Intellectual Property

Kathleen Chaffee, Ph.D. Mike McCay, Ph.D. Patent Agents, Registered with the USPTO

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- This material is provided for educational and informational purposes. It is not intended and should not be construed as legal advice.
- This presentation does not necessarily represent the opinions of the organizations with which the speakers are affiliated or standard industry practice.
- •In particular, opinions expressed and issues raised during these presentations do not represent official USPTO or US Government policies or positions, and are presented solely for the purposes of spirited discussion.
- 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
 - o What is a "patent?" Why have patents?
 - o Parts of a patent
 - o Benefits/Drawbacks (Benefits and Limitations of the Patent System for the Innovator and Society)
 - o Criteria for obtaining a patent
 - o Types of patents (US and International Patent Protection)
 - o To patent or not to patent? (Assess the IP Landscape)
 - o When to file for a patent (When to file for IP protection
 - o How to file for a patent (How to File for a Patent and How Patent System Works)
 - o Choosing IP Counsel
 - Costs
 - o Inventorship
 - 2. Copyrights
 - 3. Trade secrets
 - 4. Trademarks

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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)

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Ways to protect IP

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

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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 <u>right to exclude others from making</u>, <u>using</u>, <u>selling</u>, <u>or importing</u> 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)

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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

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Anatomy of a Patent

Intellectual Property

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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

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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.

	Unite Holtzma		tes Patent	(10) Pater (45) Date		US 9,834,596 B2 t: Dec. 5, 2017
(54)	ANTIBOE	ues то т	AU	7,348,157 1	32 3/2008 32 10/2008	Eriksson et al. Ohno et al.
(71)		Washingto (US)	on University, St. Louis, MO	7,446,180 1 7,728,109 1 8,012,936 1	32 11/2008 32 6/2010 32 9/2011	Novak Kikly Sigardsson et al.
(72)	Inventors:	Hong Jiar Marc Dia Najla Kfo	Itzman, St. Louis, MO (US); Ig. St. Louis, MO (US); mond, St. Louis, MO (US); Iry, St. Louis, MO (US); Holmes, St. Louis, MO (US)	8,084,584 8,318,917 8,673,949 8,697,076 8,703,137 8,748,346 8,778,343 8,895,714	32 11/2012 32 3/2014 32 4/2014 32 4/2014 32 6/2014 32 7/2014	Taylor et al. Albright et al. Binder et al. Chain Sigardsson Knyed
(73)		Washingto (US)	on University, St. Louis, MO	8,926,974 8,980,270 8,980,271 9,051,367	32 1/2015	Griswold-Premer et al. Griswold-Premer et al. Griswold-Premer et al.
(*)		patent is o	any disclaimer, the term of this extended or adjusted under 35 (b) by 74 days.	9,161,520 9,351,986 2002/0086009 2002/0182560	32 10/2015 32 5/2016 51 7/2002 51 12/2002	Kontsekova et al. Kunz et al. Ishigure et al. Fong
	Appl. No.:	14/41		2002/0188106 2006/0167227 2007/0134724	A1 12/2002 A1 7/2006	Mandelkow et al. Kontsekova et al.
	PCT Filed: PCT No.:		i, 2013 US2013/049333	2008/0220449 2010/0009388 2010/0284909	AI 9/2008 AI 1/2010	Vasan et al. An et al.
(80)	§ 371 (c)(1 (2) Date:).	31, 2014	2010/0316564 2011/0177109	A1 12/2010 A1* 7/2011	Sigardsson Smith, III et al C07K 14/4711 424/185.1
(87)	PCT Pub. I			2011/0305706 2011/0318358 2012/0087861 2012/0142602	A1 12/2011 A1 4/2012 A1 6/2012	Sigurdsson et al. Nitsch et al. Brady et al.
(65)	Prior Publication Data		2012/0183599 2012/0276009	A1 11/2012	Pfeifer et al. Pfeifer et al. stimmed)	
	US 2015/0	183855 A1	Jul. 2, 2015	FOR		ENT DOCUMENTS
	Related U.S. Application Data		AU 2013205313 AI 5/2013			
(60)	Provisional application No. 61/667,515, filed on Jul. 3, 2012, provisional application No. 61/694,989, filed on Aug. 30, 2012.		CN II	(Cor	11/2008 ntimed) IBLICATIONS	
(51)	Int. Cl. (2006.01) (2006.01) (2006.01) (461K 39/00 (2006.01) (461K 39/00 (2006.01)		Chen 1995 "enhancement and destruction of antibody function by somntic mutation: unequal occurrence is octariolled by V gone combinatorial associations" embe 14(12):2784-2794. 9 Kussic 1994 "single engineered amino acid substitution changes antibody fine specificity". Junusual 15(1):1146-52. 9			
	U.S. Cl. CPC			Vanamunda et al., "Ani-tun antibodies that block tan aggregate sceding in video markedy decrease pathology and improve cogni- tion in vice", Neuros, 2013, pp. 402–114, vol. 80, No. 2. Office Action for Chirene Aeptheation No. 20130045706.3, dueld Doc. 21, 2016. Frest et al., "Prion-like Mechanisms in Neurodegenerative Dis- enses", Nat Rev Neurosci, 2010, pp. 153–159, vol. 11, No. 3. Holtzman et al., "Nerve Goowth Factor Protects the Neurala Bank.		
(58)	Field of Classification Search None See application file for complete search history.		Against Hypoxic- 114-122, vol. 39,	Ischemic Inju No. 1.	ry", Annals of Neurology, 1996, pp.	
(56)	References Cited		Primary Exami	Primary Examiner — Adam M Weidner		
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	5,492,812 A 2/1996 Vooheis 5,601,985 A 2/1997 Trojanovski et al. 6,121,013 A 9/2000 Vinmochelen et al. 6,589,746 Bl 7/2003 Zemlan		(57) ABSTRACT This invention relates to antibodies to tau and methods of use thereof.			
	6,797,478 B1 9/2004 Zemlan et al. 6,900,293 B2 5/2005 Mercken et al. 7,238,788 B2 7/2007 Lee		14	Claims, 98	Drawing Sheets	

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Pros and Cons of Patents

Intellectual Property

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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

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Drawbacks

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

What is Patentable?

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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)

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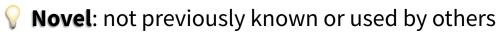
What can't be patented?

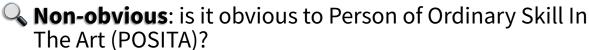
- Abstract mental ideas and mental processes
- Physical phenomena
- Scientific principle or Law of nature (E=mc² or law of gravity)
- Something found in nature
- > Examples:
 - A new mineral discovered in the earth or a new plant found in the wild
 - Many diagnostic assays and methods of detecting biomarkers (especially if a known biomarker)
 - Some methods of treating a patient using levels of known biomarker/metabolite (case specific)

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Patentability requirements





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)

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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.
- 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)
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 - The claimed invention is thought to be "obvious" if a POSITA looking at all of the pertinent prior art references, would find the claimed invention obvious.
- **We use:** Utility: an invention must provide a benefit and is capable of use; patent eligible subject matter
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 - Must describe the invention (definiteness)
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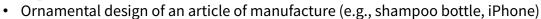
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Types of patents

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)





• Can also be protected by a utility patent if it meets certain requirements



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

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To Patent or Not to Patent

Intellectual Property

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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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E4B Entrepreneurship for Biomedicine

To Patent or Not To Patent

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 - Prior Art can be found anywhere—published works; presented information; prototype
 - Not a public disclosure if presented or discussed confidentially (e.g., under a CDA)
- 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

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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?



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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).



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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 <u>planned</u> <u>disclosure</u> or when they become aware of possible <u>competitive activity</u>.

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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 <u>application</u> (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

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PATENT AND

How to File for a Patent

- File an international (PCT; not examined), foreign (individual countries; examined), and/or U.S. Nonprovisional (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

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Prosecuting a Patent

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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

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Prosecution Continued

- A <u>Notice of Allowance (NOA)</u> or a <u>"Final" Office</u>
 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

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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 (\$\$\$)

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Choosing IP Counsel

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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)

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Disclosing the Invention

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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

OTM = Office of **Technology Management**

OTT = Office of Technology Transfer

- 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

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

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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?

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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 <u>inventorship</u> is a legal matter and will be determined by legal counsel (who conceived of the invention?)

Inventorship & Ownership

Intellectual Property

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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 <u>only one claim</u> 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)

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Cost of Patenting

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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

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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

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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.

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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

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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

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Trademarks

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Trademarks



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. Johnson Johnson

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.

P&G Procter&Gamble

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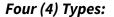
Trademarks



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





- 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



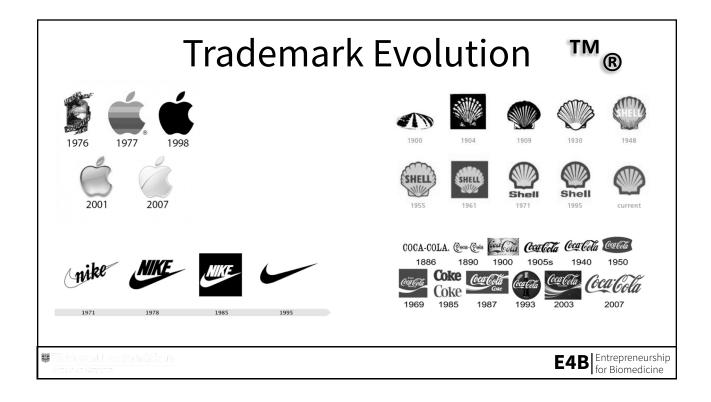






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Further Considerations

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

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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

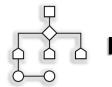
- Brief prose summary of the main points made in the claims
- All parts work together
- Convey background for claims
- End goal is that claims are allowed

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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





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Patent Eligibility

Intellectual Property

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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) <u>Conception</u> 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 <u>conception</u> of the invention.
- An inventor <u>does not need</u> to contribute to reduction to practice (RTP).

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