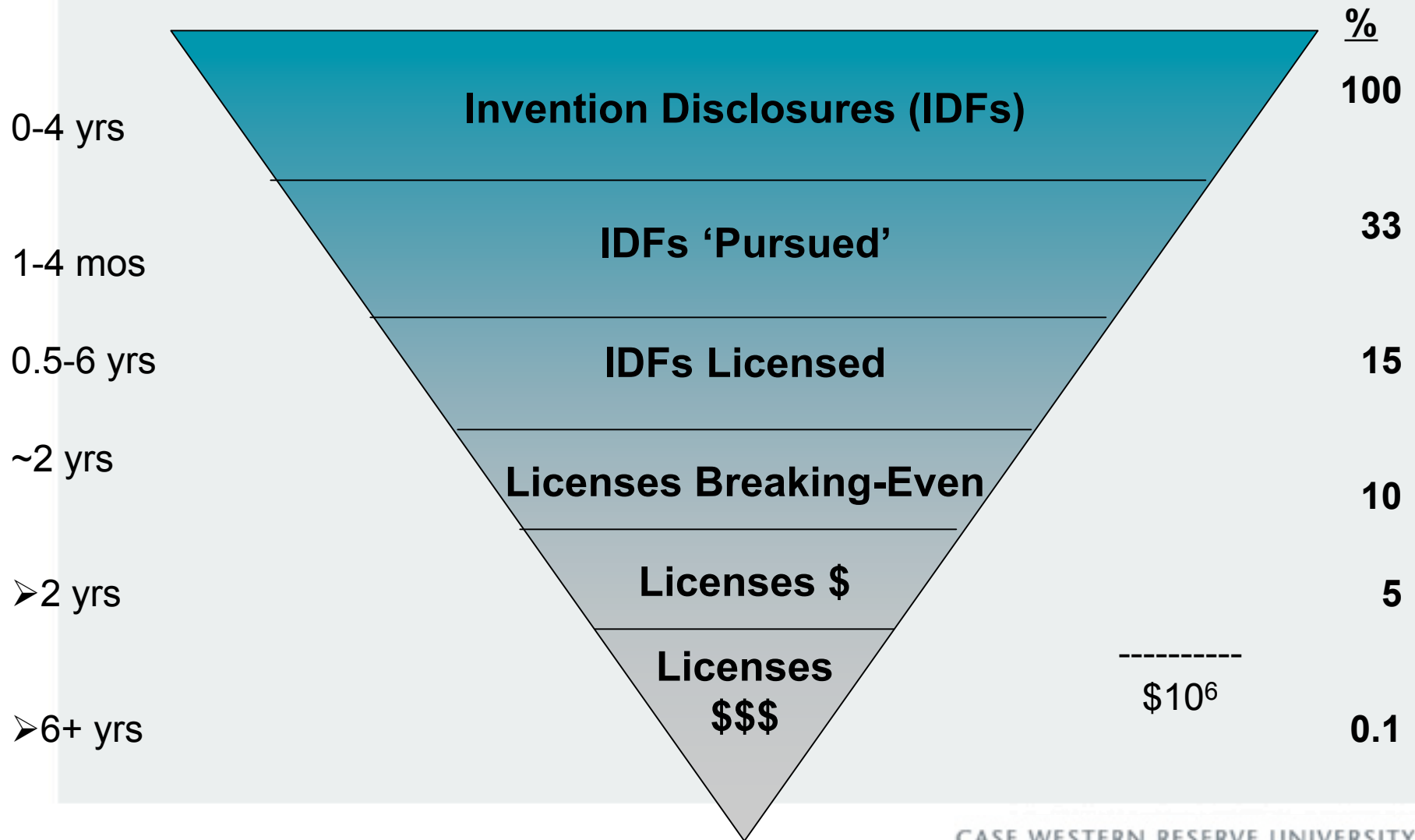
Invention Disclosure Form (IDF) is the cornerstone for all invention-based activity

One-page document signed by inventors

3-stage review

- Protectability
- Efficacy/feasibility
- Market assessment

How the Pipeline Works...



The Process (con'd)

Pursue/Not Pursue decision

- if “Pursue”, case manager and inventors work together on commercialization strategy and patent process
- if “Startup Company”, all hell breaks loose

The Role of the Inventor

Prepare and Submit Invention Disclosure

Help Identify Potential Licensees

Assist in Developing Marketing Materials

Participate in Patent Preparation and Prosecution (sporadic but long-term)

Present to Potential Licensees/Developers

Be available for continued support post-transaction

Case/UHC Tech Transfer Life Science Staff

Joseph Jankowski, Ph.D. - Asst. Vice President
Biomedical Sciences – Technology Transfer

Michael Haag - Senior Licensing Manager

Neil Veloso - Licensing Manager

Patrick Klepcyk - Licensing Associate

David Spencer – Licensing Associate

Case Physical Sciences and Engineering

Nick Frollini - Assistant Vice-President for Technology Transfer, Engineering & Physical Sciences, and Operations

Ben Kramer - Licensing Manager

Ian Spatz - Licensing Associate

Staff Education and Training

All professionals have a blend of science/engineering and business training

All biomedical team have at least a Masters degree in life sciences or business

Top-down continuing education including technology valuation, negotiation and engineering, science or medical topics

Staff Experience

All have served as professional researchers in for-profit firms and/or academic laboratories

Have been involved with formation, early-stage management and/or product development in more than 12 viable NEOhio firms

Contacting Us

First and foremost, we're here to serve you!!

We're located on the 6th Floor of Sears Library

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