

## Intellectual Property – Patents

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## Why IP Protection?

- ▶ Protect technology/brand/investment.
- ▶ Obtain financing.
- ▶ Provide an asset to increase the value of a company.
- ▶ Establish barriers to entry.
- ▶ Leverage against lawsuits.
- ▶ Establish licensing revenue.

Prof. Steven S. Saliterman

Salmela, A. *Getting from Idea to IP, Formulating a Global IP Strategy*, Innovation Fellows Presentation, University of Minnesota, Patterson Thuent Pederson, P.A., 2017.

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## Methods...

- ▶ **Patents**
  - Strongest protection.
  - Most expensive and difficult to obtain.
- ▶ **Copyrights**
  - Easiest and least expensive to obtain.
- ▶ **Trade Secrets**
  - Must be kept secret.
  - No protection against independent development.
- ▶ **Trademarks/Domain Names**
  - Protection grows based on fame.



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### IP Comparison Chart...

	PATENT	TRADE SECRET	TRADEMARK	COPYRIGHT
Subject Matter	Devices, apparatus, machines, systems, kits	All things listed under PATENTS, but <u>less strict</u> instead of <u>patenting</u>	Company names and logos, product names	Books, articles, brochures, photos, architectural and artistic designs, software code
Right to Exclude	Making, using, selling, importing	Unfairly acquiring	Using similar mark on similar product	Copying (all or part)
Scope of Protection	Potentially broad, defined by the claims	Typically narrow, limited to the secret	Proportional to the commercial strength of the mark	Typically narrow, limited to the work, fair-use exceptions
Duration of Protection	20 years from the application	Perpetual (until not secret)	Perpetual (until not used or abandoned)	Varies (usually 50+ years)
Cost	Expensive	Inexpensive	Moderately expensive	Inexpensive
Legal Requirements	New, useful & non-obvious	Commercial value & secret	Source indicating & creative	Original work & fixation (on tangible medium)

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### What Does a Patent Do?

- ▶ A patent gives you the **right to exclude others from making, using, selling, importing or patenting your invention** (as defined by claims) for 20 years from the filing date.
  - You can sue a competitor for infringement.
  - You can assign or license in exchange for payment.
- ▶ Just about anything made by a person is patentable.
  - *Abstract ideas* and *laws of nature*, not made by someone, are **not patentable**.

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### What Can be Patented?

- ▶ Any **"new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"**.
- ▶ The **patent applicant need not have actually built or produced a marketable product**, however.



Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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### Usefulness...

- ▶ Must *perform as stated with intended purpose*.
- ▶ Cannot be issued for an *idea, suggestion, law of nature, or physical phenomena*.
- ▶ The patent is a full description and instruction to the public regarding the purpose of the technology and how to build it.

Prof. Steven S. Salterman  
Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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### Novelty...

- ▶ Cannot have been previously invented, have a patent application already filed, or be known to others or otherwise available to the public anywhere in the world.
- ▶ Includes types of disclosures such as "an oral presentation at a scientific meeting, a demonstration at a trade show, a lecture or speech, a statement made on a radio talk show, YouTube™ video, or a website or other online material."

Prof. Steven S. Salterman  
Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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- ▶ If a *grant application* is disclosable (Freedom of Information Act), there may be sufficient information to violate the novelty.
- ▶ There is a *12 month grace period* in the United States (disclosure to patent).
- ▶ May not be patentable if not sufficiently different from existing methods or materials to make it *nonobvious* to someone skilled in the area and viewing the available literature.

Prof. Steven S. Salterman  
Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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### What a Patent Does *Not* Do?

- ▶ Provide a government-enforced monopoly on the invention.
  - Claims must be self-enforced.
- ▶ Protect you from being sued for infringement.
  - May still infringe other's patent.
- ▶ Guarantee
  - May be found invalid or not infringed. Courts interpret what a patent means and juries determine whether there is infringement.

Prof. Steven S. Salterman Salmela, A. *Getting from Idea to IP, Formulating a Global IP Strategy*, Innovation Fellows Presentation, University of Minnesota, Patterson Thuentje Pederson, P.A., 2017.

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### Types of Patent Applications...

- ▶ Non-Provisional
  - 20 year term
  - Published 18 mos. from earliest priority date.
  - Legally enforceable rights defined by the claims.
- ▶ Provisional
  - 1 year from date of filing.
  - Not examined or published.
  - "patent pending" status.
  - Can set priority date for non-provisional application filed within one year.

Prof. Steven S. Salterman Salmela, A. *Getting from Idea to IP, Formulating a Global IP Strategy*, Innovation Fellows Presentation, University of Minnesota, Patterson Thuentje Pederson, P.A., 2017.

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### Leahy-Smith America Invents Act (AIA)

- ▶ September 16, 2011 – effective March 16, 2013.
- ▶ First major legislative overhaul of the U.S. patent system in 60 years.
- ▶ Switching from a "first-to-invent" system to a "*first-inventor-to-file*" (harmonizing with the rest of the world).
- ▶ Grants patents to inventors *who first file* their applications with the U.S. Patent and Trademark Office, rather than *who actually conceived of the invention first*.
- ▶ Encourages inventors to file their patent applications quickly – almost *at the proof-of-concept* or *invention-formation* stage.
- ▶ Inventors can *no longer base their patent rights on proof of originality* of an invention.

Prof. Steven S. Salterman Buntz, B. *What Medtech Entrepreneurs Need to Know about Patent Reform*, Interview with David Dykeman, Medical Device and Diagnostic Industry Qmed January 17, 2012.

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### Consequences...

- ▶ Companies should make sure their patent applications are on file *before* they talk to any third parties or potential investors.
- ▶ Rush to file may lead to weaker patents.
- ▶ May need to file additional *provisional applications* to ensure all aspects of the technology are covered.
- ▶ *Harmonization* simplifies the patent process in other countries.

Prof. Steven S. Saliterman  
Buntz, B. *What Medtech Entrepreneurs Need to Know about Patent Reform*. Interview with David Dykeman. Medical Device and Diagnostic industry Qmed January 17, 2012.

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- ▶ File several *provisional patent applications* to secure priority claims while buying time to more fully develop their technology and applications.
- ▶ Cover the *current technology* as well as *future technology innovations* and *alternative embodiments* to prevent opportunities for competitors to design around their patents.

Prof. Steven S. Saliterman  
Buntz, B. *What Medtech Entrepreneurs Need to Know about Patent Reform*. Interview with David Dykeman. Medical Device and Diagnostic industry Qmed January 17, 2012.

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### Design vs Utility Patents

- ▶ **Design patents** exclude competitors from infringing on *“ornamental”* designs.
  - Aesthetic features – “wow” factor.
  - Single claim referring to a set of drawings.
  - Its “look” should not be dictated by its function.
- ▶ **Utility patents** exclude competitors from infringing subject matter that is *claimed* in numbered sentences at the end of the patent.
  - Innovative physical devices and their mechanical and electrical components make for strong patent claims.

Prof. Steven S. Saliterman  
Kennedy, Linda D. “Medical Device Patents: Design or Utility?”. *Intellectual Property & Technology Law Journal* 27, no. 11 (2015): 12.

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### Protection of Software as a Medical Device

- ▶ Patent protection is difficult to obtain for software.
  - Consider trade secret or copyright (especially of code, GUI other functional icons).
  - Copyright will protect source code.
  - The Supreme Court held in Alice Corp. Pty v. CLS Bank Int'l that *abstract ideas are not patentable*.
  - Does the software improve upon *conventional computing methods* in the medical device industry, *enhance the functioning of a computer itself*, *improve upon its associated medical device hardware*, or *serve as an element in a larger patent-eligible process*?

Olson, M.Y. and C.S. Krummen. *Protection and Enforcement of Software as a Medical Device*. Presentation to IFP August 16, 2017, Minneapolis, MN.  
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- ▶ *Software is patent-eligible if any one of the steps in the process was not well-known, routine, or conventional.*
  - Thus, medical device and diagnostics innovators should achieve patent eligibility by developing new and previously unknown ways of completing steps.
- ▶ Use a *Design Patent* for Graphical User Interface (GUI) and icons.

Olson, M.Y. and C.S. Krummen. *Protection and Enforcement of Software as a Medical Device*. Presentation to IFP August 16, 2017, Minneapolis, MN.  
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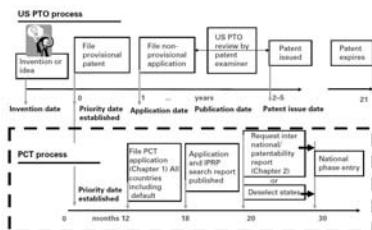
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### Patent Prosecution



Mehta, Shreefal S. *Commercializing Successful Biomedical Technologies - Basic Principles for the Development of Drugs, Diagnostics, and Devices*. Cambridge New York: Cambridge : New York : Cambridge University Press, 2008.  
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### Obtaining a Patent...

- ▶ Expect about 2–3 years from filing to issuance by the USPTO.
- ▶ Average Technology Transfer Office (TTO or *OTC at the Univ. of Minnesota*) cost \$10,000.
- ▶ Three kinds issued:
  - Utility
  - Design
  - Plant (*invents or discovers and asexually reproduces any new or distinct variety of plant.*)

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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- ▶ Check for "prior art."
- ▶ Patents are published **18 months** following filing.
- ▶ Provisional patent application:
  - **Submit a fee (~\$65)** and manuscript upon which the invention is based. Not examined. No claims.
  - **Must be converted into a full patent within a year** (else it is abandoned).
  - **Priority given for any discoveries or claims.**

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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- ▶ Full Patent Application
  - A *written document with a description and claims* regarding the invention (the "specification").
  - A *drawing* of the invention (when necessary);
  - An *oath or declaration* that the applicant believes him or herself to be the original and first inventor.
  - *Payment of application fees* for filing, search, and examination of the patent.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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## Summary

- ▶ Why IP Protection?
- ▶ Types of IP:
  - Copyrights
  - Trademarks/Domain Names
  - Trade Secrets
  - Patents
- ▶ What does a patent do and not do?
- ▶ What can be patented?

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- ▶ Types of patent applications.
- ▶ Leahy-Smith America Invents Act (AIA).
- ▶ Patent Protection of Software as a Medical Device.
- ▶ Patent prosecution - obtaining a patent.
- ▶ Addendum
  - Elements of the Specification
  - Examples of Common Fees

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TABLE 6 Elements of the "Specification"
Title of the invention
Cross-reference to related applications (e.g., provisional applications, applications of continuation)
Statement regarding federally sponsored research or development
Background of the invention—including reference to "similar art" and explaining/emphasizing differences of the new invention, and pointing out improvements.
Brief summary of the invention discussing the claims, advantages, and how the new invention solves previous problems if it is an improvement on existing technology or art
Brief description of the several drawings of the invention if drawings are included in the application
Detailed description of the invention: the most substantial section, consisting of 2 parts: <ul style="list-style-type: none"> <li>◦ A general explanation of the invention and how to practice it, and definition of key terms</li> <li>◦ Specific examples of how to practice the invention. "Prophetic" examples demonstrate how the invention would be practiced, if a working model has not been built. "Working" examples present complete undertakings of the invention.</li> </ul>
Sequence listing if the invention includes nucleic acid or amino acid sequences
Abstract: a brief summary of the entire specification

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