What we will talk about

- What is a patent?
- What is the standard for patentability?
- What is a public disclosure?
- What is prior art?
- What is the difference between inventorship and authorship?
- How to handle lab notebooks?
- What if you have federal funding?
- How is your invention commercialized?
- How does the American Invents Act change things?
What is a Patent?

- A right specified in Article I of the U.S. Constitution - “to promote the Progress of Science and useful Arts”.
- A disclosure of an invention to the public.
- An exclusive right to the invention for a term of 20 years from the earliest filing date.

- The rights are **exclusionary**
- It is **not** a right to make and use the invention – simply a right to exclude others from doing so
- The right must be affirmatively asserted by you, it is **not** automatic.
- You may **not** be able to use your invention without obtaining a license from another holding a dominant patent.
Types of Patents

- **Utility Patent:**
  - Issued to protect new, useful and non-obvious subject matter within statutorily-defined classes.
Types of Patents

• **Plant Patent:**
  - Issued to those who discover and asexually reproduce new varieties of plants that are novel, distinct and nonobvious.
  - Example:
    - Seedless grapes
Types of Patents

- **Design Patent:**
  - Issued to original, novel, nonobvious ornamental designs for articles of manufacture
    - The term for design patents is 14 years from date of issue.
PROVISIONAL vs. TRADITIONAL PATENT APPLICATIONS

• Provisional Application
  - Secures a priority date for the subject matter which is disclosed therein, but no more than this
  - No claims are required
  - Is not examined by the Patent Office
  - Expires after one year from the filing date unless it is converted to a traditional application
  - Small filing fee, no oath or declaration required
  - May be used as a priority document for foreign filed application
Traditional Application

- Secures a filing date for the claims and any disclosed embodiments of the claims
- At least one claim is required
- Is examined by the Patent Office
- Proceeds through the process of prosecution until issue or abandonment
- Filing fee depends on the number and type of claims filed; Oath or declaration is required
- May be used as a priority document for foreign filed applications
What Should You Disclose In A Patent Application?

- Information which satisfies various aspects of the Patent statute.
  - Utility
  - Novelty
  - Non-obviousness
  - Enablement
  - Written Description
  - Best Mode

- The USPTO examines all of these in respect to what is claimed
Claims, Continued

- Compositions versus Method claims
  - 1. An isolated nucleic acid encoding a cytokine.
  - 2. A method of alleviating a disease in mammal comprising administering to said mammal a vector comprising an isolated nucleic acid encoding a cytokine.

- Dependent claims
  - 3. The isolated nucleic acid of claim 1, wherein said cytokine is IL-6.
  - 4. The method of claim 2, wherein said vector is a viral vector.
Composition of Matter Claims

- If the composition is in the public domain for any purpose, you cannot get a claim to the composition *per se*

- But, you can get a composition claim to:
  - A new formulation of the composition
  - A combination of a delivery device and the composition provided the above are novel and non-obvious
Method Claims

- A new use for an old drug is patentable
- Claims to multiple new uses can be obtained by more than one party provided that the new uses are novel and non-obvious
Geographic Reach

- Patent rights are limited geographically
  - A U.S. patent is limited to the U.S. and its territories
  - A U.S. patent cannot be enforced outside the U.S.
Foreign Patents

U.S. versus Foreign Patents

- Requirement for absolute novelty
- Prior disclosure destroys novelty in most, but not all countries
- First to file takes the prize in most foreign countries
- U.S. is still a first to invent country
  - This changes in 2013
International Options

- File directly in national country
  - This is very expensive
- File in regions
  - European Patent Office
  - Eurasia
  - OAPI
  - ARIPO
- File a PCT application
Patent Cooperation Treaty (PCT)

- This is essentially a placement holder for almost all countries
- Applicants can delay national filings (and translations) for up to 30 months
- International Preliminary Examination – a limited examination
Time Lines

1. File a U.S. Provisional Application
   ↓
   File U.S. Non-Provisional Application
   and
   File in Foreign Countries

2. File U.S. Non-Provisional Application
   ↓
   File in Foreign Countries

   If foreign filing is done through the P.C.T., the application is published six months later; i.e., eighteen months after the first-filed U.S. Application.

3. Patent Term - 20 years from the earliest filing date
Patentability

- **What can be patented?**
  - “anything under the sun that is made by made may be patentable”
    - Cannot patent abstract ideas or concepts
- **The invention must be satisfy the following:**
  - Novel
  - Non-obvious
  - Useful
Utility

- This is one of the easiest of the 3 hurdles to patentability.
- The invention must be useful.
Novelty

- The invention must not exist in the public domain prior to filing the patent.
- The invention must be new and different from the prior art.
Obviousness

- You cannot simply modify an old invention and expect to obtain a patent.
- The modification must be non-obvious to one of skill in the art.
What Is a Publication – a public disclosure?

- It is not merely something which is published in a journal

- Publications include the following:
  - Scientific articles
  - A thesis that is cataloged and available in a library
  - Abstracts that describe data in a poster or talk
  - The abstract of a Government Agency Grant as soon as it has published, and the Grant itself, but only after the Grant has been awarded
  - A public talk or poster session that is open to people outside your own institution
  - An informal “chat” with a prospective licensee without executing a Non-Disclosure (NDA), Confidentiality Agreement (CA) or Confidential Disclosure Agreement (CDA)
The Effect of a Publication

- U.S. - One Year
- Most Foreign Countries - Absolute novelty
What is Prior Art?

- A disclosure in the public domain that either discloses your claimed invention, or renders it obvious
  - Can be your own disclosure or that of a third party
- Can be, the same as a publication, i.e.:
  - A journal article
  - A meeting abstract
  - A poster or presentation at a meeting
  - A sequence in a database
  - A published patent application or issued patent
  - Use or sale of the invention
Prior Art

- Novelty can only be destroyed by one prior art reference
- Obviousness can be alleged using one or a combination of several references
Inventorship is often overlooked in the area of patent law. We tend to focus on patentability, freedom to operate and infringement issues. But when you really think about it...

- What does inventorship mean?
- What does it mean to invent?
- Who should be classified as an inventor?
What does it mean to invent?

According to dictionary.com:

- **in·vent** – verb (used with object)
  1. to originate or create as a product of one's own ingenuity, experimentation, or contrivance: to invent the telegraph.
  2. to produce or create with the imagination: to invent a story.
  3. to make up or fabricate (something fictitious or false): to invent excuses.
  4. Archaic. to come upon; find.
Executors of the Oath or Declaration are presumed to be the inventors under 37 CFR 1.63

- "The existence of combination claims does not evidence inventorship by the patentee of the individual elements or subcombinations thereof if the latter are not separately claimed apart from the combination." (quoting In re Facius, 408 F.2d 1396, 1406, 161 USPQ 294, 301 (CCPA 1969) (emphasis in original)); Brader v. Schaeffer, 193 USPQ 627, 631 (Bd. Pat. Inter. 1976) (in regard to an inventorship correction: "[a]s between inventors their word is normally taken as to who are the actual inventors" when there is no disagreement).

Executing an oath or declaration provides a presumption that you are the inventor
However, it is important to know the following:

- "Courteous" giving of inventorship may have negative consequences.
- An erroneously identified "inventor" who was not actually involved in the conception of an invention, or an omitted inventor, may lead to invalidation.
- Considering that there is a presumption of inventorship based on the oath or declaration, when would we expect this to be an issue?
Authorship vs. Inventorship

- It is important to note that merely being an author does not satisfy the requirements of inventorship.

  - In the scientific world, authors of journal articles may be involved in designing or performing the experiments or in writing the resulting manuscripts.
  - In addition, authorship is sometimes granted for the recognition of hard work or even for financial support. This is NOT to be confused with inventorship.
  - Inventors of subject matter in patents have to be legally determined. In particular, inventorship is directly related to two extremely important terms:
    - conception
    - reduction to practice

http://www.bios.net/daisy/patentlens/g4/tutorials/205.html
The Non-Inventor

- A person who:
  - Contributes an obvious element to the invention
  - Merely suggests an idea
  - Simply follows instructions
  - Explains how or why an invention works
  - Adopts derived information from another
  - Actually did the experiment, but did not conceive of the invention

is **NOT** an inventor
An inventor must contribute to the conception of an idea

- The definition for inventorship can be simply stated:
  - "The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor. Insofar as defining an inventor is concerned, reduction to practice, *per se*, is irrelevant [except for simultaneous conception and reduction to practice, *Fiers v. Revel*, 984 F.2d 1164, 1168, 25 USPQ2d 1601, 1604-05 (Fed. Cir. 1993)].
  - One must contribute to the conception to be an inventor." *In re Hardee*, 223 USPQ 1122, 1123 (Comm'r Pat. 1984). See also *Board of Education ex rel. Board of Trustees of Florida State Univ. v. American Bioscience Inc.*, 333 F.3d 1330, 1340, 67 USPQ2d 1252, 1259 (Fed. Cir. 2003)
Reduction to practice may be an actual reduction or a constructive reduction to practice. Constructive reduction to practice occurs when an application on the claimed invention is filed.

The filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application.

Thus the inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998).

A reduction to practice can be done by another on behalf of the inventor. *De Solms v. Schoenwald*, 15 USPQ2d 1507, 1510 (Bd. Pat. App. & Inter. 1990).
Conception and Reduction to Practice

- Conception can be achieved via actual or constructive reduction to practice
- Merely suggesting a *desired* result without means for attaining that result is **not** inventorship
- If you have an idea, but do not reduce it to practice...are you an inventor?
- Let’s discuss this in the context of a scientific example
  - I have an idea for a cure for cancer.
  - I don’t really know how to cure cancer or how to describe how to make a cure for cancer, but I know I have an idea for what I want the cure to do.
  - Am I an inventor?
Conception and Reduction to Practice, continued

- It should be noted, participation in the reduction of the invention, without more, does not make an individual an inventor.
- Someone participating in the reduction to practice AND contributing to the final, complete conception is an inventor, but participation only in the "reduction to practice" does not warrant inventorship.
"When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though

- (1) they did not physically work together or at the same time,
- (2) each did not make the same type or amount of contribution, or
- (3) each did not make a contribution to the subject matter of every claim of the patent."
The claims are the only part of a patent that defines the boundaries of the patent owner's rights,
- Therefore, the claims determine inventorship.
- Accordingly, amendments to the claims can change inventorship.
Claim Scope and Inventorship

- The Lucent decision suggests that enforcement should also be considered at the time inventorship and claim scope decisions are made.

- Do you consider claim scope in view of inventorship?

- How do you make an inventorship decision in view of a joint development agreement?
  - Should you draft the patent application as broadly as the prior art will allow?
  - Or do you draft the claims only as broad as the inventors contributions?
  - Can you divide claims along inventorship lines and still get past Section 103 on related applications?

Correcting Inventorship

- Inventorship mistakes can be extremely costly.
  - And can lead to invalidation of a granted patent
- Fortunately, the USPTO makes it relatively easy to correct any inventorship issues
  - Essentially you simply need a few documents and, of course, payment of a fee
How can we avoid inventorship issues?

- Instruct your clients/scientists to maintain inventorship records
- Know your inventors
  - Know where they live, where they invented and what they invented
- Know your invention
- If you determine an error in inventorship, fix it!
The Lab Notebook

- The Lab Notebook is the **initial** Record of the Invention
- It is used to:
  - establish the date of the invention
    - Overcome prior art
    - Priority in a contest to determine who invented first
  - determine actual inventorship
The Lab Notebook

• The Notebook should
  ▪ Be evidence of conception of the invention
  ▪ Demonstrate diligence in reducing the invention to practice
  ▪ Establish basis for corroboration by a non-inventor

• Should:
  ▪ Record discussions with collaborators
  ▪ Every entry should be signed and dated by the Inventor, and
  ▪ Be countersigned by a non-inventor witness who understands the entries
The Lab Notebook

- The Notebook should preferably be:
  - Bound
  - Written in ink
  - On sequentially numbered pages
  - Few or no eraser marks
  - Have an index
  - Be a coherent record of the experiments and their results
The Electronic Lab Notebook

- If you use them, then:
  - Use software that permanently records dates of entries and an unalterable electronic signature
  - Print hard copies for corroboration
  - Adopt a standard procedure followed by all lab members
Federal Funding

Under the Bayh Dole Act, the US government encourages patenting of inventions made using government funds.

- Funding source MUST be disclosed in the patent application and in a separate form to the US government.
- The US Government has rights in the invention – they rarely take up these rights, but they do have them.
Commercialization
The License

- The invention/patent application may be licensed to an existing Company
  - The Company agrees to develop the invention
  - The Company agrees to certain royalty payments to Kean
  - Those royalty payments are shared with the inventors under the Kean Intellectual Property policy
Commercialization
The Start-Up Company

- The invention/patent application may be licensed to a new Company that may or may not be founded by Kean inventors
  - The NewCo agrees to develop the invention
  - The NewCo and Kean agree to some type of financial structure that facilitates future funding by venture capital, and an eventual exit by going public or by sale of the company
America Invents Act

- Under the US first to file system the inventor will still have a personal grace-period, which is not available to inventors outside the US.
  - This personal grace-period says that the inventor’s own disclosures, or the disclosures of others who have derived from the inventor, are not used as prior art as long as they occurred within 12 months of the filing date of a patent application relating to the invention.
- However, and this is a very big however, disclosures of third-parties who independently arrived at the invention information will be used against the inventor.
  - This means that there is no grace-period relative to third party, independently created disclosures.
  - HUGE difference between the old law and the new law.
First to Invent Changes to First-Inventor-To-File

**First-Inventor-To-File system**
- 18 months after enactment
- Independent conception of invention by a first filer can result in an awarded patent to the first filer regardless of whether another invented first
- However, not truly a first to file system
- The first applicant to file will be presumed to be a true inventor
- Challenges to the presumption will be allowed only on the basis of claims that the first applicant did not actually invent the subject matter claimed in the application rather than addressing who may have invented it first
  - Challenges to inventorship (i.e., derivative work) are held in a new derivation proceeding and must be raised within one year of publication of a claim
  - USPTO has 9 months to establish rules and procedures for the derivation proceeding
A publication by an inventor can be used to antedate a prior art reference cited by an Examiner with a date between the publication and the filing of a patent application.

- The inventor is allowed one year from the Date of Publication to file for a patent application.
- Other publications that are published between the Date of Publication and the filing date of the application are not considered prior art.
- Other publications published prior to the Date of Publication may be viewed as being derivatives of the inventor's own work and thereby challenged in the derivation proceeding.
  - Earlier publications may affect filing date requirements.
  - In the absence of a publication, the application filing date becomes the controlling date for priority purposes.

First to Invent Changes to First-Inventor-To-File
First to Invent Changes to First-Inventor-To-File

- First-Inventor-To-File system Cont'd
  - Risks of early publication of invention
    - Hindrance to obtaining foreign protection
      - Many countries view publication prior to filing an application as a bar against patentability
      - However, many countries around the world allow a grace period between the Date of Publication and filing date
      - Insufficient enablement
The Patent Reform Act of 2011 (America Invents Act)

- Other Changes
  - Micro-entity Status
  - Fee setting authority
  - Best Mode
  - Patentable Subject Matter on Tax Strategies
Third Party Submission During Pendency of App

Current Law:
- Patents or publications relevant to a pending published application submitted
  - A submission under this section must be filed **within two months from the date of publication** of the application or prior to the mailing of a notice of allowance, whichever is earlier

New Proposed law:
- any patent, published patent application, or other printed publication of potential relevance to the examination of the application, if submitted before the later of
  - (i) **6 months after the date on which the application** for patent is first published under Section 122 by the Office, or (ii) **the date of the first rejection** under Section 132 of any claim by the examiner during the examination of the application for patent
  - Statement of relevance
  - 12 months after enactment
Supplemental Examination (New)
- Examination of information post patent issuance by patent owner
  - Reexamination if new question of patentability
  - Ability to cure issues not addressed during examination
    - Inequitable conduct relative to information disclosed
    - Strengthen patents with more prior art references reviewed by the USPTO prior to start of litigation
Post-Grant Review

- Post Grant (other types):
  - Post-grant (New, within 9 months for any ground of invalidity), *Inter partes* Review (New, after 9 months and for novelty and obviousness) and *Ex parte* Reexamination
    - Third parties, not patent owners, may file a request for post-grant review of a patent up to nine months after issuance
    - The Director evaluates whether the petition:
      - Would demonstrate that it is more likely than not that at least [one] of the claims challenged in the petition is unpatentable
      - Raises a novel or unsettled legal question that is important to other patents or patent application
    - The determination by the Director on whether to institute a post-grant review is final and non-appealable
  - Discovery
  - Amendments by patent owner
THANK YOU!

Please feel free to contact me if you have any additional questions:

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