



The Intellectual Property of Health Care

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Today's Overview

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- Intellectual Property 101
- Intersection of Health Care and IP
 - Health Data
 - Marketing
 - Publicity / Appropriation
 - Anti-Kickback
 - Stark Law / Physician Benefit
 - Websites
- Optimizing Value and Reducing Risks
- Takeaways

My background

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□ Michael Fluhler

- ▣ Partner, Fishman Stewart PLLC
- ▣ Registered Patent Attorney practicing all areas of intellectual property law including prosecution, litigation, due diligence and agreements
- ▣ Specialize in medical, health care, software/data and electro-mechanical technologies
- ▣ Previously General/IP counsel for medical device company and outpatient center
- ▣ Enjoy talking about IP and techy stuff (you're welcome to call with any questions)

Intellectual Property 101

Types

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- Types of IP in Health Care
 - ▣ Trademarks - Names/brands
 - ▣ Trade Secrets - Sensitive information and know how
 - ▣ Utility Patents - Medical devices and methods
 - ▣ Design Patents - Aesthetic items such as Apps/User interfaces
 - ▣ Copyrights - Procedures, publications and messaging

Trademarks (brand)

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- **What:** a mark associated with goods and services
- **Requirements:**
 - ▣ In use
 - ▣ Distinctive
- **Term:** Forever so long as in use and does not become generic
 - ▣ Can be registered retroactively for federal enforcement

Trade Secrets (secret + valuable)

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- **What:** a formula, pattern, compilation, program, device, method, technique, or process
- **Requirements:**
 - ▣ Does not require any filings, but requires
 - reasonable efforts to maintain secrecy, and
 - derives independent economic value from not being generally known or readily ascertainable by others
- **Term:** Forever until publicly disclosed

Copyrights (authorship)

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- **What:** author's original expression that is fixed in a tangible medium
- **Requirements:** must be fixed in tangible medium, e.g., artwork, sculptures, musical scores, software code, etc.
- **Term:**
 - ▣ If author, life plus 70 years
 - ▣ If work for hire, the earlier of 95 from publication or 120 years from creation
- Can be registered retroactively for federal enforcement

Utility Patents (structures/functions)

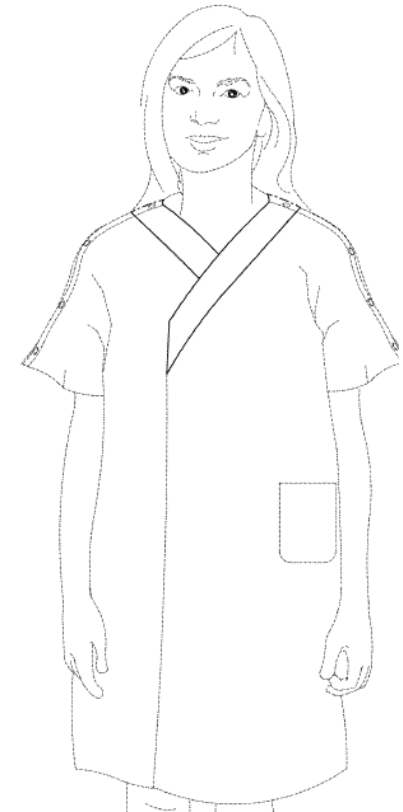
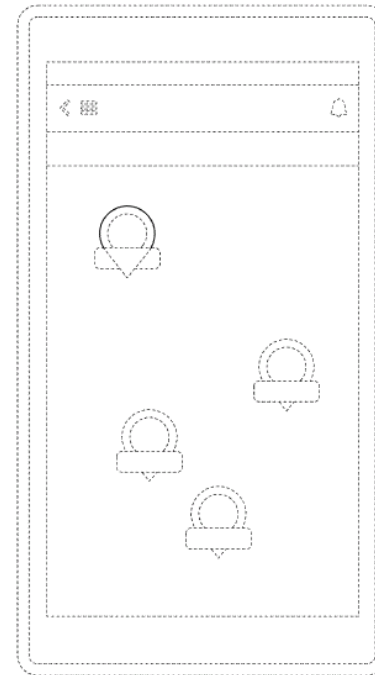
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- **What:** A **monopoly** to **exclude** *others* from making, using, selling, offering for sale and importing into US the patented invention.
- **Types:**
 - ▣ Utility: any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof
 - **Term** - 20 years from filing
 - ▣ Provisional: placeholder that must be “converted” into non-provisional application within term
 - **Term** – 1 year
 - ▣ PCT: international placeholder to file in specific country; must “nationalize” within term
 - **Term** - 30 months

Design Patents (ornamental)

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- **What:** protects the ornamental design
- **Term:** 15 years from filing
- **Examples:**
 - ▣ Graphical User Interface (e.g., [D812,082](#))
 - ▣ Hospital Gown (e.g., [D814,142](#))



IP Provisions/Agreements

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- IP Provisions/Agreements should address:
 - ▣ How is creativity shared and handled?
 - ▣ Who owns what?
 - ▣ What rights are transferred and what is retained?
 - ▣ Who owns joint developments?
 - ▣ Exclusive vs. non-exclusive use of IP?
 - ▣ What can be used by others?
 - ▣ Who bears the risks (e.g., infringement)?

Intersection of Health Care and IP

Health Data

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□ Who owns it?

- Generally, you own your health info, but your health record is owned by whomever creates and stores it
 - HIPAA restricts how your health information can be used and shared, but limited restrictions on de-identified information
- Innovation based on your health info/record
 - Whoever invents/authors it
 - Potentially subject to patents and copyrights
 - Can be assigned and licensed (read the fine print)
 - Others may own and profit from de-identified information

Marketing

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- Service line names and slogans
 - ▣ May infringe state or federal trademark rights
- Use of third-party materials/images in advertising and presentations
 - ▣ Have you obtained a copyright license?
 - ▣ Are there limited “fair uses”?
 - Education, commentary & criticism
 - Parody

Publicity/Appropriation

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- Right of an individual in their own identity, name and likeness
- Varies state by state
 - ▣ All individuals vs. only “celebrities” and “personalities”
- Michigan (common law)
 - ▣ Right of publicity (Identity)
 - Commercial interests of celebrities and their identities
 - Celebrity status considered but not required in all cases
 - Protects “Here’s Johnny” but not use of the name “Johnny Carson”
 - ▣ Tort of appropriation (Name and Likeness)
 - Protects unauthorized use of name or likeness
 - Commercial exploitation required, but profits not required

Anti-Kickback

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□ Giveaways

- ▣ Potential impermissible inducement. OIG Advisory Opinion No. 08-07 (Jun. 27, 2008)

□ Patent licenses

- ▣ If not structured properly, they can be considered impermissible inducement for referrals
 - Must be at fair market value
 - Separate consulting services from patent license
 - Must exclude sales of products used in doctor's own practice or in any hospital where they have privileges

Stark Law / Physician Benefit

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- Remuneration is any payment or other benefit made directly or indirectly, overtly or covertly, in case or in kind (42 U.S.C. § 411.351)
 - ▣ Assisting with prosecution of IP developed or owned by physician
 - ▣ Payments from patent licenses
- Exceptions
 - ▣ Fair Market Value (FMV) – no value associated with referrals
 - ▣ Nonmonetary compensation (NMC) – limit of \$416 aggregate / \$35 occurrence
 - ▣ Medical staff incidental
 - ▣ Personal services - no promotion of counseling or business arrangement
- Avoid issues by separating IP licenses/compensation from physician/consulting agreements

Websites

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- Website markings
 - ▣ Mark with patents, copyrights and trademark notices
 - ▣ Supports actual notice to start the clock on past damages from third party infringers
- Digital Millennium Copyright Act
 - ▣ Limits liability of providers of online services for copyright infringement by its users
 - ▣ DMCA notice must be included in terms of use

Optimizing Value and Reducing Risks

Scenario 1: Buy/Sell

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- Buying or selling a hospital/practice
 - ▣ What protects the brand?
 - ▣ What stops someone from copying policies and procedures?
 - ▣ What protects the website and app?
 - ▣ Are there risks of infringing third party IP?
 - ▣ Are the intangibles appropriately valued?

Scenario 2: Physician Relationships

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- A physician has agreements with a hospital, an outpatient center, and a medical device manufacturer
 - ▣ Who owns what is invented at your facility?
 - ▣ Are the hospital and outpatient center excluded from the benefits under any licenses?
 - ▣ Are consulting and license provisions bundled or separate?

Scenario 3: Trade Secrets

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- You are planning on “keeping it a trade secret,” but:
 - ▣ Have you defined what is considered to be “trade secret”?
 - ▣ How are trade secrets handled and maintained?
 - ▣ Are they access controlled?
 - ▣ Can they be copied, printed and/or emailed?
 - ▣ Are new employees aware that they shouldn’t be using trade secrets of prior employer?
 - ▣ Are interviews conducted to remind exiting employees of their continuing obligation to maintain the secrecy of your trade secrets (and not to bring to new employer)?

Scenario 4: Online Portals

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- You are submitting information through an online portal
 - ▣ What are the IP implications of the Terms And Conditions?
 - ▣ Do they own the information you just submitted?
 - ▣ Did you just absorb risks associated with infringing third party IP?

Scenario 5: Joint Developments

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- A competitor calls and asks for a meeting
 - ▣ What is the process for exchanging ideas?
 - ▣ What is the process for handling trade secrets?
 - ▣ Who owns what was jointly discussed?

Scenario 6: Product Reps

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- A product rep sends over new product information and asks for feedback
 - ▣ What is the process for exchanging potentially confidential information?
 - ▣ Are the materials marked with IP notices to put you on actual notice?
 - ▣ Who owns the “feedback”?

Takeaways

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- IP Basics
 - ▣ Trademarks = brands
 - ▣ Copyrights = anything tangible and fixed
 - ▣ Trade secrets = protects anything that is 1) secret and 2) valuable
 - ▣ Utility Patents = protects functional items
 - ▣ Design Patents = protects ornamental items
- Physician referrals and IP benefits don't mix
- Keep the IP issues in mind when buying, selling, transferring or receiving anything

THANK YOU



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Questions?



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