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Patents – Just the Basics

Presented to The Massachusetts Eye & Ear Infirmary and The Schepens Eye Research Institute

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Agenda

- Background
- Common Conceptions about Patents
- Timeline – from Invention to Patent Expiration
- Types of US Patent Applications
- Anatomy of a Patent Application
- Claims
- Requirements for Patentability in US
- Prosecution in the US
- Patent Term
- Inventorship and Ownership

Introduction

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.

U.S. Constitution, Article I, section 8, clause 8

What is a Patent?

A document that provides to the patent owner the right to prevent others from making, using, offering to sell, selling, or importing the invention(s) claimed in the patent.

- Personal property — can be bought, sold, licensed, bequeathed, etc.
- Territorial — must obtain patent in every country where protection is desired.
- United States Patent and Trademark Office (USPTO) – tasked with examining patent applications and granting patents

What is a Patent? (cont.)

- Negative right — gives its owner the right **to prevent others** from making, using, offering to sell, selling, or importing her invention.

- However, it does NOT give its owner the right to make, use, sell, or offer to sell her invention. It gives the owner only the right to exclude others.

Purposes of the Patent System

- To reward inventors and their employers and thereby encourage innovation
- To make it economically feasible to invest money in research and development
- To provide a technology "database" available to all; *e.g.,* to discourage accumulation and hoarding of trade secrets

Benefits of a Patent Portfolio

- Generation of revenue by way of royalty payments
- Exclude competitors from best products or most efficient processes
- Increase competitors' risks and levels of uncertainty
- Bargaining chips to exchange with other companies for use of their intellectual property

Question #1: True or False?

"My patent gives me the right to make, use, and sell my invention."

Question #1: Answer

"My patent gives me the right to make, use, and sell my invention." ***FALSE***

In fact, a patent is just a right to ***block others*** from making, using and selling the invention.

It is not an ***affirmative right*** to practice the invention.

-- The invention may be illegal to sell (an unapproved drug?).

-- Others may own patents that also cover some aspect of your invention.

Example: The Chair

Adam invents and claims a chair:

A chair comprising a seating surface, four legs, and a back.

Example: The Chair (cont.)

Bea discovers that adding arms to the chair makes it more comfortable, so claims:

> **A chair comprising a seating surface, four legs, a back, *and two arms*.**

Bea can't make or sell her new armchair without infringing Adam's patent, and Adam can't make or sell his armchair modified to include two arms.

QUESTION #2: True or False?

"Merely having a patent will stop others from copying my patented product."

QUESTION #2: Answer

"Merely having a patent will stop others from copying my patented product." *FALSE*

A patent does not automatically stop anyone from doing anything. It is just a "ticket to court." You must enforce the patent in court to hold others accountable for infringing behavior.

BUT, fear of liability for infringement may stop some competitors.

QUESTION #3: True or False?

"I've never seen this product on the market, so it must be patentable."

QUESTION #3: Answer

"I've never seen this product on the market, so it must be patentable." ***FALSE***

- To qualify for patent protection, the invention must be, *inter alia*, new, useful, and non-obvious
- Whether or not a similar product is "on the market" is not the test
- Before filing a patent application, it is good practice to perform a patentability analysis

QUESTION #4: True or False?

"We don't copy anyone's product, so we don't infringe anyone's patents."

QUESTION #4: Answer

"We don't copy anyone's product, so we don't infringe anyone's patents." ***FALSE***

- Lots of inventions are patented, but not on the market
- Whether you know about a patent or not, you can be liable for infringement
- Before investing in a new product, we typically recommend a "freedom to operate" analysis

QUESTION #5: True or False?

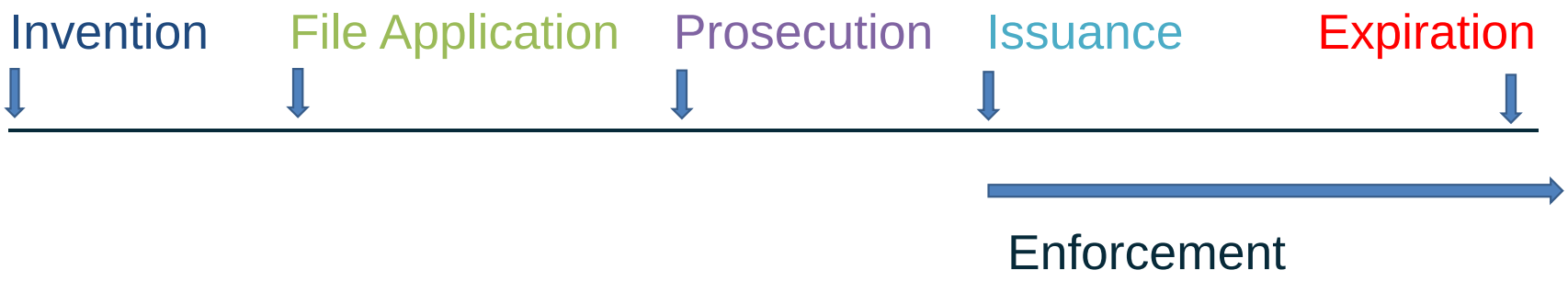
"To get a patent, all I need to do is fill out a form and send it to the Government."

QUESTION #5: Answer

"To get a patent, all I need to do is fill out a form and send it to the Government." ***FALSE***

- BIG distinction between an **application** and a **patent**
- After filing a patent application, years of back-and-forth with the USPTO examiner (**"patent prosecution"**), typically with all claims rejected at least once.

Timeline - from Invention to Patent Expiration



Types of Patent Applications

- Provisional
- Utility (Non-provisional)
- Design
- Plant
- Patent Cooperation Treaty (PCT) application

QUESTION #6

- Which of the above applications cannot become a patent?

QUESTION #6: Answer

Provisional applications and **PCT applications** cannot become a patent.

Provisional Application

- Never examined, never will issue as a patent
- Automatically expires in 12 months
- Think “place holder” for priority date
- Provides 12 months to further refine the invention (BUT! Any new matter gets only the new filing date)
- Must be “re-filed” as a utility or PCT application within 12 months of filing date to maintain priority date

Utility Application

- Unlike a provisional, a utility application is examined by the USPTO and may ultimately be granted as a patent
- Protects the **structural and functional** aspects of an invention
- After filing, no substantive changes can be made to the specification and figures without risking a "new matter" rejection
- During pendency of a "parent" utility application, one can file "**continuing applications**" such as a:
  - *Continuation* – same specification and general invention as parent
  - *Divisional* - same specification as parent but claims different invention
  - *Continuation-in-Part* – specification has added matter

Design Application

- Whereas a Utility patent application extends to the ***functionality / usefulness*** of an invention, a Design patent application covers only the ***ornamentation*** of a particular design

- Provides relatively narrow protection

Plant Application

- Plant patent applications cover distinct and new varieties of plants that are asexually reproduced

- Asexually reproduced plants are those that are reproduced *by means other than from seeds*, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc.

PCT Application

- The PCT is an international treaty which makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single “international” patent application (instead of filing several separate national or regional patent applications)
- “As if” you filed an application in each of the countries that are members of the PCT (148 Contracting States)
- Preliminary search for prior art and review of claims
- Applicant can later choose whether to proceed with actual filings in countries of interest (“**national phase**” filings)
- The granting of patents remains under the control of the national or regional patent Offices.

Example of Filing Timeline without PCT

January 1, 2010

Provisional patent application filed in U.S.

Examination

January 1, 2011

US utility application filed; any desired foreign applications filed directly in the foreign countries (all get benefit of January 2010 priority date).

Example of Filing Timeline with PCT

January 1, 2010

Provisional patent application filed in U.S.

Examination

January 1, 2011
PCT application filed

July 1, 2012
National phase (US utility and foreign) applications filed; get benefit of January 2010 priority date

Why Use PCT?

Advantages of the PCT route:

- Defers expenses while preserving priority date for up to 30 months
- Allows more time to assess marketability and patentability
- An International Search Report and International Preliminary Report on Patentability are provided

Disadvantages of the PCT route:

- Additional cost of filing the PCT application
- Delays start of prosecution, so may delay issuance of patents

Anatomy of a Utility Application

- Specification
  - Written description of the invention
  - How to make and use
  - Abstract (short summary)
  - Can contain figures (important for devices)

- Claims

Purpose of the specification is to support the claims (*e.g.*, teach how to make and use)

Anatomy of a Utility Application (contd.)

- Title of Invention
- Cross-Reference to Related Applications
- Statement Regarding Federally Sponsored Research or Development (*if Applicable*)
- Reference to Sequence Listing, a Table, or a Computer Program Listing Compact Disc Appendix (*if Applicable*)
- Background of the Invention
- Summary of the Invention
- Brief Description of the Drawings (*if any*)
- Detailed Description of the Invention (including Examples)
- Claims
- Abstract of the Disclosure
- Drawings (*if any*)

Patent Claims

- ***Most important part of the application***: they define what is being claimed as the invention
- Claims must define an invention that does not overlap with the prior art (novel, non-obvious)
- Presented at varying levels of abstraction (broad to detailed nuts & bolts)

Anatomy of a Patent Claim

1. A chair **comprising** *a seating surface, four legs, and a back***.**

- Preamble - "A chair"
- Transitional Phrase - "comprising" / "consisting of"
- Body – "a seating surface, four legs, and a back"

2. A chair **consisting of** *a seating surface, four legs, and a back***.**

Independent and Dependent Claims

Claims 1 and 2 (above) are independent claims.

Claim 3 (below) is a dependent claim.

3. The chair of claim 1, wherein the seating surface is made of wood.

Exemplary Claims

Method claim: A method of treating lung cancer in a human subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a humanized anti-XYZ antibody.

Composition claim: A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a humanized antibody that specifically binds to a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:1.

What are the Requirements for Patentability?

Must comply with the:

- Statutory Subject Matter (35 USC § 101)
- Utility (35 USC § 101)
- Novelty (35 USC § 102)
- Non-Obviousness (35 USC § 103)
- Written Description (35 USC § 112, First Paragraph)
- Enablement (35 USC § 112, First Paragraph)
- Best Mode (35 USC § 112, First Paragraph)
- Definiteness (35 USC § 112, Second Paragraph)

The Statutory Subject Matter Requirement

Requires that the invention fall into a category that Congress has designed the patent laws to protect

US law specifies four categories of patent-eligible subject matter:

- process (or method)
- machine
- manufacture
- composition of matter

Statutory Subject Matter (cont.)

Supreme Court has defined three exceptions to those four categories:

- Laws of Nature
- Natural Phenomena
- Abstract Ideas

A claim that is nothing more than an attempt to patent something within one of those exceptions is not valid

The Utility Requirement

- Requires that the invention be “useful”
- Use must be specific, substantial, and credible

The Novelty Requirement

Requires that the invention not be in the public domain prior to the filing of the patent application, *e.g.*, by way of:

- Patenting of the invention
- Publication of the invention
- Public use of the invention
- Sale or offer for sale of the invention

The Novelty Requirement (contd.)

Applicant has a one-year grace period to file an application in the US (but not in most other countries)

To protect foreign filing rights, file priority application before any public disclosure, or use, or sale, or offer for sale ("bar dates")

The Novelty Requirement (contd.)

Typical bar date triggers:

- Journal articles
- Product release brochures
- Conference presentations, abstracts
- Disclosures not protected by non-disclosure agreement (NDA)
- Website postings
- Selling/Offering for sale (even under a secrecy agreement)

The Nonobviousness Requirement

- Even if novel, invention is not patentable if it differs from the prior art only by way of an "obvious" modification
- "Obvious" means obvious to a person of ordinary skill in the art at the time the invention was made
- Highly subjective

The Written Description Requirement

- Requires the specification to describe the invention in such a way as to prove the inventor was in possession of the full scope of the invention
- Can be more difficult to satisfy for inventions in unpredictable fields (*e.g.,* pharma, biotechnology)

The Enablement Requirement

- Requires the specification to teach one of skill in the art how to make and use the invention
- Frequently an issue for the “unpredictable arts” (biology and chemistry), especially for unproven methods of treatment

The Best Mode Requirement

- Must describe the best way of performing the invention
- Public entitled to the best way you know of at the time of filing – *quid pro quo*

The Definiteness Requirement

- Requires a patent's claims to inform those skilled in the art about the scope of the invention with reasonable certainty

Prosecution of US Applications

QUESTION #7: Pick One

How long does it take, on average, to get an issued U.S. patent in biotechnology from the date the utility application is filed?

a) 6 months

b) 1.5 years

c) 2 years

d) 10 years

QUESTION #7: Answer

How long does it take, on average, to get an issued U.S. patent in biotechnology from the date the utility application is filed?

Answer: (c) 2 years

Prosecution of US Applications

(1) File application and complete any formalities, including filing an Information Disclosure Statement disclosing all pertinent prior art of which the applicant is aware

(2) Examiner may insist on splitting multiple inventions into separate applications (divisional applications) before examining each ("Restriction Requirement")

Prosecution of US Applications (cont.)

(3) First Office action nearly always rejects the claims on various grounds

(At any point after the first Office action, either the examiner or the applicant can request a telephone or in-person interview to discuss and resolve the issues.)

Prosecution of US Applications (cont.)

(4) Applicant responds to each ground of rejection with arguments, factual evidence, and/or amendments, as appropriate

(5) If examiner was not fully satisfied by Applicant's response, she will send a second Office action, most likely final, explaining what issues remain

Prosecution of US Applications (cont.)

(6) Various options after final action, including appeal

(7) Eventually prosecution concludes with either an allowance of all claims still in the case, or abandonment

(8) After allowance, applicant pays the issue fee and the patent issues

(9) To maintain the patent, maintenance fees must be paid 3.5, 7.5, and 11.5 years after the date of issuance

Patent Term

QUESTION #8: Pick One

How long is the patent term for a utility patent in the U.S.?

(a) 5 years

(b) 17 years

(c) 20 years

(d) lifetime of the inventor

Patent Term

QUESTION #8: Answer

How long is the patent term for a utility patent in the U.S.?

(c) 20 years

In most cases, the patent term is 20 years from ***earliest claimed non-provisional (i.e., US utility or PCT application) priority date.***

- Provisional filing does NOT affect term.

Inventorship

QUESTION #9: True or False?

"All of the people listed on my manuscript should always be listed as inventors on my patent application."

Inventorship

QUESTION #9: Answer

"All of the people listed on my manuscript should always be listed as inventors on my patent application." ***FALSE***

Inventorship

- An inventor is someone who **conceives** of the subject matter claimed in the patent
  - Depends on what is **claimed** in the issued patent

- Criteria are **not** the same as criteria for authorship
- A *legal* determination based on the claims
- Should not be over-inclusive or under-inclusive in listing inventors
- Determining inventorship correctly is important in the US - can impact the enforceability of the patent

Ownership of Patents

- Default rule: Inventor is the owner of the patent
- Circumstances where employer may own patent:
  - Employment agreement may prospectively assign inventions to employer
  - Local law may make employer owner of invention made by employee during the course of employment
- Transfer of ownership: Assignment
- Collaboration/consulting agreements should address ownership of resulting patents

Questions?

Thank you!

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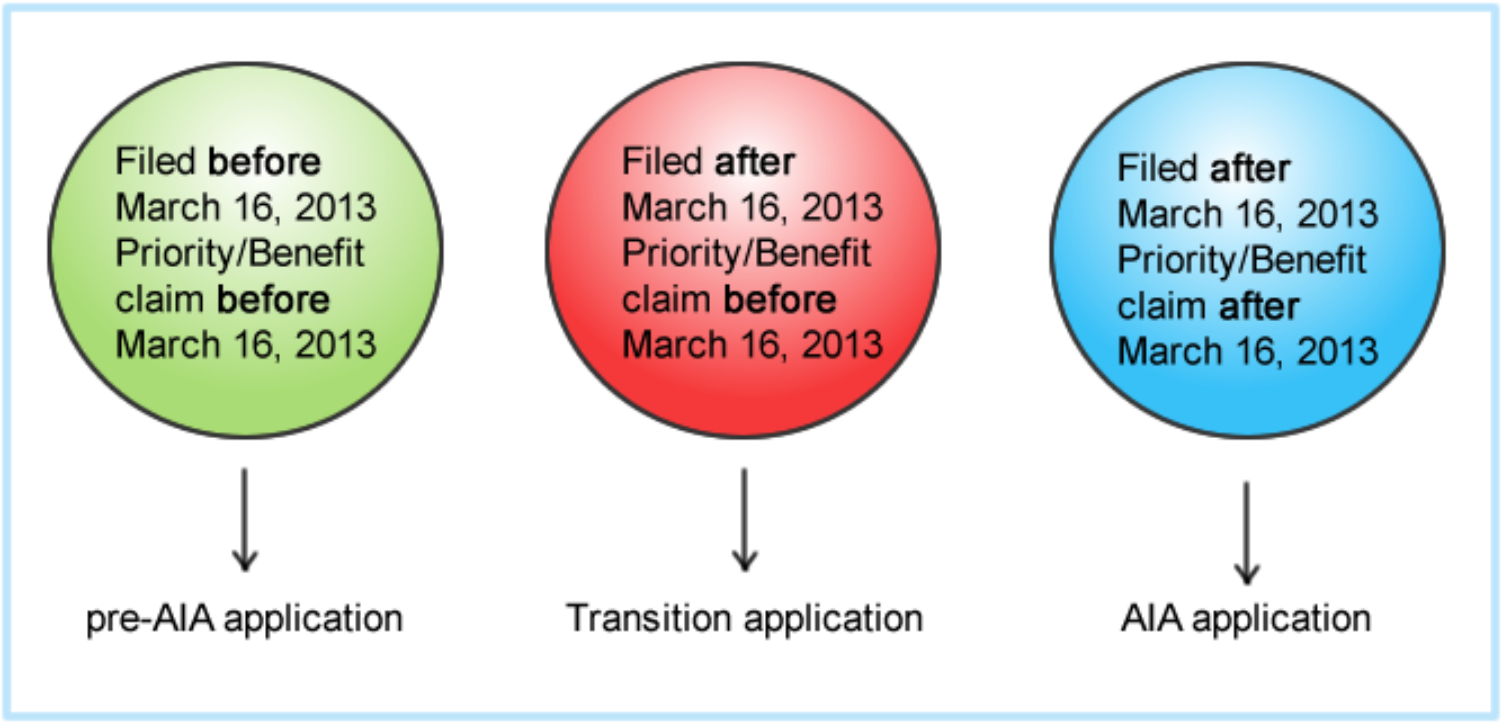
AIA – Effects on Patent Strategy

First-to-file now under **America Invents Act** (AIA)



AIA – Effects on Patent Strategy

- First to file – BUT still need to meet statutory requirements of written description and enablement – a trade-off
- Still some "grace periods" based on own work or even others' work (joint inventors)
- "Applicants" may request a US patent, not just inventors
  - Inventors
  - Assignee
  - One with sufficient proprietary interest