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.

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.

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".

• 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.

<table>
<thead>
<tr>
<th>TABLE 3: Works Protectable by Copyright Under U.S. Law</th>
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<tbody>
<tr>
<td>Literature</td>
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<tr>
<td>Musical works, including lyrics</td>
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<tr>
<td>Drama, including musical accompaniment</td>
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<td>Choreography and pantomime</td>
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<tr>
<td>Pictorial or graphic work</td>
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<td>Sculpture</td>
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<td>Motion pictures and other audiovisual works</td>
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<td>Sound recordings</td>
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<tr>
<td>Architectural works</td>
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<tr>
<td>Certain computer programs</td>
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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.

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.

Olson, M.Y. and C.S. Krummen. Protection and Enforcement of Software as a Medical Device. Presentation to IFP August 16, 2017, Minneapolis, MN.
Examples of SaMD include:

- Mobile medical applications.
- Software that allows smartphones 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.

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.

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.
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.

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).

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.
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.

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.

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).

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.

https://cyber.harvard.edu/metaschool/fisher/domain/tm.htm#toc
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.

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