



Biotechnology
Innovation Organization

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#BIO2023
#StandUpForScience

Biotechnology Entrepreneurship Boot Camp

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BIO Recognizes Course Sponsor:



**McDonnell Boehnen
Hulbert & Berghoff LLP**
Intellectual Property Law

“The patent system added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.”

Abraham Lincoln



TOPICS

Getting to the First (\$) and Next (\$\$) Round

- Exclusive Rights Primer
- Patents
- Inventors and Owners
- Filing
- Focus
- Timing
- Costs
- Patent Challenges
- Patent Term
- Patentability/FTO



IP RIGHTS



Patent – protects **inventions**

Trade Secret – protects **a secret** – may or may not be “inventive” (e.g., secret formula, manufacturing process, customer list)

Trademark – protects **a brand** (Apple[®], Bud Light[®], Bears[®], Gattari[™])

Copyright [©] – protects the **original expression of an idea** (this presentation[©], a song, a book, an app, a photo, a painting, a performance, etc)

OTHER FORMS OF EXCLUSIVITY

- Biologic Exclusivity – 12 years
- Orphan Drug Exclusivity (ODE) – 7 years
- New Chemical Entity (NCE) Exclusivity – 5 years
- Qualified Infectious Disease Product (QDIP) Exclusivity – 5 years (added to any existing exclusivity)
- Clinical Investigation Exclusivity (CIE) – 3 years
- Pediatric Exclusivity (PED) – 6 months (added to any existing exclusivity)
- Generic Drug Exclusivity (GDE) – 180 days



RIGHT TO EXCLUDE

Right to exclude others from use:

- Patents
- Trademarks
- Copyrights

No right to exclude

- Trade Secrets (assuming no theft or breach)

No right to use

- IP of any kind **does not provide a right to use**



PATENT BASICS

PATENT REQUIREMENTS

- **Utility** and **Non-natural** (35 U.S.C. §101)
- Novel (35 U.S.C. §102)
- **Non-obvious** (35 U.S.C. §103)
 - “Inventive Step” in ROW
- Claims are **enabled by the specification** as-filed (35 U.S.C. §112)
- Claims **satisfy the written description** requirement (35 U.S.C. §112)



WHAT IS PRIOR ART?

- A **scientific article**
- A **thesis** which is cataloged and available in a library
- An **abstract** which describes data in a poster or talk
- The abstract of a **Government Agency Grant** which is available to the public after the grant issues
- A **public talk** or **poster**
- **Funding/partnering pitch** not under CDA
- A **published patent application**



INVENTORS AND OWNERS

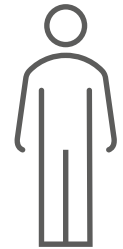
INVENTORSHIP



- A patent application **must name the correct inventors**
- A legal determination
- “one of muddiest concepts in the muddy metaphysics of the patent law”
 - *Mueller Brass Co. v. Reading Industries, Inc.*, 352 F.Supp. 1357, 1372 (E.D.Pa. 1972)

OWNERSHIP

- Ownership resides solely with the named inventor(s), unless there is **an agreement that assigns** the invention to another
- Each co-inventor owns **an undivided interest in the entire patent**, irrespective of their level of contribution
- A joint inventor who contributed to the invention **of only one claim** has an undivided interest in the whole patent
- Critical concept
 - Patents can be declared unenforceable if inventorship is not correct
 - Rogue inventors don't show up until you are making money



OWNERSHIP

Consider in **Every Agreement**

- Employment Agreements
- License Agreements
 - University Pitfalls
- Consulting Agreements
- Material Transfer Agreements
- CRO/CMO Agreements



CDA/NDA

- Who gets to see your Confidential Information
 - Affiliates?
 - Consultants?
 - Consultants of Affiliates?
 - For the “Purpose” of the Agreement
- How long is it Confidential
 - 5 Years?
 - Trade Secrets **should never be allowed** to be disclosed



FILING

WHEN TO FILE

Sufficient Disclosure

- Can you appropriately **describe and enable the “invention”**
- What **data** do you have now?
 - When will the better data going to be available?

Every Pre-Patent Filing **Disclosure Creates a Risk** of Loss of Patent Rights

- Common Fire Drills:
 - Publication of Conference Abstract
 - Submission of the Abstract usually not a “Disclosure”
 - Before a “Pitch” or partnering discussion, regardless CDA/NDA
 - Not a public disclosure, but creates still risk
 - But document your inventions
 - Not required, but recommended



WHAT TO FILE

No Such Thing:

- Paper Provisional
- Quick and Dirty Provisional



The specification **shall contain a written description of the invention,**
and of the **manner and process of making and using it,**
in such **full, clear, concise, and exact** terms
as **to enable any person skilled in the art** to which
it pertains...
to **make and use** the same,
and **shall set forth the best mode**
contemplated by the inventor or joint inventor of
carrying out the invention.

35 U.S.C § 112(a)

WHAT TO FILE

- What are your current resources?
- What will your resources realistically be?
- How much time do you have?
- Current Product Plans
- Future **realistic product plans** you can **support today**



WHAT NOT TO FILE

Future “Wish Lists”

unless...

- you **purposely** want to create prior art, or
- you can **support a claim**

Patent Offices Everywhere

- **narrow view** of your disclosure as support for your inventions/claims
 - “make and use the invention without undue experimentation”
- **liberal view** of your disclosure for the purposes of “obviousness” (a/k/a inventive step)
 - Your application will (usually) publish in 18 months and become prior art
 - then used to show what is obvious to one of skill in the art

FILING TIMELINE

U.S. Provisional Application

- \$10-15K or more
- File multiple provisionals with additional data or disclosure within one year

One year

- File in the international (PCT) or US (or both)
- \$5-10K

Thirty months

- National-phase applications globally
 - \$20-200K
- “Top Ten” (US, AU, CA, CN, EP, IN, JP, KR, MX, ?)
 - \$30K
- Others
 - Central/South America
 - Mid-East Northern Africa (MENA)
 - Other Asia (SG, PH, TH, ID)

PROSECUTION \$\$ EXPLOSION

- Five Years, **Ten** Countries
 - **Ten** Foreign Agent Fees
 - **Ten** Patent Office Fees
 - Translation Fees (CN, KR, JP, MX)
 - US counsel fees to manage **ten** foreign applications
- **Burn Rate** (could easily be 2X+)
 - Y1 = \$15,000 (provisional)
 - Y2 = \$10,000 (US/PCT)
 - Y3 = \$30,000 (10 National Stage Applications)
 - Y4 = \$15,000 (slow time)
 - Y5 = \$25,000 (ramping back up)
 - Y6 = \$60,000 (full steam)
 - Y7 = ++++++ (continuations, divisionals, grant/validation etc.)



PATENT CHALLENGES



USPTO

- Inter Partes Review (IPR) - Any time
- Post Grant Review (PGR) - Within 9 months of grant
- Timing = 18 months
- Costs = \$400,000 +++/-

EPO

- Opposition
 - Within 9 months of grant
 - Costs \$100,000 ++/-

Litigation

- Nobody wants to buy a lawsuit

PATENT TERM

- 20 Years from filing of US/PCT application
 - Provisional filing date does not count
- Patent Term Adjustment
 - For delays at the USPTO
 - Numerous Pitfalls

• Possible Extensions

- Hatch-Waxman
 - Up to 5 years for FDA delay
 - For one patent on one product
 - Similar foreign rights in major jurisdictions



PATENTABILITY/FREEDOM TO OPERATE

FTO vs. PATENTABILITY



FTO = Can you sell your product?

Patentability = Can you get a patent?

Very different topics

Very different analysis

Very different costs

Which do you need to know now?

Which do your investors want to know?

FREEDOM TO OPERATE (FTO)

- Do you have FTO?
 - FTO is a process, not an event
 - What do **you need now**
 - What **your investors want to see**
- Work Product
 - Search Results
 - Summary
 - **Simple e-mail** (“You’re OK”) or **Formal Letter**
- Consider
 - What do you expect for your commercial product?
 - What patents do you already know about?
 - What should be searched?



ADDRESSING FTO PROBLEMS

When does the patent expire?

- Will you even be on the market by then
 - Okay to infringe for research, development and clinical trials

Deep Dive

- Does the Specification support the claims
 - Many changes to patent laws over last 12 years effect older patents
- What is the state of the prior art?
 - How does this affect your own IP?
- Costs

Real Problems

- Is a license available?
- Can you Design Around?
- Patent Challenge (\$\$\$)



NEXT ROUND

IP PITCH TO INVESTORS

- **Complete Patent Report**
 - Is your tech even patentable?
- **Does Your IP Cover your Product?**
 - Are you relying on trade secrets?
- **Clear Chain of Title**
 - Current Licenses
 - Patents properly assigned to Company or Licensee
- **FTO**
 - What have you done?
 - What are the problems?
 - What is the plan to address?
- **Is anyone practicing your IP?**
 - Who is going to buy your lawsuit





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THANK YOU