

Intellectual Property

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Patent Agents, Registered with the USPTO

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- Specific questions about your particular fact pattern or situation should be referred to your own attorneys or other representatives.

Overview

- Overview of “Intellectual Property”
- Ways to Protect IP (**Apply the Appropriate IP Protection for your Innovation**):
 1. Patents
 - What is a “patent?” Why have patents?
 - Parts of a patent
 - Benefits/Drawbacks (**Benefits and Limitations of the Patent System for the Innovator and Society**)
 - Criteria for obtaining a patent
 - Types of patents (**US and International Patent Protection**)
 - To patent or not to patent? (**Assess the IP Landscape**)
 - When to file for a patent (**When to file for IP protection**)
 - How to file for a patent (**How to File for a Patent and How Patent System Works**)
 - **Choosing IP Counsel**
 - Costs
 - Inventorship
 2. Copyrights
 3. Trade secrets
 4. Trademarks

What is IP?

Intellectual Property

Intellectual Property

- **Creations of the human mind**

- Inventions, literary and artistic works, symbols, names, images/logos, designs, collections, etc.



- **Analogous to physical-property, if someone trespasses on physical-property, the courts will enforce those property rights:**

- Damages (money) awarded to “make the plaintiff whole”
- In the case of intellectual property (IP), the “trespass” is *unauthorized use*, (infringement)



Ways to protect IP

- **Patents:** Protect “new, useful, & unobvious” inventions for a limited term
- **Copyrights:** Protects original works of authorship embodied in a tangible medium of expression for a limited term
- **Trademarks:** Protects marks that identify the source of goods or services for as long as the mark continues to be used in commerce
- **Trade Secrets:** Protects commercially valuable, protected information for as long as the information remains secret and valuable

Public Disclosures

- Public or non-confidential disclosures can prevent you from protecting your invention with a patent
 - Sale (even secret sale under CDA)
 - Publication
 - Chat room
 - Presentations
 - Published Abstracts
- CDAs or at least an expectation of confidentiality
 - Mark communications/presentations with *Confidential Information*
- “Grace periods” (US 1 year only for own disclosure; International, generally none)



What are Patents?

Intellectual Property

What is a patent?



- Patents are often the most valuable piece of a startup's intellectual property portfolio
- Original document from the United States Patent and Trademark Office (USPTO) or other foreign jurisdiction
- Claims delineate rights
- Gives an owner the right to exclude others from making, using, selling, or importing the invention for a period of 20 years from the filing date
- No affirmative right to make, use, or sell
 - Freedom to operate (i.e., non-infringement)

Why Have Patents?

- **“Quid pro quo” for Inventor & Public**
 - *Inventor Gives*: public disclosure of invention
 - *Inventor Receives*: a limited monopoly to use/exploit the patented invention exclusively
- **Rewards Inventiveness**
 - To reward the creator of a new technology, not one who just copies it

Anatomy of a Patent

Intellectual Property

Anatomy of a Patent

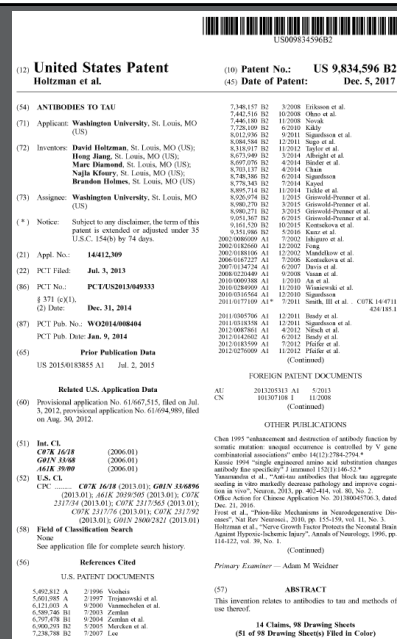
- Abstract
- Background
- Summary
- Figures with brief descriptions
- Detailed description
 - Fully discloses what the invention is, defines claim terms
 - How made?
 - How used?
 - Examples, experimental data
- Claims: sets the legal boundaries of protection
 - claims = protected IP

Claims

- A claim is one sentence long and includes the elements of the invention
- *Example:* U.S. Pat No. 9,834,596 to Professor David M. Holtzman, MD, Department of Neurology

What is claimed is:

1. An isolated monoclonal anti-tau antibody, wherein the antibody comprises:
- a light chain variable region comprising a CDR1 of amino acid sequence SEQ ID NO: 16, a CDR2 of amino acid sequence SEQ ID NO: 17, and a CDR3 of amino acid sequence SEQ ID NO: 18, and
- a heavy chain variable region comprising a CDR1 of amino acid sequence SEQ ID NO: 19, a CDR2 of amino acid sequence SEQ ID NO: 20, and a CDR3 of amino acid sequence SEQ ID NO: 21.



Pros and Cons of Patents

Intellectual Property



Benefits

- Patent owner can make, use, or sell their invention (as long as they have FTO)
 - License to commercial partner
 - Manufacture and sell product yourself
- Prevent others from practicing the invention
 - Sanctioned “monopoly” for a set number of years
- Prevent competition from patenting obvious variations of your invention



Drawbacks

- Enforceability
- Limited term of patent protection
- Design around claims
- Expense
- Limited to countries where a patent is filed and issued

What is Patentable?





Intellectual Property

What can be patented?





- "Anything under the sun that is made by man"
 - Diamond v. Chakrabarty, USPQ 193, 196 (US 1980)
- Inventions that can be patented:
 - Machines (e.g., imaging modalities)
 - Devices (e.g., probes)
 - Articles of manufacture (e.g., adhesive bandages)
 - Compositions of matter (e.g., pharmaceuticals)
 - Processes (e.g., methods of treating cancer)



What can't be patented?

-  Abstract mental ideas and mental processes
-  Physical phenomena
-  Scientific principle or Law of nature ($E=mc^2$ or law of gravity)
-  Something found in nature
- Examples:
 - A new mineral discovered in the earth or a new plant found in the wild
 - Many diagnostic assays and methods of detecting biomarkers (especially if a known biomarker)
 - Some methods of treating a patient using levels of known biomarker/metabolite (case specific)

Patentability requirements

-  **Novel:** not previously known or used by others
-  **Non-obvious:** is it obvious to Person of Ordinary Skill In The Art (POSITA)?
-  **Utility:** an invention must provide a benefit and is capable of use; patent eligible subject matter
-  **Written Description:**
 - Must describe the invention (definiteness)
 - Enable a POSITA to make and use the invention (enablement)
 - Must particularly point out and distinctly claim the invention (possession)

Patentability requirements

- 💡 Novel: not previously known or used by others
 - New to everyone – not just the inventor.
 - In most of the world, disclosing an invention before filing a patent application causes a loss of patent rights.
 - IMPORTANT: However, in the U.S., we have a one year “grace period” after the first public use or publication.
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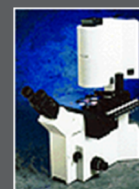
📝 Written Description:

- Must describe the invention (definiteness)
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Types of patents

💡 Utility

- Most common type granted
- Process/method (e.g., synthesizing a new chemical)
- Machine (e.g., camera)
- Article of manufacture (e.g., gloves)
- Composition of matter (e.g., adhesive)



🎨 Design

- Ornamental design of an article of manufacture (e.g., shampoo bottle, iPhone)
- Can also be protected by a utility patent if it meets certain requirements



🌱 Plant

- Distinct and new variety of asexually propagated plant (e.g., hybrid rose plant with a novel color)
- Can also be protected by a utility patent if it meets certain requirements

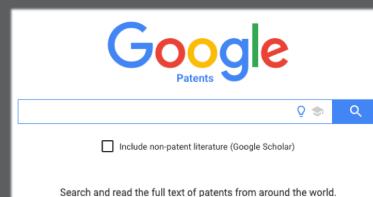


To Patent or Not to Patent

Intellectual Property

To Patent or Not To Patent

- **Search** – databases for “prior art”
(e.g., Google Patents, SciFinder, PubMed)
 - Prior Art can be found anywhere—
published works; presented information;
prototype designs
 - Not a public disclosure if presented or
discussed confidentially (e.g., under a CDA)



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- What is considered “Prior Art”?
 - Patent Applications
 - Abstracts and posters
 - Journal articles (even titles)
 - Talks & slide shows
 - Internet postings
 - Offers to license or sell
 - Commercial beta-testing
 - Free/promotional prototypes
 - Even graduate theses can qualify

To Patent or Not To Patent

- Searching the databases for prior art helps you refine your invention's description
- If prior art searches yield nothing, this field of technology might be wide open



To Patent or Not To Patent

- Evaluate
 - Patentability
 - Is there any prior art? Is this invention new, useful, non-obvious, and enabled?
 - Marketability/Commercial Interest
 - What product could come from this patent?
 - Is there a market for the product?



When to File for a Patent

Intellectual Property

When to file For a Patent

- ***Before*** public disclosure

- Ideally, when the patent application can be properly written to enable the invention (enabling for reduction to practice).



When to file For a Patent

- Generally, waiting to file a patent application until as close to product launch or public disclosure as possible will ensure that the application will be “enabled” enough to provide a priority date.
- Waiting to file “extends” patent term.
 - Typically, applicants file when there is a planned disclosure or when they become aware of possible competitive activity.



How to File for a Patent

- Disclosure to Patent Practitioner or Technology Transfer Office (patentable? marketable?)
 - Describe invention and what it accomplishes, advances over the prior art
 - Avoid public disclosure, sale, or use
- File a U.S. Provisional patent application (or a provisional in a foreign country)
 - “Patent pending”
 - Preserves international rights and “priority” date
 - Does not count against patent term
 - “Secret”: not published or examined
 - Gives you 1 year to decide whether or not to pursue patent protection



How to File for a Patent

- File an **international** (PCT; not examined), **foreign** (individual countries; examined), and/or **U.S. Non-provisional** (examined)
 - PCT-Patent Cooperation Treaty
 - Option for protection in up to 152 countries
- PCT followed by national stage applications (examined)
 - Required to file nationally (generally) 30 months from initial filing

Prosecuting a Patent

Intellectual Property

Prosecution (examination) of a US Patent Application

- U.S. Non-Provisional (from a U.S. Provisional) or U.S. National Stage (from a PCT Application) is filed
- Examination (1-3 years after filing) (negotiation between your patent counsel and an Examiner at the USPTO)
 - A first Office Action is issued from the USPTO
 - Expect multiple rejections-anticipation (102), obviousness (103), 112 (indefiniteness, enablement, possession, subject matter eligibility)
 - Your Patent Practitioner will draft and submit a Response to the Office Action (optionally interview the Examiner)
 - Rebutting rejections
 - Claim amendments
 - Affidavit from Inventors supporting arguments



Prosecution Continued

- A Notice of Allowance (NOA) **or** a “Final” Office Action (FOA) is issued from USPTO
- Notice of Allowance
 - If ROA was persuasive and overcame all rejections, a **NOA** is issued
 - Next Steps:
 - Owner pays issue fee and the application issues into a patent (i.e., a patent is “granted”)
 - Decide NOW if filing continuing applications claiming priority to provisional

Prosecution Continued

- Final Office Action issued from the USPTO
 - Withdraw some or all previous rejections, Make new rejections, or Maintain rejections
 - Next Steps (*not exhaustive*):
 - Request Interview (Examiner not obligated to grant interview after final)
 - File a Response to the Final Office Action (RFOA) no later than 2 months after FOA issued to provoke advisory action (no \$)
 - File RFOA with Request for Continued Examination (RCE) (\$\$)
 - File a RFOA with an After Final Consideration Pilot Program (AFCP) (specific requirements apply) (no \$)
 - File a Continuation Application and abandon the present application (\$\$)
 - File a Notice of Appeal (\$\$\$)

Choosing IP Counsel

Intellectual Property

Choosing IP Counsel

- Registered to practice before the USPTO
- Agents (\$\$) vs. Attorneys (\$\$\$)
 - Patent Attorneys (registered with USPTO, litigation, prosecution)
 - IP attorneys (contracts, licenses, trademarks, copyrights)
 - Patent Agents (registered with USPTO, patent prosecution)
- Ask others and your technology transfer office for recommendations
- Larger Firms (more expensive)
- Boutique Firms (more expensive)
- Individual Practitioners (more risky)



Disclosing the Invention

Intellectual Property

Disclosing the Invention to Technology Transfer Office or **Patent** Practitioner

- Technology Transfer Offices usually have an Invention Disclosure Form
- Title
- Type of Invention
 - Patent-New Process, compositions, device, etc.
 - Material/Research Tools
 - Software/Copyright
- Description of the Intellectual Property (can attach a manuscript, slideshow)
 - Features that make it new and different, the problem this intellectual property solves, advantages over existing technologies, etc.
 - Attach any drafts of manuscripts, abstracts, presentations, drawings, etc. you have at this time

OTM = Office of
Technology Management

OTT = Office of
Technology Transfer

Disclosing the Invention Continued

- Publications and Public Verbal/Oral Presentations (**Past and Future**)
- Are you aware of any publications or patents **relevant (similar)** to this Intellectual Property?
- **Describe any work** you may have done to demonstrate that the Intellectual Property works, or is useful, or has the properties, features or benefits that are desirable

Disclosing the Invention Continued

- This Intellectual Property is or could be **commercially useful** for the following reason...
- **List any companies** you know of who may be interested in licensing this Intellectual Property
- Was any aspect of the Intellectual Property made possible, in whole or in part, by the use of Materials, Software or Data **supplied by another party**?

Disclosing the Invention Continued

- Research support for this Intellectual Property
 - Federal funds
 - Non-Profit Organizations / Foundations
 - Industrial Sponsors
 - University Departmental Funds
 - Other Funding Sources
- List all persons who are believed to have made significant contributions to the intellectual property including WU personnel as well as any other contributors at other institutions.
 - Detail contributions: i.e., conceived of the invention, ran experiments to show idea works, etc.
- Determination of inventorship is a legal matter and will be determined by legal counsel (who conceived of the invention?)

Inventorship & Ownership

Intellectual Property

Invention and The Law of Inventorship

- “The Invention” refers to subject matter **claimed** in the patent application
 - As such, inventorship can change during prosecution, as claims are amended, abandoned, or deferred for prosecution in child applications.
 - Inventors do not need to contribute to every patent claim.
 - In fact, a contribution to only one claim suffices.

Ownership

- Who owns the Intellectual Property?
 - IP Policy
 - Employment contract
 - Obligation to assign
- If institutional funds or resources are used, the IP generally belongs to the institution
- Institution has the option of waiving the rights back to you if they do not wish to pursue
- A percentage of revenue can be given to a creator (e.g., 35% at WU)



Cost of Patenting

Intellectual Property

Cost of obtaining a patent

- Provisional Patent Application (up to ~\$10K or more)
- International PCT Application (~\$10-20K)
 - National Phase fees (~\$1-5K per country plus translations)
 - Can file U.S. National (instead of below U.S. Non-Provisional Patent Application)
- U.S. Non-Provisional Patent Application (~\$8-15K)
- Examination
 - About 2 years waiting; 1-4 more years of Actions & Responses
 - Response (~\$2-6K per)
 - Appeal (~\$6-15K)
- Issuance and maintenance fees in each country (~\$4-14K per country)



Copyrights

Intellectual Property

Copyrights



Definition:

Protects “original works of authorship” (like books, music, plays, sculpture, or films)

- NOT raw facts or data
- NOT functional aspects of artistic objects
- NOT slogans, titles, or monikers

Copyright exists the instant the author’s work is “fixed in any tangible medium of expression” copyright does NOT depend on whether it was registered with U.S. Copyright Office

Ownership in Employment Context:

- If a work is created by an author-employee within the scope of the employee’s regular duties, or if a work is created under a contract that expressly states the work is being made as a “work for hire,” the employer owns it

Copyrights



Owner's Rights: A copyright includes the exclusive right

- To **duplicate**, including into a different medium
- To prepare **derivative works** (e.g., translations, edited versions, compilations, etc.)
- To **distribute** copies to the public (not just sale)
- In the case of literary, musical, dramatic, or similar works, to **perform** the work publicly
- In the case of literary, visual, dramatic, or similar works, to **display** the work publicly
- To **import** copies made outside the U.S.

“Fair Use” Doctrine

Acts which might technically infringe can be lawful -- if the purpose is to criticize, comment, report news, parody, teach, or engage in research.

Software: Copyright or Patent? ©

- The organization of commands and the manner of processing data -- the “architecture” represents a “method” or “process”; **this can be patented**
- The particular codes typed into the computer, whether in human-readable form or computer-readable form, constitutes a “work of authorship”; **this is protected by copyright**
- When a new device requires software to operate (say, an improved fuel injector in a car), both the device and software are components of a single invention

Trade Secrets

Intellectual Property

Trade Secrets

Definition:

- “Trade secret” is defined in over fifty ways (each state, DC, territory has its own twist)
- Generally, a trade secret:
 - Has **commercial value** and is **secret in fact** (at least your competition doesn’t know about it).
 - The owner must **take reasonable steps** to keep it secret.

Scope:

- Duration of a trade secret: as long as it stays secret in fact (don’t file a patent application!)
- Protection is state-specific: the owner may have to sue in each state where there is a violation

Trademarks

Intellectual Property

Trademarks

TM ®

Definition:

A trademark is any word, phrase, logo, symbol, shape, number, letter(s), color, sound, scent, or other device (or combination of these) that **serves to identify the source** of specific goods or services, **and to distinguish them** from similar goods or services sold by others.



A trademark may “identify the source” even if the mark does not identify either *the manufacturer or the merchant*, provided the mark serves to distinguish whoever put the article into the market from the sources of similar goods in the same market.



Trademarks

TM ®

Philosophical Basis:

1. To protect the consumer's ability to identify the source of particular goods/services
2. Quality assurance/proxy for goodwill
 - a. A recognized trademark encourages a business to maintain a steady level of quality, or risk losing customers
3. To protect the reputation of a *famous* Mark

Four (4) Types:

1. **Trade Marks:** Identifies the source of goods
2. **Service Marks:** Identifies the source of services
3. **Collective Marks:** Identifies the provider as a member of a select group
4. **Certification Marks:** Identifies the source of goods or services as fulfilling criteria of selection or quality

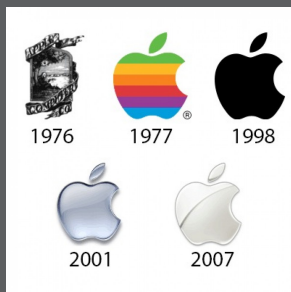


Washington University in St. Louis
SCHOOL OF MEDICINE

E4B Entrepreneurship
for Biomedicine

Trademark Evolution

TM ®



Washington University in St. Louis
SCHOOL OF MEDICINE

E4B Entrepreneurship
for Biomedicine

Further Considerations

Intellectual Property

Other considerations

- IP Ownership
- Freedom to Operate
- Registering a Corporate Name doesn't mean you can use it.
- Patent Validity
- Patent Infringement
- Business model (produce product?, license tech?, or sell?) should drive IP strategy, not vice versa.

Claims Section

- Wording is critical
- You want to be as broad as possible
- Other parts of patent are driven by the scope and wording of these claims
- Explicitly define terms

Background Section

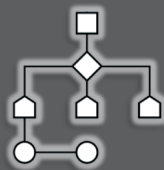
- Brief description of the state of the art in your field
- Challenges posed in the field that may be solved by your invention
- Compact so that no additional information can be used against you

Summary Section

- Brief prose summary of the main points made in the claims
- All parts work together
- Convey background for claims
- End goal is that claims are allowed

Gray Area: Computer Programming

- Algorithms are *abstract mental ideas*, and not eligible for patent protection
- However, if algorithm is termed as machine-related, it may be patentable



NO



MAYBE

Patent Eligibility

Intellectual Property

To Patent or Not To Patent

- Find an expert – *USPTO* registered patent attorney or patent agent
 - Patent agents (prosecution)
 - Write and prosecute patent applications
 - Cannot defend or enforce a patent in court
 - Patent attorneys (prosecution, transaction, litigation)
 - Legal advice, agreements (e.g., CDA/NDA, license, collaboration), enforce patent in court

Invention and The Law of Inventorship

- Under U.S. patent law, “invention” has two aspects:
 - (I) **Conception** is the formation of a definite and permanent idea of the complete and operative invention in the mind of the inventor.
 - (II) **Reduction to practice** (RTP) is the process of showing that the claimed invention works for its purpose.
- An inventor must contribute to the **conception** of the invention.
- An inventor **does not need** to contribute to reduction to practice (RTP).