

GC'S ROLE IN THE LIFE OF AN INVENTION

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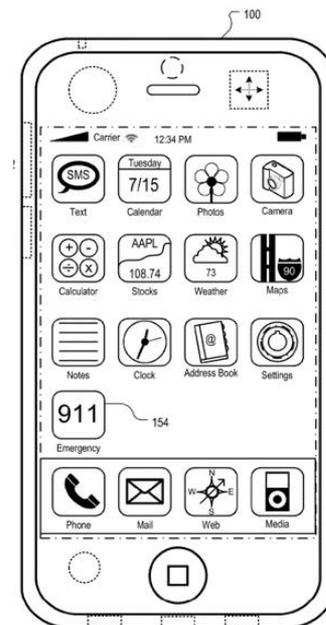
Intellectual Property

- IP protection is important to U.S. investors
- IP protects the ideas or the vision of a company in the absence of brick-and-mortar assets
- Types:
 - Patents
 - Trade secrets
 - Trademarks
 - Copyrights
- Each vary in scope and duration



Patents

- Protects the functional and structural aspects of an invention
- Enforce through litigation
- Scope
 - Determined by claims
- Duration: 20 years from the earliest U.S. priority



What Technologies to Protect

- Identify the technology to be protected
 - Is it relevant to your commercial objective?
 - Does it fit into the overall patent portfolio strategy?
- Defensive patents: patents that exclude others from practicing your technology
 - Try to capture aspects of the technology that provide a clinical or marketing advantage
- Offensive patents: patents that exclude others from practicing their technology
 - Block competition
 - Complementing portfolio of a potential acquirer

Patenting: Core Considerations

- Why:
 - If you're successful, it's because you invented something – protect it
 - Investors want assets
 - Advertisement – quality of patent application shows level of sophistication
- When:
 - Before public disclosure
 - Before clinical trials
 - Before discussions with potential customers (even with nondisclosure agreement (NDA) in place)
- What:
 - Pharmaceuticals, chemical compounds, and biotech
 - Processes for making pharmaceutical and industrial compositions
 - Methods of treating/preventing disease
 - Software applications

Patenting: Additional Considerations

- Timing
 - One year to file in the U.S. directly from a foreign application
 - PCT provides 18 more months before deadline to file in U.S.
 - One year grace period for applicant's own disclosures
- U.S. allows the filing of a provisional application
 - Preserves priority date and strict novelty
 - Can supplement with additional disclosure/data when converting to regular application
- Foreign filing license
 - Must obtain a foreign filing license for any invention made in the U.S.
 - Made in the U.S. – any U.S.-based inventor

Trade Secrets

- Protect core ideas by keeping them secret
- Trade secrets are “protected” by having in place safeguards to protect secrecy
 - Must exercise “reasonable efforts” to maintain secrecy
- Duration: indefinite as long as secret
- Enforceable through litigation to stop disclosure or obtain damages for loss of secret
- Not recommended if technology can be “reverse engineered” – look to patents



Trade Secret vs. Patent Protection

Patent	Trade Secret
<u>Must</u> disclose invention – teach the world about it	<u>Cannot</u> disclose invention
Granted by US Patent & Trademark Office and other countries – expensive	No government filing – just keep secret
Lasts 20 years from filing	Lasts as long as it's a secret – Coca Cola formula over 100 years old; in a bank vault
A legal monopoly that includes protection against someone who independently invents	Reverse-engineering is legal – analysis of a lawfully obtained product to determine how it is made and copy it
Requires novelty, non-obviousness	Broader subject matter – just requires secrecy; may not have little spark of invention (Example: Failed efforts)
The main kind of IP protection for inventions in an academic setting	Generally not useful in academic setting, where policies favor publication and dissemination of knowledge

What is a Trade Secret?

“Trade secret” means information, held by one or more people, without regard to form, including a formula, pattern, business data compilation, program, device, method, technique, design, diagram, drawing, invention, plan, procedure, prototype, or process, that:

- (1) 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
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy

New Jersey Trade Secrets Act (*N.J. Stat. §§56:15-1 through 56:15-9 (2012)*)

The Basics

- Anything can be a trade secret
 - Formulas
 - Processes
 - Methods of doing business
 - Abstract ideas
- It has to be secret
 - Limit access and dissemination
 - Use and enforce NDAs
 - Follow appropriate employment practices
 - Offensive
 - Defensive
- Trade secret protection does not protect you from others figuring out the information on their own
- Trade secret protections are about the process as much as the idea

Examples of Trade Secrets

- Business methods
- Source (and, in some cases, object) code
- Client or customer lists
- Strategic plans
- Marketing plans
- Pricing strategies
- Technical information
- Records of original research
- Laboratory notebooks
- Internal Reports
- Manufacturing processes and recipes
- Manufacturing Formulas
- Risk Assessments
- Standard Operating Procedures
- Information contained in proprietary hardware or software deployed on site, or discernible from observing activities on site

Copyrights

- Copyrights protect original works of authorship
 - Software can be copyrighted
- Duration: life of author plus 70 years
- Federal only
- Enforced through litigation, but must be registered with U.S. Copyright Office to be enforced

Why Conduct a Freedom to Operate Analysis

- To find out potential road block to make R&D or investment decision
- To design around and deal with the patent holder
- To help you in negotiating a licensee
- To counter willful infringement attack in the future in the U.S.
- To minimize the risk of losing a patent infringement law suit in other jurisdictions (*e.g.*, Germany and UK) where the losing party pays courts costs and a portion of prevailing party's legal fees

Typical Process for FTO Analysis

- Design strategy based on the key elements of the products and processes to be launched
- Broad initial search for patents within the target jurisdiction for the relevant patent terms
 - Computerized key word search v. hand search
- Usually, the search hits can be narrowed substantially by reviewing the claims alone

Typical Process for FTO Analysis, cont'd.

- Further analyze the specification and prosecution history of the potentially relevant patents
- If necessary, look for prosecution history estoppel, or prior art, to limit the doctrine of equivalents application
- If any relevant patent is identified, need to decide to license, design around, and/or invalidate the identified patent

Preemptive Strategies

- Are the third-party patents invalid?
 - Consider obtaining an invalidity opinion
 - Consider challenging the patent in the patent office or in the court
- Are the blocking patents available for acquisition or licensing?
 - Anything in your own patent portfolio that can be offered for cross-licensing?

Additional Benefit of FTO Analyses

- Understand the competitor landscape
- Helps in strategizing the company's patent portfolio
- Identifies third-party rights that may be acquired or licensed

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QUESTIONS?

MATT HAYENGA KAARE LARSON

Matt is the former Head of Intellectual Property for the Surgical Franchise at Alcon, where he oversaw patent prosecution, litigation, licensing, and freedom-to-operate work for Alcon's cataract, vitreoretinal, and surgical glaucoma franchises. Prior to that, Matt spent several years as Alcon's Head of IP Litigation & Patent Strategy, handling the company's Hatch-Waxman/generic drug litigation, among other things. Before joining Alcon, Matt was an attorney with Baker Botts in Dallas, TX, and clerked for Judge Sharon Prost at the U.S. Court of Appeals for the Federal Circuit in Washington, DC.

Kaare leads the Dexcom intellectual property group. Dexcom is a San Diego-based medical device that developed and commercialized a revolutionary continuous glucose monitoring system. The glucose monitoring technology continuously measures the patient's glucose levels in real-time, empowering the patient to take control of their diabetes. Kaare has been with Dexcom for 10 years, during which time Dexcom has experienced rapid growth and has been consistently recognized as one of the top innovation companies in the country. Kaare oversees all aspects of IP, including patent procurement, IP risk mitigation and IP litigation.

ERIC ACKER

Eric has tried more than 50 trials (including more than 47 jury trials) in courtrooms across the country and was inducted into the American College of Trial Lawyers in 2018. Eric's trials have addressed a wide variety of technologies and significant legal issues. Prior to joining Morrison & Foerster in 1999, He spent 10 years as a federal prosecutor in the U.S. Attorney's Offices for the District of Columbia and the Southern District of California. Eric is a litigation partner at Morrison & Foerster.

BRIAN KRAMER

Brian focuses primarily on patent litigation, often defending companies accused of patent infringement. His work spans diverse technology areas, such as pharmaceuticals, medical devices, diagnostic tools, and DNA sequencing techniques. He has also represented makers of ultracapacitors, video compression techniques, and wireless technology. Brian is a litigation partner at Morrison & Foerster.

KAREN POTTER

Karen is a cellular and molecular biologist with a Ph.D from Duke and many years of experience managing and building patent portfolios in the life sciences. Karen focuses on patent preparation, prosecution, and strategic counseling for start-up, emerging, and established life sciences and biotechnology companies. She did her post doc work in San Diego at the La Jolla Institute for Allergy and Immunology, Department of Molecular Immunology. She is a patent partner at Morrison & Foerster.