

**Growing Your Company While
Protecting Your Idea:
Intellectual Property for
Emerging Healthcare and Digital
Health Companies**

Basics

- Role of patents—Prevent competition.
- “First inventor to file” system.
- Keep things confidential.
 - Consider NDAs; limited presentations
 - 1 year grace period
- Patent parts
 - Specification v. claims.
- Design versus Utility Patents.
- Provisional v. Non-provisional
- What do I need to put in my patent application?

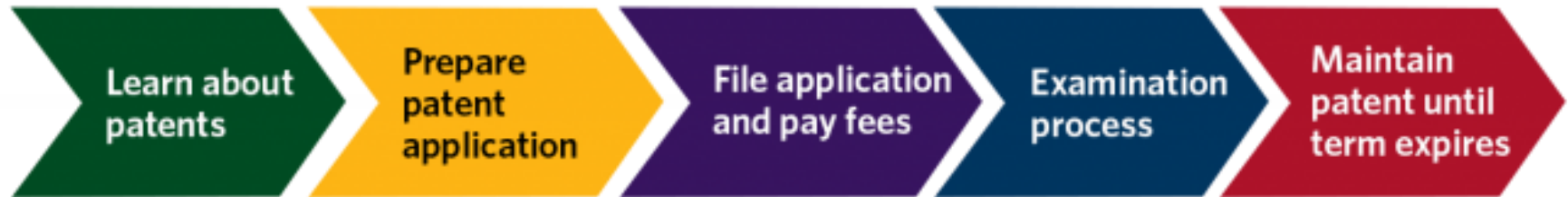
Strategic Considerations

- Patentability search v. Freedom to Operate (“FTO”).
 - Prior Art
- US v. International.
- Cost considerations.
- Tech transfer considerations
 - Who owns it?
 - License v. ownership.
 - Licensing terms.

Healthcare and Digital Health Considerations

- Do I need it?
 - Patent applications become public at a certain point.
- Can I patent AI?
 - Software and code.
 - Algorithm—Method v. product v. process.
- Do I need proof that my product works?
 - Utility=useful.
 - Limitations without it.

- Understanding the patent life cycle



- What is a patent infringement & how to avoid it.

Shhhhh....

TRADE SECRET

Don't tell anyone.

- Examples of trade secrets:
 - ✓ product formulas, recipes
 - ✓ algorithms
 - ✓ data compilations
 - ✓ research data
 - ✓ blueprints, plans
 - ✓ know-how
 - ✓ inventions
 - ✓ business techniques
 - ✓ financial information, profit and loss data
 - ✓ sales and marketing data, strategies
 - ✓ customer lists
 - ✓ inventions

- State law protection:
 - 49 states, DC, PR and VI have adopted versions of the Uniform Trade Secrets Act (UTSA)
 - Applies to: “information, including a formula, pattern, compilation, program, device, method, technique, or process that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.”
 - New York relies on common law
- Federal law—Economic Espionage Act (1996) & Defend Trade Secrets Act (2016)
 - Applies to: “all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing – if (A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.”

- Trade secrets vs. patents

	Trade Secrets	Patents
Governing Law	State law-Uniform Trade Secrets Act (UTSA) adopted by 49 states, DC, PR and US Virgin Islands with variations (but not NY)	Patent Act of 1954 (35 U.S.C. § 101 et seq.)
Source of Authority	Common law, as recognized by U.S. Supreme Court; state statute	U.S. Constitution, art. I, § 8, cl. 8
Jurisdiction	Exclusively state for civil actions, absent diversity jurisdiction; federal for criminal violations (EEA)	Exclusively federal
Regulatory Agency	None	U.S. Patent Office (PTO)
Scope	Information that “derives independent economic value... from not being generally known” and “is the subject of efforts that are reasonable under the circumstances to maintain its secrecy” (USTA)	“any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” (35 U.S.C. § 101)
Key Element	Secrecy/Confidentiality	Invention
How Obtained	Business practices to maintain and protect confidentiality	Application; only effective when issued
Duration	Infinite, as long as valuable and kept secret/confidential	If filed after 6/8/95, for plant and utility patents, 20 years from filing
Protection Against	Misappropriation: obtaining someone’s trade secret through “improper means”; unauthorized disclosure and/or use of another’s secret	Infringement: make, use or sell same or equivalent device or process as the patented invention; also importation of products made by infringing process (ITC)—gives right to exclude others
Cost	No fees; only administrative costs for establishing and enforcing internal procedures	\$30,000-50,000 per country
Time to Get	As long as it takes to establish and maintain internal procedures	1-3 years, on average

- Considering trade secret protection:
 - 1) Can what you are seeking to protect be patented?
 - 2) Must it be disclosed?
 - 3) Could a competitor come up with the same?
 - 4) How long do you need protection?
 - 5) At what stage is the company in developing?

- Protecting your trade secrets:
 - 1) Exercise due diligence when hiring
 - 2) Use warning labels
 - 3) Develop a plan for terminating or restricting access
- Contracts:
 - 1) Employment agreements
 - 2) Agreements with third parties with access to the information
 - 3) Non-disclosure agreements (NDAs)
 - 4) Letters of intent
 - 5) Purchase and sale agreements
- Other measures:
 - 1) Internal policies and procedures
 - 2) Appropriate security
 - 3) Compliance monitoring

- Key difference between copyright and patents and trademarks.
- Scope of copyright coverage.
- Why use copyright notices?
- Why register copyrights in the U.S. Copyright Office?
 - Burden of shifting and presumptions.
 - Time periods for registration
- When the work made for hire rule does not apply and what to do about it.
 - Work for hire rules are different in other countries.
- Why record copyright assignments and licenses?

- Key advantage of registration and recordation is to protect the company when its own employees leave for a competitor.
- What must be established to prove copyright infringement?
 - What are defenses to infringement?
 - Defenses compared to defenses for patent infringement.
 - What are “clean rooms?”

- What does case law require for an effective grant of a copyright license?
- What is the effect of granting a perpetual copyright license?
- What is the effect of prohibiting reverse engineering?
- Open source licenses are still copyright licenses.
 - Permissive licenses vs. “copyleft” licenses.
 - IP risk of some copyleft open source licenses.

- What are Trademarks?
- Scope of trademark protection.
- Key differences between trademark and patents.
- Benefits of trademarks.
- “TM” and “SM” symbol compared to the use of the registered marks[®].
- Classification of trademarks—Strong, Acceptable, and Unacceptable.

- Protecting the trademarks:
 - 1) Evaluate your services offered.
 - 2) Identify product categories.
 - Software and Application (Class 9)
 - Pharmaceutical (Class 5)
 - Medical Equipment (Class 10)
 - Digital Services and SAAS (Class 42)
 - Medical Services (Class 44)
 - Personal and Social Services (Class 45)
 - 3) Apply for trademark registration.
 - 4) Monitor your trademark.

Trademark registration process



- Trademark registration process
- Benefits of registering TMs.
- Importance of clearing and registering key trademarks.

Thank you for your attention!

Questions?

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