

## Intellectual Property – Copyrights, Trade Secrets and Trademarks

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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.

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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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## Copyright

- ▶ Copyright holders have *exclusive rights to reproduce the work, create derivative works, distribute copies of the work, perform the work publicly, display the work publicly, or perform a sound recording by means of digital audio.*
- ▶ *Does not protect ideas, procedures, processes systems, methods of operation, concepts principles, or discoveries,* “regardless of the medium in which they are described, explained, illustrated or embodied in such work”

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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- ▶ The *mere creation* of a material copy of an original work that falls under the copyright protection act is all that is required to acquire copyright protection.
- ▶ *Registration within 5 years* of a work’s creation can be used as *prima facie evidence of ownership* in a court of law.
- ▶ Furthermore, if a creator chooses at any time to pursue an action against another for *copyright infringement*, they will be required to first register the work with the Copyright Office.

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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**TABLE 3 Works Protectable by Copyright Under U.S. Law**

- Literature
- Musical works, including lyrics
- Drama, including musical accompaniment
- Choreography and pantomime
- Pictorial or graphic work
- Sculpture
- Motion pictures and other audiovisual works
- Sound recordings
- Architectural works
- Certain computer programs



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**TABLE 4 Factors Considered in Determining Whether Unauthorized Use Constitutes Copyright Infringement**

The purpose and nature of the use (commercial versus educational)
The nature of the copyrighted work (fictional or factual, the degree of creativity involved)
The amount and substantiality of the portion of the work that is used
The effect of such use on the marketplace for the original work

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### Copyright & Software Protection

- ▶ Original works of authorship fixed in a tangible medium of expression:
  - Source code.
  - Graphic interface.
  - Protect the structure, sequence and optimize use of the software program.
- ▶ *Does not protect any idea, procedure, process, system, method of operation, concept, principle or discovery.*

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 as a Medical Device (SaMD)...

- ▶ **FDA categories that are regulated:**
  - **App controls a medical device – FDA considers it an accessory.**
    - Example: Software that controls an insulin pump.
  - **App that transforms the mobile device into a regulated device. May include attachment for standard mobile device. App may be labeled for medical specific uses.**
    - Example: App that allows for control of attached transducer that converts a smartphone into a glucose meter.
  - **App that performs patient-specific analysis and provides patient-specific diagnosis or treatment recommendations.**
    - Example: App that calculates dosage or creates a dosage plan for radiation therapy.

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▶ **Examples of SaMD include:**

- Mobile medical applications.
- Software that allows smart phones to view images obtained from an MRI.
- Software that performs image post-processing for detecting cancer.
- Software used to diagnose a condition using a digital camera.

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▶ **FDA Guidance on what qualifies as SaMD:**

- SaMD in software used for one or more medical purpose without being part of a hardware medical device.
- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms.
- "without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose.

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- ▶ Software does not meet the definition of SaMD if its *intended purpose is to drive a hardware medical device*.
- ▶ SaMD may be *used in combination* (e.g., as a module) with other products including medical devices.
- ▶ SaMD may be *interfaced with other medical devices*, including hardware medical devices and other SaMD software, as well as general purpose software.
- ▶ *Mobile apps* that meet the definition above are considered SaMD.

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▶ Under the **21st Century Cures Act**, *certain medical software*, including certain software that supports administrative functions, encourages a healthy lifestyle, serves as electronic patient records, assists in displaying or storing data, or provides limited clinical decision support, is *no longer regulated as a medical device*.

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### Software Copyright Limitation...

- ▶ **Code is often changed.**
  - Update registration with major version changes.
- ▶ **Independent development** is an absolute defense.
- ▶ **Must prove the defendant had access to the copyright protected software.**
- ▶ **Commissioning software.**
  - Representations and warranties
  - Acceptance criteria.
  - Deadlines.
- ▶ **Ownership - "Hereby assign.."**
  - Nine categories of Work Made for Hire (contribution to a collective work, part of a motion picture, translation, supplementary work, compilation, instructional text, test, answer material for a test or an atlas).

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### What Does Copyright Protect for SaMD?

- ▶ If there are many ways to express the idea embodied in a given subroutine, it is protectable.
- ▶ When there is only one way to write something, the *merger doctrine* bars someone from claiming ownership of that feature as a copyright.
- ▶ Copyright law does not confer ownership over any and all ways to implement a function no matter how creative the implementation or specification may be.

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### Patent vs Copyright of Software...

- ▶ Obtaining a patent is more difficult for software.
- ▶ Copyright lasts the life of author plus 70 years.
- ▶ For works made for hire the term lasts 95 years from the publication of the copyrighted work or 120 years from creation whichever is shorter.
- ▶ Must show infringer had access (opportunity to observe work) to the copyrighted work to assert infringement.
  - Access is not required for patent infringement claim.
- ▶ Illicit copying must be shown to establish the works are substantially similar.
- ▶ If it is possible for a third party to independently develop similar software and not violate the copyright in software.

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### Registering...

- ▶ Required\*:
  - Completed application form.
  - Nonrefundable filing fee \$35 to \$55.
  - Nonreturnable copy or copies of the work being registered.
- ▶ Software\*\*\*:
  - Must deposit first and last 25 pages of source code.
  - Code that is considered a trade secret can be redacted.



\*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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### Trade Secrets

- ▶ Owner of a business chooses not to disclose information, innovations or processes that it develops.
- ▶ Once disclosed for any reason, they are no longer trade secrets.
- ▶ Trade secret law does not apply to information, innovations, or other materials that are readily deducible or obvious.
- ▶ Only recourse of a breach is against the one who disclosed ("morally offensive breach").



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### Trade Secret Protection for Software...

- ▶ Reasonable measures must be taken to protect the secrecy of the code.
- ▶ Use of Non-Disclosure Agreement.
- ▶ License Agreement with appropriate restrictions.
  - No reverse compiling of code.
- ▶ Limited protection.
  - Common ideas/routines can be copied.

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### Trademarks

- ▶ Governed by federal & state law.
- ▶ A trademark is a word, symbol, phrase, color, packaging used to identify a particular manufacturer or seller's products and distinguish them from the products of another (e.g. Nike swoosh).



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- ▶ A mark must be distinctive -- that is, it must be capable of identifying the source of a particular good. The courts group marks into four categories, based on the relationship between the mark and the underlying product:
  - Arbitrary or fanciful e.g. Nike swoosh, McDonald arches,
  - Suggestive - e.g. Coppertone,
  - Descriptive - requires time to obtain secondary meaning - e.g. "Holiday Inn"),
  - **Generic - no trademark protection - e.g. "Apple" by an apple seller - unfair competitive advantage.**

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- ▶ Registration gives a party the right to use the mark nationwide.
- ▶ Enables a party to bring an infringement suit in federal court.
- ▶ After five years, become "incontestable."
- ▶ Rights to a trademark can be acquired in one of two ways:
  - By being the first to use the mark in commerce;
  - By being the first to register the mark with the U.S. Patent and Trademark Office.

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## Summary

- ▶ Why IP protection?
- ▶ Copyright
- ▶ Copyright and software protection
  - Software as a medical device.
  - Patent vs copyright.
  - Registering a copyright.
- ▶ Trade secrets
  - Trade secret protection of software.
- ▶ Trademarks
- ▶ Addendum: Characteristics of Patents/Copyright/Trade Secrets

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	Patents	Trade Secrets	Copyrights
Registration and protection of IP rights	Required to protect IP rights	Not required; protection is depending on owner's ability to keep a secret	Not required; the natural existence of the item is proof enough of copyright
Owner's recourse for infringement	Can take action to prevent marketing of the invention	Can take action against the entity that disclosed the secret, but cannot prevent others from using it	Can take action against the user after registering copyright
"Fair use" exceptions	Not allowed	N/A	Allowed for limited specified uses without the author's permission. Examples include use to criticize the original work, report the news, to teach, for scholarship, for research, and for other uses that might meet exceptions
Eligible inventions	New process, machine, manufacture, or composition of matter, or new and useful improvement thereof	Information and processes that are kept confidential by the owner and that give the business a competitive edge in the marketplace	Creative expressions including fiction, nonfiction, music, paintings, choreography, architecture, certain computer software
Requirements	Must be novel, useful, and non-obvious	Must be kept confidential by the owner and/or their employees	Must be set down in some tangible medium of expression
Exclusions	Cannot patent laws of nature, physical phenomena, or other abstract concepts, or inventions solely for the utilization of nuclear material or atomic energy in an atomic weapon		Cannot copyright ideas, procedures, processes, methods of operation, concepts, principles, or discoveries
Duration of protection	Generally 20 yrs from time of registration; may be extended in certain circumstances	Until secret is disclosed	Generally 70 yrs beyond the life of the creator; for works copyrighted before 1978, the total term is 95 yrs

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