



AI in Health Care: IP Ownership and Data Sets

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Agenda

- Introductions
- What is Artificial Intelligence (AI)?
- How AI is Used in Health Care (HC)
- IP Protection
- Data Licenses
- Status of Machine-generated data and algorithms
- Takeaways

Playing Jeopardy with IP

- Arises automatically
- Shifts burden of proof
- 20 years
- Potentially forever
- Confusing similarity
- Substantial similarity

Jeopardy – continued

- Innocent infringement is no defense
- Allows licensing to competitor without permission
- PCT
- Provisional vs. utility vs. design
- Compilation
- Protects software

What is AI?

- AI
- Machine Learning
- Deep Learning
- Strengths and Weakness of Machine Learning
- “Black Box” in Health Care
- Models verify models
- Augmented vs. Artificial Intelligence

Data

- Data vs. Databases
- Data vs. Information
- Role of data in Machine Learning
- Role of doctors in training Machine Learning
- Data as an asset
- Data as a Service
- Data as a Medical Device

Who Owns Data in Health Care?

- Patient
- Hospital
- Researchers
- Hospital bed manufacturers
- Preview: How are ownership issues addressed?

Patent Fundamentals

- Why a patent is not a true monopoly
- Requirements for patentability
- Inventorship
- Prior art
- Importance of dates
- Offensive and defensive patent protection

Patents and AI

- Key issues for AI under U.S. patent law
- What are the important considerations for patent lawyers?
- How to be a good patent client
- The impact of the Alice case
- AI under foreign patent laws
- How worldwide can patent protection for AI be?

AI in the Cloud

- What is the problem?
 - Disparate data sets
- What is a “data fabric?”
- What is “AI in the Cloud”
- IP and commercial considerations

Copyright and Data

- Copyright requirements
- Copyright registrations and recordings
- How databases are protected as a “compilation”
- Derivative data sets

Copyright and Algorithms

- Status of software and algorithms
- Derivative works
- Authorship vs. Inventorship

Trade Secret Protection

- Requirements
- Application to algorithms
- Using in combination with patent and copyright regimes
- When is trade secret protection more advantageous than patent protection?

Non-IP Property Protection

- Personal property
- Contractual treatment

Collaborative Improvements

- Collaborative improvements – between people
- Hidden risks under statutory default rules
- Under-appreciated risks between inventorship and authorship and property right ownership
- How contracts are the solutions?



Machine-Generated Data

- What is machine-generated data?
- What is ownership analysis?



Machine-Generated Algorithms

- Applying patent law
- Applying copyright law
- Apply trade secret law

Limits of IP Regimes and Alternatives

- Personal property
- Inventorship and “originality”
- What contractual solutions take place on lawyers’ desks?



Data Sharing as the Objective

- Ownership vs. Sharing
- Sharing = licensing
- Licensing to allocate rights
- Licensing to control scope of permitted use

Data Sharing Agreements

- Contract for sharing non-public data
 - Imposes limits on use
 - Regulatory protections for institution
- Examples:
 - Clinical trial agreements
 - Sponsored research agreements
 - NIH grants
 - Material transfer agreements
- When used: to transfer clinical, research and other data from human subjects to others

Data Sharing Agreement Issues

- Health Care Institution and third party want to combine data into one database and conduct medical research
- Institution hosts database
- Identify research purposes, permitted uses, follow-up data deposits
- Limit access to persons who deposited data
- Keep all downloaded data confidential until publicly available
- May disclose within laboratory subject to confidentiality

Data Use Agreements

- Data Use Agreement = other party can use Health Care Institution's data for that party's purposes
- Regulatory level: protect Health Care Institution by limiting use to HIPAA-compliant uses
- Institutional level: protect by adopting its own rules and procedures

Data Use Agreements and HIPAA

- HIPAA Privacy Rule and HIPAA Security Rule
- De-identified data = all 18 HIPAA personal information identifiers are removed
- If de-identified pursuant to a proper agreement, then the data is no longer PHI and no longer subject to HIPAA restrictions
- Scope of use depends on authorizing agreements
- Does use require Data Use Agreement?
- Depends on Institution's policies

HIPAA and Limited Data Sets

- Under HIPAA Privacy Rule, a limited set of identifiable data can be shared with covered entities, and researchers who is not a covered entity, for purposes of research, healthcare operations and public health activities without prior patient consent if . . .
- A Data Use Agreement is used
- Most PHI identifiers must be removed but certain ones can remain
 - Address; all dates (birth, dates of medical services); other unique identifier number or code

Takeaways


- Different IP regimes, different scope of protection, different rules for protection
- Machine-generated data and algorithms – uncertainly under IP rules
- Ownership vs. Sharing
- Multiple roles of contracts and licenses

Questions?

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