



WILMER CUTLER PICKERING HALE AND DORR LLP

WEBINAR

Rights in AI and Data in Digital Health

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Speakers: Jeff P. Johnson, Kirk J. Nahra and Mark D. Selwyn

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- Participants are in listen-only mode
- Submit questions via the Q&A feature
- Questions will be answered as time permits
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WEBINAR

Speakers



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Introduction and Overview

- Structural Privacy Issues in Digital Health
- Protecting Rights in AI and Data in Digital Health Contracts
- Patents in AI and Digital Health



*Structural Privacy Issues in
Digital Health*



Structural Privacy Issues in Digital Health

- HIPAA has always been a limited scope privacy/security rule
- It applies to healthcare information only where a covered entity is involved.
- Accordingly, there always have been gaps where various entities collect or maintain health care data but are not covered by the HIPAA rules.



The Biggest “next generation” Issue

- What is “outside” of HIPAA is growing
- Web sites gather and distribute healthcare information without the involvement of a covered entity.
- These range from commercial web sites (e.g., Web MD) to patient support groups to the growth of personal health records.



The Biggest “next generation” Issue

- We also have seen a significant expansion of mobile applications directed to healthcare data or offered in connection with health information
- Broad range of digital health products and services are “near” these lines



More “next generation” Issues

- An emerging (and related) issue - bringing “outside” HIPAA information “inside” HIPAA
- CEs are gathering all kinds of data about their patients/customers/insureds from outside the health care system and using it for “health care purposes”



Recent Headlines

When a Health Plan Knows How You Shop.” (New York Times)

- Health plan prediction models using consumer data from data brokers (e.g., income, marital status, number of cars), to predict emergency room use and urgent care.



Recent Developments

SAS Institute Study (2013)

- Television usage patterns, mail order buying habits and investments in stocks and bonds were all variables with predictive power to understand patient risks for particular health outcomes.



Structural Reminder

Why does this matter?

- HIPAA doesn't cover all health information – only health information that has a defined connection to a “covered entity” (typically a health care provider or health insurer/health plan)
- Think wearables/mobile apps
- Typically no covered entity involved
- Lots of individual health information
- No HIPAA coverage



Structural Reminder

Now think that wearable/mobile app partners with a big health insurer.

- Under the partnership, the app provides rewards, including an option to earn a free device, to members who engage in healthy behaviors like getting regular exercise and more hours of sleep. The new app – co-branded with the app and the health insurer - also provides members who sign up with nudges, such as to get an annual flu shot or take their medication on time.



Why Does This Matter

- Your obligations, rights and opportunities depend on what you are doing, for whom, and in partnership with whom
- Under HIPAA you could be a health care provider (some of which are not even covered by HIPAA because of their billing process)
- Under HIPAA you could be a business associate – meaning a service provider to a “covered entity” – a hospital or health insurer



Why Does This Matter

- Under HIPAA you could be nothing (which frees you up somewhat, but may create tensions with HIPAA-regulated entities)
- But you still have to worry about the Federal Trade Commission (which regulates “unfair and deceptive” trade practices)
- And the state health care privacy laws (e.g., broad California and Texas laws)
- And the CCPA (overall consumer privacy including “unregulated” health care)



Why Does This Matter

- You have to figure out what rules apply to your activity
- You need to think about what rights you “get” under these rules
- You need to think about what rights you can seek under these rules
- You need to think about what rights you can’t have under these rules (and how to address this problem)



Why Does This Matter

- De-identification of data is an option in most situations (HIPAA regulates very extensively, other laws provide easier opportunities)
- Each law provides some contracting opportunities
- Think about your data sources, your sharing for your own business activities, and what else you might want to do with your data



Why Does This Matter

- You will need to think about data security
- You will need to think about compliance policies and procedures
- You will need to think about a consumer facing privacy policy
- You will need to think about your user’s “individual rights” and how you will address them



Why Does This Matter

- You will need to think about big data and artificial intelligence implications – your opportunities and obligations in this area will be driven by where you fit into the legal structure (and by your contracts)
- Be aware of the ongoing debate about the risks and benefits of big data



*Protecting Rights in AI and
Data in Digital Health
Contracts*



Unique Characteristics of Digital Health Deals

- Intersection of Data, Technology and Life Sciences
 - Software/Platform/App/Service versus drugs/clinical treatment
 - Different business models
- Regulatory Considerations
 - arising from Data source/type
 - arising from use of resulting Platform/App and/or drug products/clinical treatment
 - Regulatory Approval process and disclosures
- Use of Data to train AI
- Resulting IP: Allocation of rights in Patents or Know-How/Trade Secret
- Counterparties: Dr, patient, AI developer, pharma co, medical device co, consumer



Types of Digital Health Contracts

- Confidentiality Agreements
- Data Sharing/License Agreements
- Pilot Agreements
- R&D Agreements
- Collaboration Agreements
- Distribution/Reseller Agreements
- Clinical Trial Agreements
- Companion Diagnostics Agreements
- Term Sheets



Key Data Concerns

- Supplier rights in data
 - Provenance, Permissions, Compliance with Law/Regulation
- Confidentiality
 - Exceptions, Suggestions, AI/machine learning, Residuals
 - Can you return all Confidential Information?
- Developed Data/Clinical Data
- Derived Data
 - Aggregation
 - AI/machine learning
- Scope of Permitted Use
 - Collaboration/Project; Train Platform/App/Software; Commercial Use; Publication



General Allocation of IP Rights

- Background or Pre-existing IP
- Individually Developed IP
- Joint IP
- IP Developed based in part on the other Party's data
- Deliverables/Results
- Specific Allocations
- Suggestions



Who Will Own the Key Resulting IP

- Improvements to the Platform
 - AI learning
 - From Use of Data
 - Algorithms
 - Models
- Improvements to the Drug/Medical Device
- Aggregated Data
- Deliverables/Results



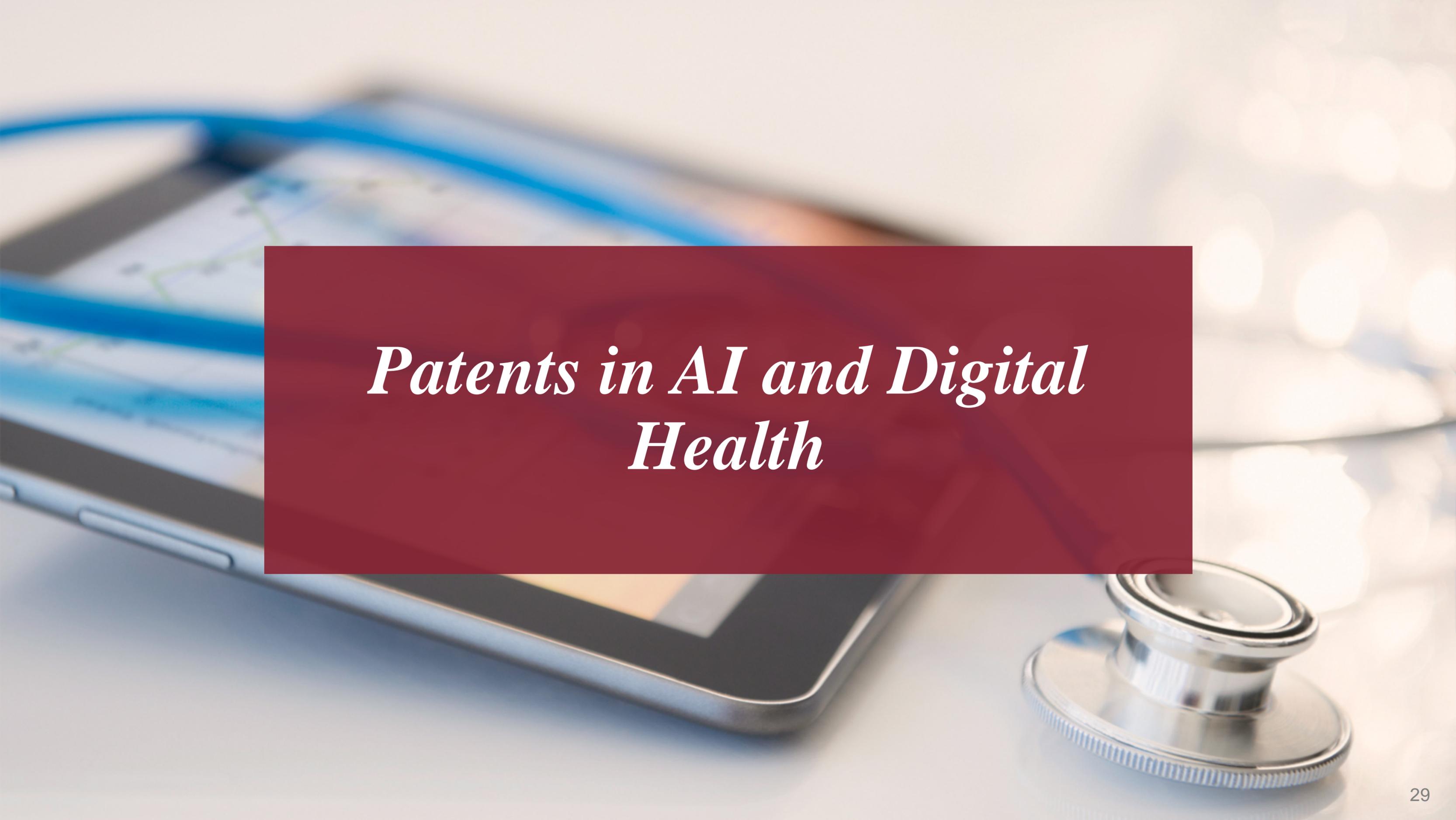
What Licenses Do You Need To The Other Party's Data/IP?

- What is Licensed?
 - Data
 - Deliverables/Results
 - Background/Developed IP
- Scope of Use
 - Project
 - To make general Platform Improvements
 - To make Drug/Device Improvements
- What happens if the license is terminated?
- What terms apply?
 - Royalties; Reporting; Field; Territory; Assignability



What IP Protections Will Apply

- If Patent,
 - Who owns; who controls prosecution and enforcement
 - What is patentable? Discussed further by Mark Selwyn
- If Trade Secret (algorithms, methodologies, processes, source code, models, etc.)
 - What will be required to be disclosed in any regulatory filing?
 - Requirement to disclose to the other party?
 - Confidentiality of Results/Deliverables?
- Copyright and Trademark
- What terms apply?
 - Royalties; Reporting; Field; Territory; Control



Patents in AI and Digital Health



AI is Raising Difficult Questions For Patent Law

- Can a computer take an inventive step?
- If so, what happens when a computer, rather than a person, takes the inventive step and creates patentable subject matter?
- Should computers be considered inventors?



AI is Raising Difficult Questions For Patent Law

- Do patent applicants need to disclose to the Patent Office the role of computers in their claimed inventions?
- What would be the impact on innovation if computers could be inventors under the patent laws?
- What would be the impact on innovation if computers could **not** be inventors under the patent laws?



April 18, 2018 Hearing of the Committee on the Judiciary

Sen. Harris: So, I'm curious. E equals MC². Would that have received any patent protection?

Dir. Iancu: Well, probably not

. . . .

Sen. Harris: Are algorithms mathematical representations of law[s] of nature?

. . . .

Dir. Iancu: So, this is one place where I believe courts have gone off the initial intent. There are human made algorithms . . . that are the result of human ingenuity that are not set from time immemorial and that are not absolutes. They depend on human choices. Those are very different from "E equals MC²" . . . [and] the Pythagorean Theorem, for example.



August 27, 2019 PTO Request for Comments on Patenting AI Inventions

USPTO: “Because execution of AI invariably requires some form of computer implementation, many of the patentability issues relating to computer-implemented inventions (e.g., software) are germane to discussions of AI inventions.”

Examples of questions:

- What are the different ways that a natural person can contribute to conception of an AI invention and be eligible to be a named inventor?
- Do current patent laws and regulations regarding inventorship need to be revised to take into account inventions where an entity or entities other than a natural person contributed to the conception of an invention?



August 27, 2019 PTO Request for Comments on Patenting AI Inventions

Examples of questions:

- Should a company that trains the artificial intelligence process that creates the invention be able to be an owner?
- How can patent applications for AI best comply with the enablement requirement, particularly given the degree of unpredictability of certain AI systems?
- Are there any new forms of intellectual property protections that are needed for AI inventions, such as data protection?



What Is The State Of The Law Regarding Computer Inventors?

- The US Patent Office has never expressly addressed the concept of computer inventorship.
- In contrast, the US Copyright Office has issued guidance on the issue of non-human authorship. The Office will not register works produced by, inter alia, computers without human inventorship.
 - “[T]he Office will not register works produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or inventorship from a human author.” *Compendium of U.S. Copyright Office Practices* § 313.2



US Patent Law

The law is not currently structured to allow computers to be inventors.

- 35 U.S.C. § 100(f): Named inventors must be “individuals.”
 - “The term ‘inventor’ means the individual ... who invented or discovered the subject matter of the invention.”
- 35 U.S.C. § 101: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter ...”
 - “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” *Diamond v. Charkrabarty*, 447 U.S. 303, 309 (1980) (quoting Congressional Reports accompanying 1952 Act).



US Patent Law

- “Conception”: An invention’s “conception” refers to “**formation in the mind**’ ... of a definite and permanent idea.” *University of Utah v. Max Planck*, 734 F.3d 1315, 1323 (Fed. Cir. 2013).
 - “To perform this mental act, inventors must be natural persons...” *Id.*
- Can a computer perform a mental act?
- The reality is that computers today are undoubtedly making creative contributions to claimed inventions.



AI Meets Patent Law Meets Digital Health

Digital health is one of the areas where the issue of patentability of AI is most prominent

- Why?
 - Diagnoses based on large data sets
 - Discovery of new drugs based on AI
 - AI contributions to improved designs for medical equipment and tools



Considerations For Drafting Patent-Eligible Claims In Digital Health Arena

The Supreme Court's decision in *Alice Corporation Pty. Ltd. v. CLS Bank International* (2014):

- “[I]f a patent’s recitation of a computer amounts to a mere instruction to ‘implemen[t]’ an abstract idea ‘on . . . a computer,’ that addition cannot impart patent eligibility.”



Considerations For Drafting Patent-Eligible Claims In Digital Health Arena

- “[C]ollecting information, including when limited to particular content (which does not change its character as information)” is “within the realm of abstract ideas.”
- “[A]nalyzing information by steps people go through in their minds, or by mathematical algorithms, without more,” is “essential mental processes within the abstract-idea category.”
- “[M]erely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis.”
 - *Electric Power Group v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016).



Considerations For Drafting Patent-Eligible Claims In Digital Health Arena

BUT:

- “[S]pecific improvement to the way computers operate” may be patent eligible.
 - *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2017).
- “[I]ncorporation of claimed rules, not the use of the computer, that ‘improved [the] existing technological process’ by allowing the automation of further tasks” may be patent eligible.
 - *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016).



Considerations For Drafting Patent-Eligible Claims In Digital Health Arena

- “Phenomena of nature, though just discovered, . . . are not patentable, as they are the basic tools of scientific and technological work.”
 - *Gottschalk v. Benson*, 409 U.S. 63 (1972).
- “If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”
 - *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).



Considerations For Drafting Patent-Eligible Claims In Digital Health Arena

BUT:

- “[A] process is not unpatentable simply because it contains a law of nature.” “[A]n application of a law of nature . . . to a known structure or process may well be deserving of patent protection.”
 - *Diamond v. Diehr*, 450 U.S. 175 (1981).



Questions

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