

W. NICHOLSON PRICE II

University of Michigan Law School
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EDUCATION

Columbia Law School, J.D., James Kent Scholar, 2011

Columbia University Department of Biological Sciences, Ph.D., 2010; M.Phil., 2008; M.A., 2007

Harvard College, A.B. in Biological Sciences, cum laude, 2004

ACADEMIC APPOINTMENTS

University of Michigan Law School, Assistant Professor of Law, 2016–
Affiliated Faculty, Institute for Healthcare Policy and Innovation, 2017–
Affiliated Faculty, Science, Technology, and Public Policy Program, 2017–

University of Copenhagen Faculty of Law, Permanent Visiting Scholar, 2017–
Core Partner, Center for Advanced Studies in Biomedical Innovation Law, 2018–

Harvard Law School, Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics,
Co-PI, & Affiliated Faculty, Project on Precision Medicine, Artificial Intelligence, & Law, 2018–
Academic Fellow, 2012–2014

University of New Hampshire School of Law, Assistant Professor of Law, 2014–2016

U.C. Hastings College of the Law, U.C.S.F./U.C. Hastings Consortium on Law, Science and
Health Policy, Visiting Scholar, 2011–2012

CLERKSHIP

Hon. Carlos T. Bea, U.S. Court of Appeals for the Ninth Circuit, law clerk, 2011–2012

PUBLICATIONS AND WORKS IN PROGRESS

The Problem with Novelty, (draft manuscript)

Grants, Berkeley Technology Law Journal (forthcoming)

Drug Approval in a Learning Health System, 102 Minnesota Law Review 101 (2018)

Privacy in the Era of Medical Big Data (draft manuscript) (with I. Glenn Cohen)

Biobanks as Innovation Infrastructure for Translational Medicine (draft manuscript)

Medical Malpractice and Black-Box Medicine (chapter) in *Big Data, Health Law, and Bioethics*
(I. Glenn Cohen et al., eds.) (Cambridge University Press, 2018)

Regulating Black-Box Medicine, 116 Michigan Law Review 421 (2017)

Expired Patents, Trade Secrets, and Stymied Competition, 92 Notre Dame Law Review 1611
(2017)

Promoting Healthcare Innovation on the Demand Side, 4 *Journal of Law & the Biosciences* 3 (2017) (with Rebecca Eisenberg)

Risk and Resilience in Health Data Infrastructure, 16 *Colorado Technology Law Journal* 65 (2017)

The Need for the Privacy Standard for Medical Devices That Transmit Protected Health Information Used in the Precision Medicine Initiative for Diabetes and Other Diseases, 11 *Journal of Diabetes Science & Technology* 220 (2017) (with David Klonoff)

Privacy and Accountability in Black-Box Medicine, 23 *Michigan Telecommunications & Technology Law Review* 1 (2016) (with Roger Ford)

Regulating Secrecy, 91 *Washington Law Review* 1769 (2016)

Big Data, Patents, and the Future of Medicine, 37 *Cardozo Law Review* 1401 (2016)

Manufacturing Barriers to Biologics Competition and Innovation, 101 *Iowa Law Review* 1023 (2016) (with Arti Rai)

Codon influence on protein expression in E. coli correlates with mRNA levels, 529 *Nature* 358 (2016) (with Greg Boel et al.)

Describing Black-Box Medicine, 21 *BU Journal of Science & Technology Law* 347 (2015)

Innovation Policy Failures in the Manufacturing of Drugs (chapter) and *Timing is Everything: Balancing Access and Uncertainty* (section introduction) in *FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies* (I. Glenn Cohen & Holly Lynch, eds.) (Columbia University Press, 2015)

Black-Box Medicine, 28 *Harvard Journal of Law & Technology* 419 (2015)

Will clinical trial data disclosure reduce incentives to develop new uses of drugs?, 33 *Nature Biotechnology* 685 (2015) (with Timo Minssen)

Are trade secrets delaying biosimilars?, 348 *Science* 188 (2015) (with Arti Rai)

Patent Trolling—Why Bio & Pharmaceuticals Are at Risk, 17 *Stanford Technology Law Review* 773 (2014) (with Robin Feldman)

Generic Entry Jujitsu: Innovation and Quality in Drug Manufacturing, 4 *IP Theory* 1 (2014)

Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing, 55 *Boston College Law Review* 491 (2014)

Nudging the FDA, 10 *American Interest* 35 (2014) (with I. Glenn Cohen)

Models of Consent to Return of Incidental Findings in Genomic Research, 44 *Hastings Center Report* 22 (2014) (with Paul S. Appelbaum et al.)

Chemotherapy drug shortages in pediatric oncology: a consensus statement, 133 *Pediatrics* e716 (2014) (working-group member)

Problems of Innovation-Deficient Pharmaceutical Manufacturing, *Harvard Business Review/New England Journal of Medicine Insight Center on High-Value Health Care* (2013), available at <http://www.nejm.org/page/leading-health-care-innovation>

Informed Consent for Return of Incidental Findings in Genomic Research, 16 *Genetics in Medicine* 367 (2013) (with Paul S. Appelbaum et al.)

Legal Implications of an Ethical Duty to Search for Genetic Incidental Findings, 13 *American Journal of Bioethics* 48 (2013)

Unblocked Future: Why Gene Patents Won't Hinder Whole-Genome Sequencing and Personalized Medicine, 33 *Cardozo Law Review* 1601 (2012)

Does Whole-Genome Sequencing Circumvent Gene Patents?, *Bio-IT World* (Dec. 10, 2012)

Large-Scale Experimental Studies Show Unexpected Amino Acid Effects on Protein Expression and Solubility in vivo in E. coli, 1 *Microbial Informatics and Experimentation* 6 (2011) (with Samuel Handelman et al.)

Am I My Son? Clones and the Modern Family, Note, 11 *Columbia Science & Technology Law Review* 118 (2010)

The Deepwater Horizon Oil Spill: Potential Insurance Coverage Implications, *Insurance Law Coverage Bulletin* (September 2010) (with Lynn K. Neuner)

Understanding the Physical Properties that Control Protein Crystallization by Analysis of Large-Scale Experimental Data, 27 *Nature Biotechnology* 51 (2009) (with Yang Chen et al.)

Patenting Race: The Implications of Ethnic Genetic Testing, Note, 8 *Columbia Science & Technology Law Review* 119 (2007)

MxA Gene Expression Analysis as an Interferon-beta Bioactivity Measurement in Patients with Multiple Sclerosis and the Identification of Antibody-Mediated Decreased Bioactivity, 7 *Molecular Diagnosis* 17 (2003) (with Andrew Pachner et al.)

TEACHING

University of Michigan Law School: Patent Law (Winter 2018, Fall 2016); Innovation in the Life Sciences (Winter 2018); Science Fiction & the Law (Winter 2018); Health Law (Winter 2017)

University of New Hampshire School of Law: Patent Law (Fall 2015, Fall 2014); Health Law (Fall 2015, Fall 2014)

Harvard Law School: Genetics & the Law (Spring 2014)

Columbia Law School: Property (TA Spring 2009)

Columbia Graduate School of Arts & Sciences: Protein Biochemistry Lab (TA Fall 2008)

GRANTS

1 R01 CA214829-01A1: The Lifecycle of Health Data: Policies and Practices: Co-Investigator (Principal Investigator: Sharon Reilly Kardia) (2018–2022: \$2,446,187)

NNF17SA0027784: Collaborative Research Program in Biomedical Innovation Law (CeBIL): Core Partner & Co-Principal Investigator (Principal Investigator: Timo Minssen) (2018–2022: \$5,543,175)

CONFERENCE AND INVITED PRESENTATIONS

Medical AI and Contextual Bias

- University of Copenhagen CeBIL workshop, June 2018
- Health Law Professors Conference, June 2018
- Michigan Law School Fawley Faculty Workshop, June 2018

The Problem with Novelty

- Junior Scholars in IP Workshop, May 2018
- bioip Workshop, May 2018
- Regulation and Innovation in the Biosciences Workshop, April 2018

Legal and Ethical Issues with Biomedical Artificial Intelligence

- National Academy of Sciences, Engineering, and Medicine Working Group on AI, Health, and Society, May 2018

AI and Biomedical Resource Creation, Biopharmaceuticals and Digital Health (panelist)

- Duke Conference on AI in the Administrative State, May 2018

Artificial Intelligence and Tort Law (panelist)

- Seton Hall conference on AI & Law, April 2018

Black-Box Medicine: Innovation and Regulation

- Yale Information Society Project, March 2018
- University of Amsterdam Institute for Information Law, March 2018

Innovation in Biopharmaceutical Manufacturing

- University of Copenhagen Collaborative Research Program in Biomedical Innovation Law Opening Conference, March 2018

Legal and Policy Issues Associated with Cutting-Edge Cancer Treatments (panelist)

- Yale Conference on the Politics, Policy, and Law of Cancer, February 2018

The Failure of Trickle-Down Innovation

- South NeBrooklyn, February 2018

Grants

- Works in Progress in Intellectual Property, February 2018
- Junior IP Scholars Association Workshop, January 2018
- Wiet Life Sciences Conference, October 2017
- UNH IP Scholars Roundtable, October 2017
- Health Law Professors Conference, June 2017

Drug Approval in a Learning Health System

- University of Utah Law & Biosciences Colloquium, February 2018
- Minnesota Law Review Symposium, October 2017
- UC Hastings Faculty Colloquium, September 2017

Privacy in Diabetes Technology

- Diabetes Technology Association Annual Meeting, November 2017

Black-Box Medicine: Regulation and Transparency

- University of Copenhagen Center for Regulatory Science Conference on Regulatory Transparency, October 2017

Black-Box Medicine: Regulation, Liability, and Implementation

- University of Michigan Bioethics Grand Rounds, September 2017

Complicating the Mix of Incentives for Biomedical Innovation

- Regulation & Innovation in the Biosciences, April 2017
- BioLawLaPalooza, April 2017
- Patent Con VII, April 2017
- UNH IP Scholars Roundtable, October 2016

Ethical, Legal, and Social Issues Across the Life Cycle of Data: Implications for Learning Health Systems (panelist)

- LHS Collaboratory, University of Michigan, April 2017

Biobanks as Innovation Infrastructure

- University of Copenhagen, March 2017

Risk and Resilience in Health Data Infrastructure

- Silicon Flatirons Conference on Digital Broadband Migration, February 2017

Patent Failures on Life Science Frontiers

- Gnocchi Workshop, January 2017
- Intellectual Property Scholars Conference, August 2016
- Works in Progress in Intellectual Property, February 2016
- Junior IP Scholars Association Workshop, January 2016
- UNH IP Scholars Roundtable, November 2015

Expired Patents, Trade Secrecy, and Stymied Competition

- Notre Dame Fall Symposium on Overlapping IP Rights, November 2016
- University of Michigan Law School Fawley Lunch, October 2016
- Big Ten Juniors Conference, August 2016
- Junior IP Scholars Association Workshop, June 2016

Intellectual Property for Diagnostics: *Prometheus*, *Myriad*, *Alice*, & *Ariosa*

- Gordon Research Conference on Circulating Rare Cells, August 2016

Promoting Health-care Innovation on the Demand Side

- Health Law Professors Conference, June 2016
- University of Michigan Law School Legal Theory Workshop, March 2016 (with Rebecca Eisenberg)

Data Infrastructure for Medical Algorithms

- University of Copenhagen, May 2016

Regulating Black-Box Medicine

- Harvard Law Petrie-Flom Center Conference on Big Data in Medicine, May 2016
- University of Texas at Austin Center for Politics and Governance Panel: Technology vs. the Rule Makers, April 2016

Regulating Secrecy

- Vanderbilt Intellectual Property Scholars Roundtable, April 2016

Privacy and Accountability in Black-Box Medicine

- Yale Conference on Unlocking the Black Box, April 2016 (with Roger Ford)

Health Innovation Policy and Regulating Novel Technology (panelist)

- Harvard Law Petrie-Flom Center Conference on the Future of Health Law, March 2016

FDA's New Rules Amending Hatch-Waxman (panelist)

- Northwestern Journal of Technology & IP Law Symposium, March 2016

Assessing the Validity of the FDA's Biosimilars Pathway (panelist)

- Harvard Law Petrie-Flom Center, February 2016

Black-Box Medicine

- Stanford Center for Law and the Biosciences Workshop, February 2016

Drugs, Secrecy, and the FDA

- George Washington IP Workshop, January 2016

The ACA and Technology Innovation: What's New in Bio-Tech and Bio-Pharm Innovation

- UNH Conference on Innovations in Health Law and Policy, October 2015 (with Jordan Paradise)

Regulating Complex Medical Algorithms

- Health Law Scholars Workshop, October 2015
- Health Law Professors Conference, June 2015

Demand-Side Innovation in Health Care

- Intellectual Property Scholars Conference, August 2015

Secrecy and Innovation

- Patent Con V, April 2015
- Yale Conference on Innovation Law Beyond IP 2, March 2015
- UNH Scholarly Works in Progress Luncheon, March 2015
- UNH IP Scholars Roundtable, November 2014

Patent Prosecution of Biologics (panelist)

- Indiana University Biopharma/Technology Symposium, March 2015

Incentives, IP, and Black-Box Medicine

- University of Tulsa Faculty Colloquium, March 2015
- Suffolk University IP Roundtable, October 2014
- Michigan State University Junior Scholars in IP Workshop, October 2014
- Boston University Workshop on Personalized Medicine and Incentives, August 2014
- Intellectual Property Scholars Conference, August 2014
- Munich Conference on Innovation and Competition, June 2014
- Health Law Professors Conference, June 2014

Biosimilars and Manufacturing Trade Secrets

- Works in Progress in Intellectual Property, February 2015

Regulation of Black-Box Personalized Medicine

- Food and Drug Law Institute Conference on Emerging Issues and New Frontiers for FDA Regulation, October 2014

Patent Trolling—Why Bio and Pharmaceuticals Are at Risk

- Patent Con IV, April 2014

Patent Trolls and Misuse (panelist)

- Harvard/MIT Broad Institute Innovation & Intellectual Property Symposium, April 2014

Biosimilarity: Manufacturing, Regulation, and Intellectual Property

- Presentation to senior officials of the China Food and Drug Administration, February 2014

Regulatory Exclusivity for Biologics and Manufacturing Methods (panelist)

- Harvard Law Petrie-Flom Center Lunch Panel on Patents without Patents—Regulatory Incentives for Innovation in the Drug Industry, February 2014

Clinical Trial Data Disclosure: Updates from 2013

- New England Journal of Medicine/ Harvard Law Petrie-Flom Center Health Law Year in P/Review, January 2014

Innovation Policy in Pharmaceutical Manufacturing

- UNH IP Scholars Roundtable, November 2013
- Yale Reading Group: Patent Law from the Law-and-Economics Perspective, September 2013
- Intellectual Property Scholars Conference, August 2013
- National Institute for Pharmaceutical Technology Conference on the Future of Pharmaceutical Manufacturing, June 2013
- Health Law Professors Conference, June 2013
- Harvard Law Petrie-Flom Center Conference on FDA in the 21st Century, May 2013
- Harvard Health Law Policy & Bioethics Workshop, April 2013

Intellectual Property Rights in Genetic Research

- Harvard Medical School/Massachusetts General Hospital Course on Responsible Conduct of 'Omics Research, November 2013

Major Issues in Device Regulation (moderator)

- Harvard Law Petrie-Flom Center Conference on FDA in the 21st Century, May 2013

Restricting Conflicts, Restricting Science: How Commercialization Incentives and Conflicts of Interest Clash in the Context of Modern Scientific Research

- U.C.S.F./U.C. Hastings Consortium on Law, Science, and Health Policy Summer Roundtable, June 2011

Elucidating the Chemical and Physical Properties Controlling Protein Expression and Crystallization

- American Crystallographic Society Annual Meeting, July 2009

Data Mining Structure Solution Determination in the NESG Pipeline

- NIH Protein Structure Initiative “Bottlenecks” Workshop, April 2008

Ethnic Genetic Testing Patents

- Genetic Alliance Annual Conference, July 2007

CONFERENCES ORGANIZED

Regulation and Innovation in the Biosciences Workshop, University of Michigan Law School, April 2017

Junior IP Scholars Association Workshop, Franklin Pierce Center for Intellectual Property, University of New Hampshire School of Law, June 2016

Fifth Annual UNH IP Scholars Roundtable, Franklin Pierce Center for Intellectual Property, University of New Hampshire School of Law, November 2015

Health Law Symposium: Innovations in Health Law and Policy: Regulatory Challenges and Strategies for Change, Health Law and Policy Program, University of New Hampshire School of Law, October 2015

Fourth Annual UNH IP Scholars Roundtable: Intellectual Property on the Ground, Franklin Pierce Center for Intellectual Property, University of New Hampshire School of Law, November 2014

PUBLIC AND UNIVERSITY SERVICE

Referee work: Cambridge University Press; Columbia University Press; JAMA-Internal Medicine; Journal of Law & the Biosciences; Stanford Technology Law Review; Yale Journal of Health Policy, Law, & Ethics; Drug Discovery Today; Journal of Diabetes Technology; PLoS Biology

Executive Board, AALS Section on BioLaw, 2017–

Michigan Law: Academic Standards & Practices Committee, 2018–; Alumni Academic Placement Committee, 2016–; Student Recognition & Awards Committee, 2017–2018

UNH Law: Appeals Committee, 2014–2016; Student Intellectual Property Law Association Co-Advisor, 2014–2016

PROFESSIONAL EXPERIENCE

Simpson Thacher & Bartlett, LLP, summer associate, 2010

Quinn Emanuel Urquhart Oliver & Hedges, LLP, summer associate, 2006 & 2005

PATENT APPLICATIONS

Methods for altering polypeptide expression and solubility, Patent Cooperation Treaty App. No. PCT/US2011/024251, filed February 9, 2011 (patent pending) (with John Hunt et al.)

Engineering surface epitopes to improve protein crystallization, Patent Cooperation Treaty App. No. PCT/US2011/033135, filed April 19, 2011 (patent pending) (with John Hunt et al.)