

PABST PATENT GROUP



Don't lose control of your  
invention: why you need a patent  
lawyer

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# NOTES

- The opinions expressed today and herein are those of Adam Raymond, and may not necessarily reflect the opinion of Patent's Patent Group.
- The content of this presentation is for information purposes only and is not intended as legal advice.
- This presentation is intended interactive. Please stop me with questions.

# OVERVIEW

- Why Patent Law?
- The Patent Prosecution Process.
- Other Considerations:
  - Assignment
  - Collaborations

# WHY DID I CHOSE PATENT LAW?

- I love to read and write about science.
- Patents are a business asset, and without them the biomedical potential of many discoveries would go unrealized.
- I have the opportunity to work with very diverse technologies, and inventors from all over the country.

# WHAT IS A PATENT?

- A legal monopoly granted by the government in exchange for your disclosure. The system is designed to promote the dissemination of technology and reward, for a limited time, those that do so.
- Its legal basis is found in Article I, Section 8 of the U.S. Constitution:

*The Congress shall have power ... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.*

# WHAT IS A PATENT?

- A patent is a legal document that gives the patent owner the right to **exclude** others from making, using, selling, or importing the claimed invention into the patent jurisdiction.
- The invention is defined by its **claims**, which must identify a novel and inventive (non-obvious) composition, device, or component thereof, method of making, or method of using.

# MISCONCEPTIONS ABOUT PATENTS

- A patent does not give the patent owner the right to practice the patented invention.
- Prior patents can be used to stop a later patent owner from practicing his own patent.
- Freedom to practice of your invention is an important consideration in determining the value of your patent.

# TYPES OF PATENTS

## United States of America

- **Utility** patent, which protects compositions, methods of making and methods of using, including methods of treatment and diagnostics.
- **Design** patent which protects the way an article looks.
- **Plant** patent, which protects asexually reproduced plants.

# TYPES OF PATENTS

## Patent Cooperative Treaty (PCT)

- one has one year from the date of first filing to file a single international application
- subsequently must be filed in the individual countries and regions in which protection is sought
- Patents are effective ONLY in the issuing jurisdiction

Most applications for patent are filed initially in the country of origin.

# HOW DOES THE PATENT PROSECUTION PROCESS WORK?

- You start with an **idea**, but ideas are not patentable.
- You mold the idea into an **invention** – tangible embodiment(s) of the idea.
- You **expand** it to cover what you hope your partner or your licensee will market.
- **Value** is created by expanding the idea to cover other compositions, methods of making and methods of using.

# HOW DOES THE PATENT PROSECUTION PROCESS WORK?

- A Technology Transfer Office or company sends us an invention disclosure, along with previously filed patent applications, patents, and/or inquiries from a potential founder, investor or company.
- We review the materials, identify potentially patentable subject matter, problems including earlier publications, patents or other prior art, competitors and/or freedom to operate issues, potential products and develop a strategy.

# IMPORTANT CONSIDERATIONS

- What are the prospective products?
- Do you have a novel composition or method?
- Does your invention solve a long standing problem?
  - Can it be used to do something others have tried to do and failed?
  - Is the field very crowded – and, if so, does your technology stand out compared to the rest?
- For a patent, think where the technology will be in five to ten years.

# HOW DOES THE PATENT PROSECUTION PROCESS WORK?

- Next, we draft a patent application and file it with the Patent Office.
- Patent prosecution involves working with the Patent Office to determine the “metes and bounds” of your claims.
- The process involves written exchanges between the inventors or their representatives and patent examiner, but can also include telephonic and in-person interviews.

# WHAT IS THE MOST IMPORTANT ASPECT OF YOUR PATENT?

- **THE CLAIMS!**
- Make sure your claims are as **broad** as possible
- Make sure your claims **exclude** as many competitors as possible
- Make sure you have claims to as many **commercial embodiments** as you can imagine.

# REQUIREMENTS FOR A PATENT

- The claims must define a **useful** composition, article, device or component thereof, a method of making and/or a method of using.
- The claimed invention must be novel – *i.e.*, **not disclosed** orally, electronically, in writing, or on sale prior to an application for patent being filed.
- The claimed invention must be **inventive** and **non-obvious** to one of ordinary skill in the art over what others have done, alone or in combination.
- The claimed invention must be **described** in sufficient detail, clarity, and explication for one of ordinary skill in the art to conclude that the inventors were in possession of the invention and have told others how to make and use it.

# PUBLIC DISCLOSURE: *In re Klopfenstein*, No. 03-1583 (Fed. Cir. Aug. 18, 2004)

- Claims were directed to methods of preparing foods containing extruded soy cotyledon fiber (“SCF”), which lowers serum cholesterol levels while raising HDL cholesterol levels.
- Two years before applying for a patent:
  - Inventors presented the method at a meeting of the American Association of Cereal Chemists. During the meeting, the presentation, which disclosed every limitation claimed in the application, was displayed on poster boards for two and a half days.
  - Also displayed for less than a day, at an Agriculture Experiment Station at Kansas State University.
  - The presentation consisted of fourteen slides, including a cover page, an acknowledgement slide, and four slides presenting experimental data.
- The Court found that the presentations were sufficiently “publically accessible” to constitute a “printed publication.”
- The relevant statute recently changed to include “otherwise available to the public.”

## WRITTEN DESCRIPTION: *Ariad Pharmaceuticals et al. v. Eli Lilly and Company*, 598 F.3d 1336 (Fed. Cir. 2010)

- Example Claim: A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF- $\kappa$ B mediated intracellular signaling, the method comprising reducing NF- $\kappa$ B activity in the cells such that expression of said genes is reduced . . .
- The application hypothesized 3 types of molecules for reducing the activity of NF- $\kappa$ B: decoy, dominantly interfering, and specific inhibitor, but insufficient examples were provided to support the claim breadth.
- The Court concluded: “Patents are not awarded for academic theories, no matter how ground breaking or necessary to the later patentable inventions to others.”
- Filed 1995, issued 2002, court decision 2010. As of 2006 - 785 NF- $\kappa$ B inhibitors and counting (*Oncogene* (2006) 25, 6887–6899) .

# WHAT IS AND ISN'T PUBLICALLY ACCESSIBLE?

- Exemplary public disclosures include publications in journals, magazines, or newspapers; presentations at scientific meetings including abstract presentations, presentations to potential licensees without a confidentiality agreement, and publications on the internet. For example, publicly displayed documents can constitute a “printed publication” even if the duration of display is for only a few days. An orally presented paper can constitute a “printed publication” if written copies are available without restriction.
- Documents and items only distributed internally within an organization which are intended to remain confidential are not “printed publications” no matter how many copies are distributed, however, *there must be an existing policy of confidentiality or agreement to remain confidential within the organization.*

# PATENTS ARE NOT PEER-REVIEWED JOURNAL ARTICLES

- The amount of data needed to support a patent application is not even close to the data needed in a peer-reviewed journal article.
- Do not be afraid to use your **imagination**.
- All that is required is to describe the invention in enough detail that someone skilled in the art could read the application and carry out the invention without engaging in **undue experimentation**.
- This is for the US; Some non-US jurisdictions limit the claims to the scope of the data **disclosed in the application**.
- Adding additional embodiments can prevent others from patenting those embodiments.

## WHEN DOES IT END?

- Patent “prosecution” culminates with issuance of a patent or abandonment of the application.
- Abandonment = dedication to the public.
- Issuance of patent = the right to exclude others from using your invention, as defined by the claims.
- The right to exclude can be carried out in number of ways, and can lead to patent “litigation” on issues of patent validity and/or infringement.
- U.S. patent rights expire 20 years from the filing of the first non-provisional application, plus any time associated with specifically enumerated Patent Office-related delays.
- Once a patent expires, the public is no longer “excluded.”

## OTHER CONSIDERATIONS

- Assignment - The transfer of an owner's property rights in a given patent/patent application.
- Employees often assign or are obligated to assign their rights to any IP developed within scope of employment to employer.
- Employment Contracts – Often Spell Out
  - ownership of the IP rights to all of employees' or contractors' creations,
  - who has the right to use that IP,
  - whether ownership of the IP will transfer from employee to employer,
  - who will pay for securing rights in the IP

# ASSIGNMENT: *Stanford University v. Roche Molecular Systems, Inc.*, 131 S.Ct. 2188 (2011)

- Dispute arose over patents covering diagnostic tests for HIV infection originally owned by Stanford University, allegedly infringed by HIV diagnostic tests sold by Roche.
- Roche asserted co-ownership as a defense to infringement of Stanford's patents.
- One of the inventors was Stanford faculty that did research at Cetus, a company later acquired by Roche.
  - His employment agreement with Stanford said he “agree[d] to assign' to” Stanford.
  - His confidentiality agreement with Cetus said he “will assign and do[es] hereby assign” to Cetus.
- The Court confirmed the long standing notion that “ownership rights in inventions belong first and foremost to inventors.” The confidentiality agreement transferred his rights in the invention to Cetus, and superseded his “obligation” to assign to Stanford.
- Employment agreements are now written differently.

# COLLABORATIONS

- Between Universities
- Between University and company
- Between University/Company and individual
- How do you protect against dissemination of your IP
  - A Non-disclosure Agreement (NDA) or Confidential Disclosure Agreement (CDA)
  - Material Transfer Agreement
- Ensure that all agreements with companies or contractors in different countries are drafted in conformity with applicable foreign intellectual property law.

# FINAL THOUGHTS

- There is one year exception for public disclosures by the inventors in the United States, but not other countries.
- Utilize the Emory Office of Technology Transfer.
- Contact them:
  - Before any public disclosure – including submission of meeting abstracts, posters, and seminars.
  - Before you publish.
  - Before submission of grant application – particularly if there are concerns about public accessibility or being scoped by your competitor during the review process.
  - Before submitting your thesis or dissertation.