

# Protecting and Licensing AI Inventions in the Life Sciences

April 22, 2022

# BCLT BY THE NUMBERS

**#1**

IP law program,  
**19 years in a row,**  
by US News



**3**

Faculty Directors ranked among  
top 5 most cited IP scholars



**35**

Practitioner instructors  
teaching advanced and  
technology courses

**50+**

Law & tech courses  
planned for 2021-2022



**9**

BCLT faculty-authored textbooks



**13**

Tech-focused Student  
Groups



**9**

Major conferences  
planned for 2021-2022

**20+**

Other expert-level  
events planned for  
2021-2022

**24**

Years BCLT has been  
collaborating with  
Federal Judicial Center



**800+**

Federal judges  
trained at the BCLT/  
FJC IP seminar

# Instructors



**Hogene L. Choi**

Partner, Patents Group, Morrison & Foerster LLP  
Patent prosecution, transactions, and counseling  
Bioinformatics, medical devices, healthcare, supply chain  
Neural networks, machine learning, computer vision,  
natural language processing, smart sensors



**Andrew Whitehead**

Director and Assistant General Counsel  
Intellectual Property – PHC & Informatics Lead



**Hans Sauer**

Deputy General Counsel, Vice President, IP, BIO



**Bruce Wexler**

Global Co-Chair, IP, Paul Hastings LLP  
Partner in the Litigation Group  
Patent litigation and appeals, PTAB proceedings,  
Arbitrations, Pre-suit and IP Portfolio Counseling

# What you will learn today

- 1. Impact:** use of AI technology can create or affect business opportunities and/or risk
- 2. Breadth:** protecting and licensing AI inventions touches on many areas of legal practice
- 3. Uncertainty:** the speed of technological innovation is outpacing evolution in the legal system.

# How we will get there

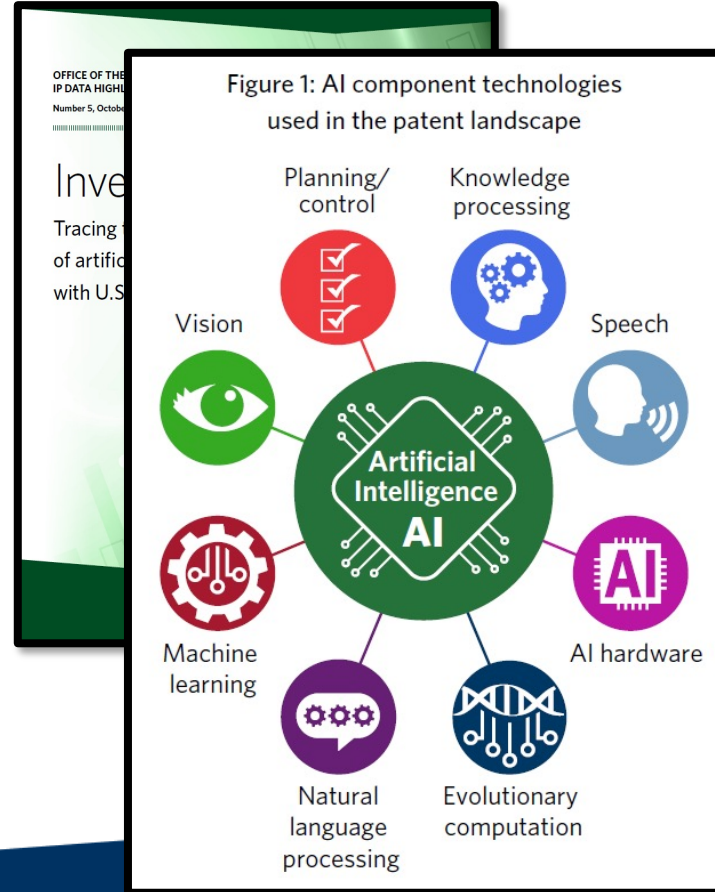
- AI paradigms
- Life science paradigms
- AI protection strategies
- Patent prosecution considerations
- Litigation considerations
- Licensing/transactions
- AI policy
- Upcoming legal developments

# AI Paradigms

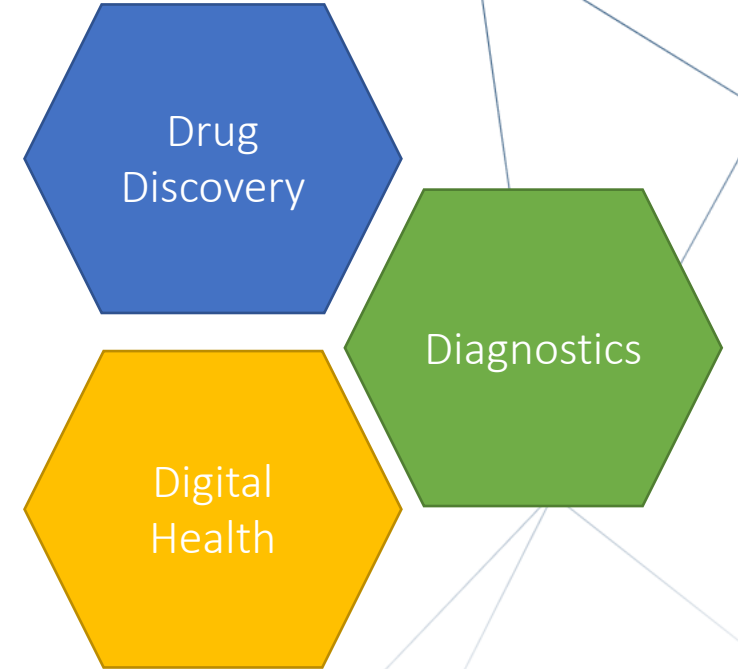
## Infrastructure



## Methods



## Applications

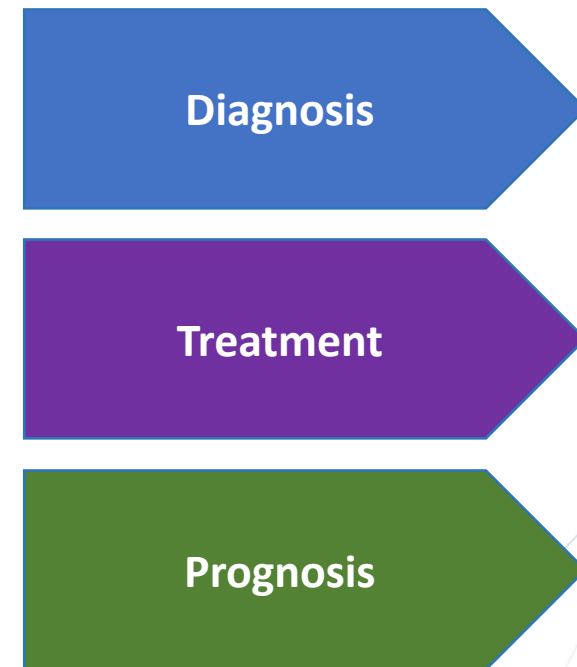
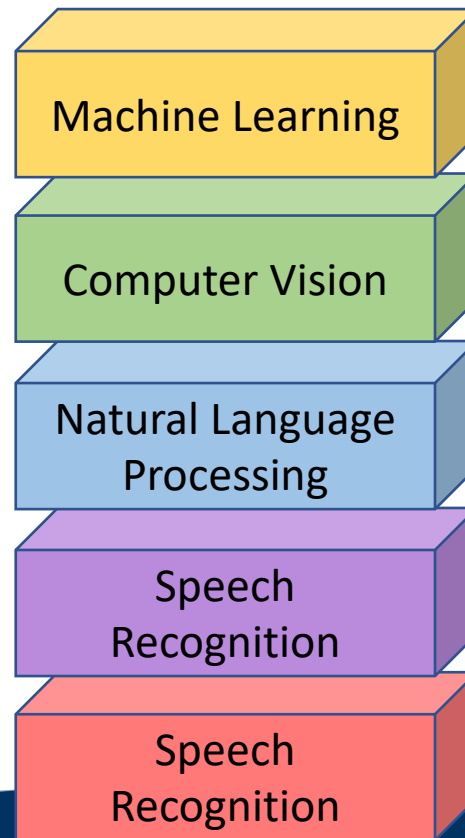
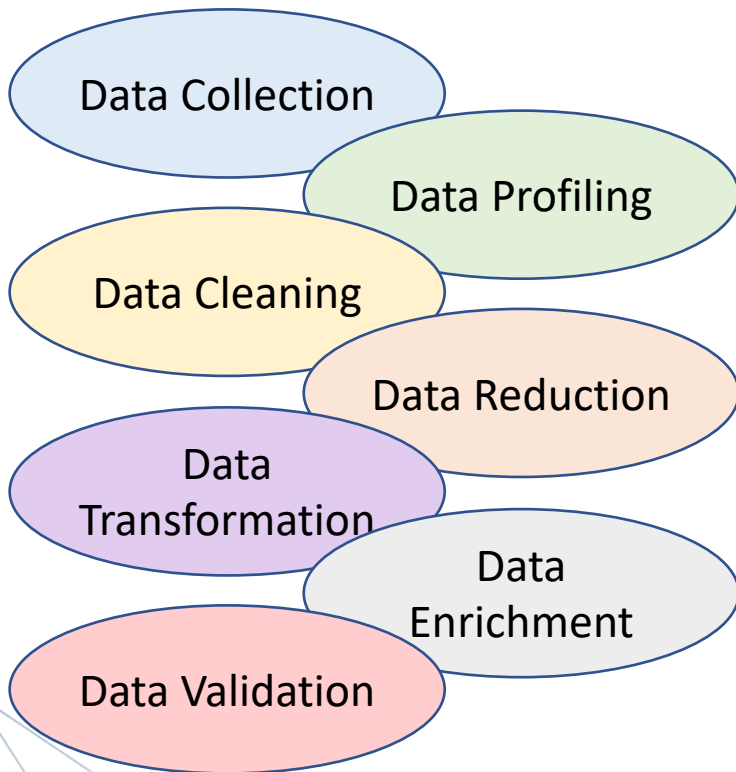


# Life Sciences Paradigms



# AI Protection Strategies

## Copyright, Patent/Defensive Publication, Trade Secret





# Patent Portfolio Development

## Business Goals

- Obtain funding and increase valuation
- Drive sales, increase brand recognition and market share
- Support corporate culture/policy
- Value of a monopoly on the patented technology
- Budget constraints

## Competitive Landscape

- Defensive publication
- Patenting for defensive purposes vs. offensive purposes
- Independent development/reverse engineering/workarounds
- Speed of innovation

## Feasibility of Trade Secret Protection

- Detectability:
  - user-facing vs. internal, secret use
- Pitching investors
- Selling and marketing
- Disclosure to development partners
- Regulatory disclosure requirements
- Whitepapers, conference presentations, blogs
- Employee attrition
- Trade secret theft
- Hacking and cybersecurity

# Litigation Considerations

## Intellectual Property

- Inventorship
- Prior art proliferation
- “POSA”
- Patent Eligibility § 101
- Damages apportionment
- Who or what conceived the invention?
- Written description and enablement of AI-“generated” invention
- Trade secrets

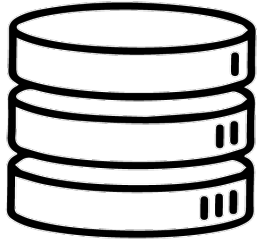
## Compliance

- Data privacy considerations (e.g., EU’s GDPR)
- Good Machine Learning Practices (e.g., [FDA’s Oct. 2021 Guiding Principles](#))

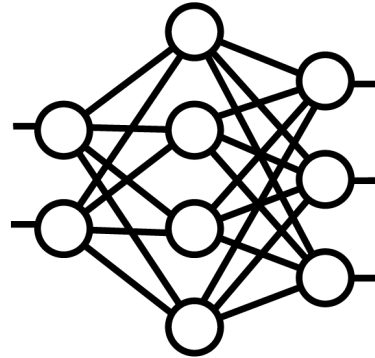
## Forum Disputes

- Collaboration (e.g., pharma + tech companies)
- Arbitration
- Company v. Company
- Class action

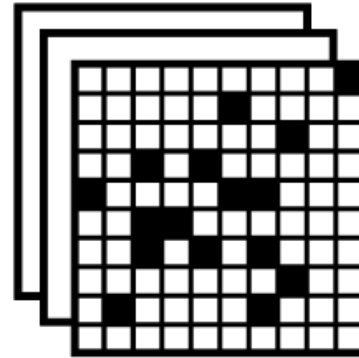
# Licensing and Transactions



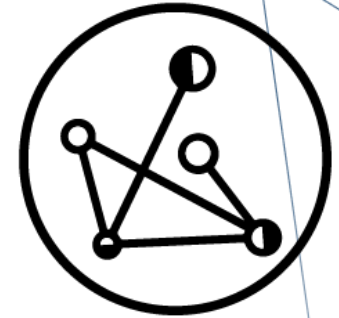
**Data** –  
Training,  
Validation,  
Derivative,  
otherwise



**Architecture /  
Algorithm**

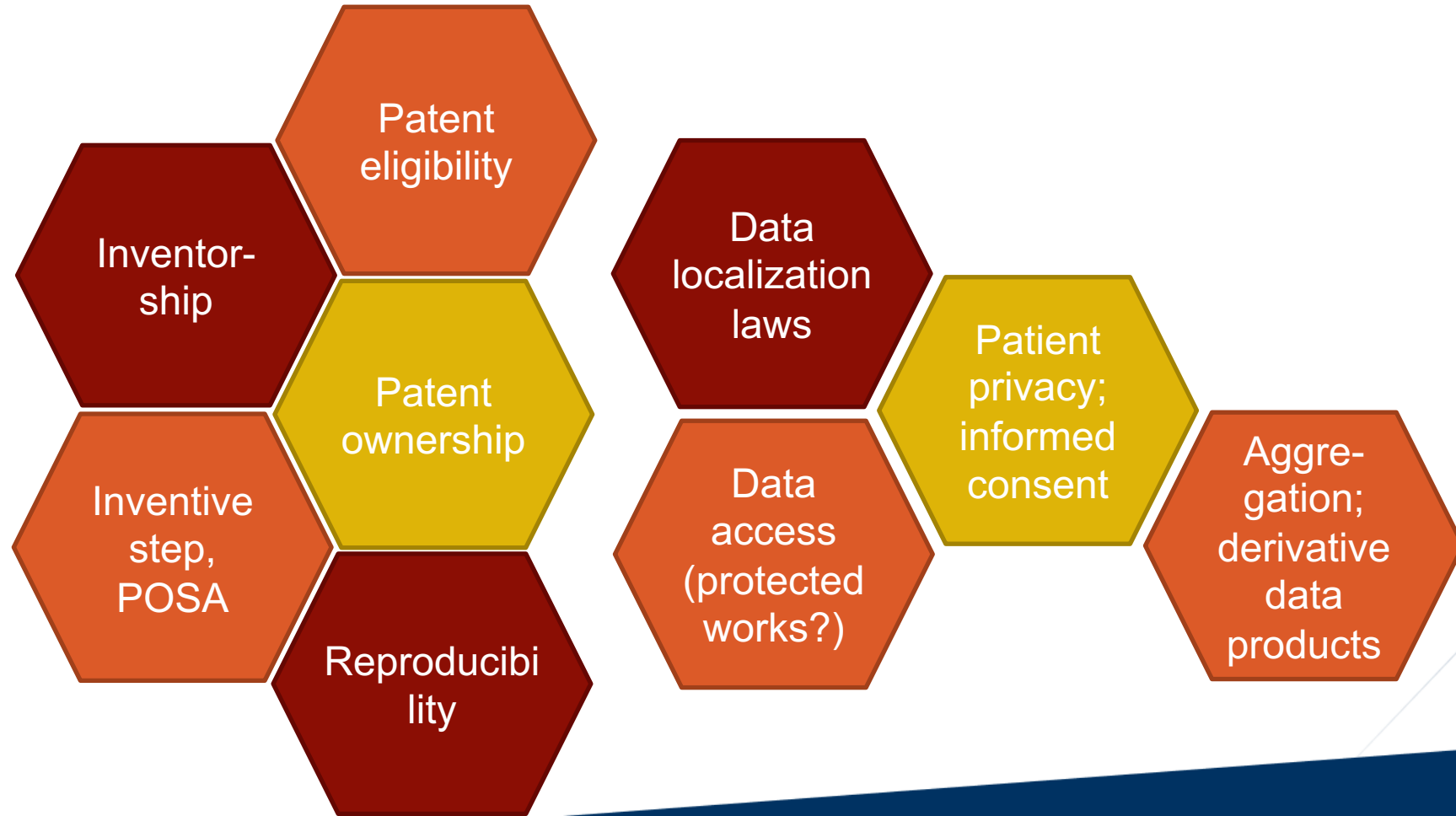


**Model(s)** -  
Weights,  
Parameters, etc.



**Outputs** –  
Predictions,  
Decisions,  
Creations, etc.

# AI Policy



# Upcoming Legal Developments

- § 101 at the U.S. Supreme Court: *American Axle & Manufacturing Inc. v. Neapco Holdings LLC*
  - Waiting for the Solicitor General
- European Unitary Patents and the Unified Patent Court (H2 2022)
- USPTO Director Kathi Vidal
- New privacy regulations

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**Expertise:** bioinformatics, medical devices, artificial intelligence, machine learning, computer vision, blockchain, cloud infrastructure and services, virtual reality and augmented reality, internet applications and server-side architecture, mobile applications, operating systems, graphics and audio/video, sensors, semiconductors, electronics, and mechanical arts

Learn more @ LinkedIn

# Andrew Whitehead



**Director and Assistant General Counsel Intellectual Property**

**PHC & Informatics Lead**

Andrew manages a small team of IP attorneys at Genentech supporting informatics and personalized healthcare initiatives.

This includes spearheading patent portfolio development, supporting external partnering, and developing internal open source and data protection best practices.

Prior to Genentech, he was a patent attorney at a Silicon Valley law firm for just short of a decade, spending the first half of that time supporting technology companies and the latter half of that time supporting companies straddling the divide between the life sciences and high tech.

Learn more @ LinkedIn

# Hans Sauer



Hans is the Deputy General Counsel and Vice President for Intellectual Property for the Biotechnology Innovation Organization, a major trade association representing over 1,000 biotechnology companies from the medical, agricultural, environmental and industrial sector.

At BIO, Hans advises the organization's board of directors, amicus committee, and various staff committees on patent and other intellectual property-related matters.

Prior to BIO, he was at MGI Pharma, Inc., and Guilford Pharmaceuticals Inc. where he worked on several drug development programs, being responsible for patent prosecution and portfolio oversight, clinical trial health information privacy, and sales and marketing legal compliance.

Hans did his postdoctoral fellowship at Genentech, Inc. in South San Francisco, and he holds a Ph.D. in Neuroscience from the University of Lund, Sweden and a J.D. degree from Georgetown University Law Center.



# Bruce Wexler

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HASTINGS



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**Bruce Wexler** is the Global Co-Chair of the Intellectual Property practice at Paul Hastings, overseeing the firm's 100-plus lawyer IP practice. Mr. Wexler is a trial lawyer with extensive experience litigating high-stakes patent cases in a range of technologies. He has represented clients as lead counsel defending their patents covering multi-million and multi-billion dollar drug products.

He forms close partnerships with his clients to achieve successful outcomes, including in bet-the-company cases. In Hatch-Waxman Act matters, he has litigated against virtually every generic drug company. He has helped his clients with important drug products such as Aricept®, Pradaxa®, Mirapex®, Cyltezo®, Basaglar®, Entereg®, Emend® oral and Emend® for Injection, Aciphex®, Banzel®, Gocovri®, and Opsumit®.

Mr. Wexler is also an Adjunct Professor of Law at New York University School of Law, where he teaches an advanced course in "Life Sciences Patent Law."

### ACCOLADES AND RECOGNITIONS

- Ranked by *Chambers Global* and *Chambers USA* (2021-2022) for Intellectual Property and lauded as "incredibly innovative and smart" with referees noting that he is "very good at thinking ahead and formulating a strategy."
- Mr. Wexler is recognized by *The Legal 500* (2021) as a "consummate first chair trial attorney" and "a superb writer" who "really has the complete arsenal of skills" for his litigation and life sciences expertise, with clients noting his ability to strategize and synthesize complex ideas in a clear manner. Previously, *The Legal 500* noted that Mr. Wexler has "extensive patent litigation experience, with strategic considerations and observations being very sophisticated and right to the point" and that he is "splendid at trial."
- Mr. Wexler is ranked as one of the world's leading patent practitioners by The Intellectual Asset Management's *IAM Patent 1000* (2021) and has been referred to as a "wonderfully gifted lawyer" who "is phenomenally prepared- there is nobody better at digging into the facts. He is a big picture thinker with excellent presentation skills." Recognized as an "awesomely effective trial lawyer" who operates "at a championship level" for clients, Mr. Wexler is a 2022 IAM Global Leader and ranked in the Gold band identifying him as the "crème de la crème" for Litigation by reputation and work on the most high-profile, big-ticket work from the most demanding of clients. According to *IAM*, Mr. Wexler "the value of his leadership cannot be overstated in the context of big-ticket litigation, which is why he is highly prized by some of the largest drug companies in the world." Mr. Wexler has additionally been recognized in the *IAM250* leading New York IP Litigators report as a "really strong substantive lawyer."
- Mr. Wexler led his practice to win the *LMG Life Sciences' Hatch Waxman Litigation Firm of the Year-Branded* award both in 2020 and 2018. He is recognized as a 2020 Life Sciences Star and shortlisted for Litigator of the Year. Previously, Mr. Wexler was named one of the "preeminent litigators in the industry" by *LMG Life Sciences Guide* and has been a Life Science nominee for Litigator of the Year recognized as General Patent Litigator of the Year – New York, and his representation of Eli Lilly was also honored by *LMG* as Hatch-Waxman Impact Case of the Year in 2016.
- He has been recognized as *The American Lawyer's* 2015 Transatlantic Lawyer of the Year – IP and helped lead the team to its 2018 recognition as Transatlantic IP Team of the Year.
- Mr. Wexler is recognized as a "Litigation Star" and "National Practice Area Star" by *Benchmark Litigation* (2021).
- Mr. Wexler is consistently recognized among *Managing IP's* IP Stars (2021).
- The *Financial Times* awarded his successful defense of the Aricept® drug franchise a "standout" notice for innovative lawyering.

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