

ARTI K. RAI
rai@law.duke.edu
@rai_arti

RECENT EMPLOYMENT

2008-Present

DUKE LAW SCHOOL

Elvin R. Latty Professor

Founding Director, [Center for Innovation Policy](#) (2014-present)

- Principal Investigator, Arnold Ventures grant on patents, innovation incentives, and drug pricing (2020-2021)
- Principal Investigator, Greenwall Foundation grant on secrecy, innovation, and accountability in health-related machine learning software (2019-2020)

Core Faculty, Duke Innovation & Entrepreneurship Initiative

Faculty, Duke-Margolis Center for Health Policy

Research and Teaching Interests: Patents; Administrative Law; Intellectual Property; Life Sciences Innovation; Health Law & Policy

3/2021-12/2021

U.S. DEPARTMENT OF COMMERCE, OFFICE OF GENERAL COUNSEL

Senior Advisor

- Advised on intellectual property-related aspects of Executive Order 14036 (“Promoting Competition in the American Economy”)
- Advised on high-priority intellectual property projects at USPTO, NIST, EDA

RECENT POLICY EXPERIENCE

Member, Polaris Advisory Council to GAO’s Science Technology Assessment, and Analytics Group (2020–present)

Expert for California Department of Justice on potential “innovation markets” antitrust challenge to Abbvie-Allergan merger (2019-2020)

Public Member, Administrative Conference of the United States (2013-2017)

Member, National Advisory Council on Human Genome Research (2012-2016)

Testimony before U.S. Congress (Senate and House), federal agencies

GRANTS/HONORS (SELECTED)

Member, National Academies’ Forum on Drug Discovery (2020-present)

Member, National Academies’ study on Accelerating Commercialization from the Federal Labs (2019-2020)

Co-Investigator, Kauffman Foundation and NSF Award to study decline in U.S. basic research investment (2016-2018)

Principal Investigator, NIH research grant to study “genomics as information” (2010-2015)

Principal Investigator, NIH/DOE research grant to study collaborative R&D models in genomics research (focus on bioinformatics, synthetic biology) (2004-2009)

Principal Investigator, Kauffman Foundation award to study technology transfer in software (2007-2009)

Investigator, Chatham House (U.K.) grant to study role of intellectual property rights and alternatives in green innovation, domestic and international (2008-2009)

Winner, World Technology Award (Law Category), 2011

Member, American Law Institute (2013-present)

Member, Institute of Medicine Committee, Strategies for Responsible Sharing of Clinical Study Trial Data (2013-2015)

Editorial Board, Journal of Law and the Biosciences

Referee (selected journals): SCIENCE; RESEARCH POLICY; MANAGEMENT STUDIES; HEALTH AFFAIRS; JOURNAL OF LEGAL STUDIES; NEW ENGLAND JOURNAL OF MEDICINE; JAMA; numerous NASEM studies; National Institutes of Health/National Human Genome Research Institute study sections; top 10 law reviews

EDUCATION

HARVARD LAW SCHOOL, J.D., *cum laude*, 1991
Best Brief and Team, Harvard (Ames) Moot Court Competition

HARVARD MEDICAL SCHOOL, medical student for 1987-88 academic year
Award for research analyzing use of cost-benefit analysis in studies of biomedical innovation (resulted in publication)

HARVARD COLLEGE, A.B., *magna cum laude*, in Biochemistry and History (History and Science), 1987
John Harvard Scholarship for highest academic achievement
National Merit Scholar
Radcliffe science award for research on genetic origins of retinitis pigmentosa (resulted in publication)

FULL EMPLOYMENT

2008-Present	DUKE LAW SCHOOL Elvin R. Latty Professor
2021	DEPARTMENT OF COMMERCE, OFFICE OF GENERAL COUNSEL Senior Advisor
2009-2010	US PATENT AND TRADEMARK OFFICE Administrator, Office of External Affairs (now Office of Policy and International Affairs) (leave of absence from Duke Law School) Directed PTO Office responsible for policymaking, Congressional relations, and international relations. Conducted policy analysis of legislation that became America Invents Act of 2011 and established Office of the Chief Economist. Prior to assuming role as Administrator, served as Expert Advisor to Department of Commerce's Office of General Counsel and conducted transition review of USPTO for Obama transition team.
2003-2008	DUKE LAW SCHOOL Professor
January 2007	HARVARD LAW SCHOOL Hieken Visiting Professor in Patent Law
Fall 2004	YALE LAW SCHOOL Visiting Professor
2001-2003	UNIVERSITY OF PENNSYLVANIA LAW SCHOOL Assistant Professor
1997-2001	UNIVERSITY OF SAN DIEGO SCHOOL OF LAW Assistant Professor

- 1996-1997 **PROGRAM IN ETHICS AND THE PROFESSIONS, HARVARD UNIVERSITY**
Faculty Fellow
- 1995-1996 **UNIVERSITY OF CHICAGO LAW SCHOOL, MEDICAL SCHOOL,
AND GRADUATE SCHOOL OF PUBLIC POLICY**
Lecturer in Law
- 1994-1995 **UNITED STATES DEPARTMENT OF JUSTICE, CIVIL DIVISION, FEDERAL
PROGRAMS BRANCH**
Trial Attorney
- 1992-1994 **JENNER & BLOCK, Washington D.C.**
Associate
- 1991-1992 **JUDGE MARILYN HALL PATEL, UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF CALIFORNIA, San Francisco, CA**
Law Clerk

Focused on administrative law. Briefed and argued cases involving the Administrative Procedure Act, Federal Advisory Committee Act, Medicare, and Medicaid.

Wrote briefs in U.S. Supreme Court cases as well as federal appellate and district court cases. Focused on patent litigation.

Drafted opinions on cases, including numerous patent cases.

MONOGRAPHS

TRUST BUT VERIFY: INFORMATIONAL CHALLENGES SURROUNDING AI-ENABLED CLINICAL DECISION SOFTWARE (2020) (Duke Law Center for Innovation Policy and Duke-Margolis Center for Health Policy) (with Christina Silcox and Isha Sharma)

OVERCOMING THE LEGAL AND REGULATORY HURDLES TO VALUE-BASED PAYMENT ARRANGEMENTS FOR MEDICAL PRODUCTS (2017) (as part of Duke-Margolis Center for Health Policy Task Force on Value-Based Consortium)

VALUING HEALTH CARE: IMPROVING PRODUCTIVITY AND QUALITY (April 2012) (as part of the Kauffman Task Force on Cost-Effective Health Care Innovation)

CRITICAL CONCEPTS IN INTELLECTUAL PROPERTY LAW: BIOTECHNOLOGY (Edward Elgar Publishing 2011) (editor)

LAW AND THE MENTAL HEALTH SYSTEM, 5th edition (West Group 2008) (with Professors Ralph Reisner and Chris Slobogin)

ARTICLES

Post-Grant Adjudication of Drug Patents: Agency and/or Court, 36 BERKELEY TECHNOLOGY LAW JOURNAL (forthcoming 2022) (with Saurabh Vishnubhakat, Jorge Lemus, and Erik Hovenkamp)

Expanding Access and Reducing Prices for Drugs to Prevent HIV, 323 JAMA 821 (2020) (with Lawrence Gostin)

Clearing Opacity Through Machine Learning, 106 IOWA L. REV. 775 (2020)
(with W. Nicholson Price II)

Accountability, Secrecy, and Innovation Incentives in AI-Enabled Clinical Decision Software, 7 JOURNAL OF LAW & THE BIOSCIENCES 1 (2020) (with Isha Sharma and Christina Silcox)

An Administrative Fix for Manufacturing Process Patent Thickets, 39(1) NATURE BIOTECHNOLOGY 20 (2020) (with W. Nicholson Price II)

Knowledge Transfer for Large-Scale Vaccine Manufacturing, 369 SCIENCE 912 (2020)

Machine Learning at the Patent Office: Lessons for Patents and Administrative Law, 104 IOWA L. REV. 2617 (2019)

How Logically Impossible Patents Block Biosimilars, 37 NATURE BIOTECHNOLOGY 862 (2019) (with W. Nicholson Price II)

Racing for Academic Glory and Patents: Lessons from CRISPR, 358 SCIENCE 874 (2017) (with Robert Cook-Deegan)

Risk Regulation and Innovation: The Case of Rights-Encumbered Biomedical Data Silos in Symposium, Negotiating IP's Boundaries in an Evolving World, 92 NOTRE DAME LAW REVIEW (2017)

Strategic Decisionmaking in Dual PTAB and District Court Proceedings, 31 BERKELEY TECH. L. J. 45 (2016) (with Saurabh Vishnubhakat and Jay Kesan)

Administrative Power in the Era of Patent Stare Decisis, 65 DUKE LAW JOURNAL 1563 (2016) (with Stuart Benjamin)

When Software Meets Biopharma: Bioinformatics at the Patent Office, 29 HARVARD JOURNAL OF LAW & TECHNOLOGY 205 (2015) (with Saurabh Vishnubhakat)

Are Trade Secrets Delaying Biosimilars? 348 SCIENCE 188 (2015) (with W. Nicholson Price II)

Manufacturing Barriers to Biologics Competition and Innovation, 101 IOWA L. REV. 1023 (2015) (with W. Nicholson Price II)

Use Patents Can Be Useful: The Case of Rescued Drugs, 6 SCIENCE TRANSLATIONAL MEDICINE 249fs3 (2014) (with Grant Rice)

Improving (Software) Patent Quality Through the Administrative Process, in *Symposium Issue, Intellectual Property and Information Law in the Administrative State*, 51 HOUSTON LAW REVIEW 503 (2013)

Use Patents, Carve-Outs, and Incentives: A New Battle in the Drug-Patent Wars, 367 NEW ENGLAND JOURNAL OF MEDICINE 491 (2012).

Accountability in the Patenting of Federally Funded Research, 30 NATURE BIOTECHNOLOGY 963 (2012) (with Bhaven N. Sampat)

Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development, 61 DUKE LAW JOURNAL 101 (2012)

Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control, 157 UNIVERSITY OF PENNSYLVANIA LAW REVIEW 2051 (2009)

University Software Ownership and Litigation: A First Examination, 87 NORTH CAROLINA LAW REVIEW 1519 (2009) (with John Allison and Bhaven Sampat) (reprinted in F. SCOTT KIEFF AND TROY PAREDES, ED., PERSPECTIVES ON COMMERCIALIZING INNOVATION (Cambridge University Press 2011))

Intellectual Property and Alternatives: Strategies for Green Innovation (working paper commissioned by Chatham House) (2009) (with Richard Newell, Jerome Reichman, and Jonathan Wiener) (reprinted in MARIO CIMOLI ET AL., EDS., INTELLECTUAL PROPERTY RIGHTS: LEGAL AND ECONOMIC CHALLENGES FOR DEVELOPMENT (Oxford Univ. Press 2012))

Proprietary Science, Open Science, and the Role of Patent Disclosure: The Case of Zinc Finger Proteins, 27 NATURE BIOTECHNOLOGY 140 (2009) (with co-authors)

Fixing Innovation Policy: A Structural Perspective, 77 GEORGE WASHINGTON LAW REVIEW 101 (2008) (with Stuart Benjamin) (summary presented by the Information Technology and Innovation Foundation as June 2009 whitepaper "Structuring U.S. Innovation Policy: Creating a White House Office of Innovation Policy")

Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerating Drug Discovery, 8 YALE JOURNAL OF HEALTH POLICY, LAW & ETHICS 53 (2008) (with Jerome Reichman, Paul Uhlir, and Colin Crossman)

Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation in Symposium Issue, Patent Law in Perspective, 43 HOUSTON LAW REVIEW 1037 (2008)

Synthetic Biology: The Intellectual Property Puzzle, 85 TEXAS LAW REVIEW 1745 (2007) (with Sapna Kumar)

Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons, 5 PLOS BIOLOGY e58 (2007) (with James Boyle)

Who's Afraid of the APA: What the Patent System Can Learn from Administrative Law 95 GEORGETOWN LAW JOURNAL 269 (2007) (with Stuart Benjamin)

Harnessing and Sharing the Benefits of State-Sponsored Research, 21 BERKELEY TECHNOLOGY LAW JOURNAL 1187 (2006) (with Rebecca Eisenberg)

Finding Cures for Tropical Diseases: Is Open Source an Answer?, PLOS MEDICINE, December 2004 (with Stephen Maurer and Andrej Sali) (also reprinted in 6 MINNESOTA JOURNAL OF LAW, SCIENCE, & TECHNOLOGY 169 (2004))

Allocating Power over Fact-Finding in the Patent System, in *Symposium Issue, Ideas Into Action: Implementing Reform of the Patent System*, 19 BERKELEY TECHNOLOGY LAW JOURNAL 907 (2004)

Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform,

103 COLUMBIA LAW REVIEW 1035 (2003)

Bayh-Dole Reform and the Progress of Biomedicine, 66 LAW AND CONTEMPORARY PROBLEMS 289 (Winter/Spring 2003) (with Rebecca Eisenberg)

Specialized Trial Courts: Concentrating Expertise on Fact, 17 BERKELEY TECHNOLOGY LAW JOURNAL 258 (2002)

Pharmacogenetic Interventions, Orphan Groups, and Distributive Justice: The Role of Cost-Benefit Analysis, 19 SOCIAL PHILOSOPHY & POLICY 246 (2002)

Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust, 16 BERKELEY TECHNOLOGY LAW JOURNAL 813 (2001)

The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era in Symposium Issue, *Intellectual Property Challenges in the Next Century*, 2001 UNIVERSITY OF ILLINOIS LAW REVIEW 173

Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials, in Symposium Issue, *Re-engineering Patent Law: The Challenge of New Technologies*, 2 WASHINGTON UNIVERSITY JOURNAL OF LAW & POLICY 199 (2000)

Regulating Scientific Research: Intellectual Property Rights and the Norms of Science, 94 NORTHWESTERN UNIVERSITY LAW REVIEW 77 (1999)

Intellectual Property Rights in Biotechnology: Addressing New Technology in Symposium Issue, *Genetic Technology: Social Values and Personal Autonomy in the 21st Century*, 34 WAKE FOREST LAW REVIEW 827 (1999)

Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care, 72 INDIANA LAW JOURNAL 1015 (1997)

Cost-Effectiveness and Cost-Benefit Analyses in the Medical Literature, 116 ANNALS OF INTERNAL MEDICINE 338 (1992) (with co-authors)

BOOK CHAPTERS

Patent Institutions in RESEARCH HANDBOOK ON THE LAW AND ECONOMICS OF INTELLECTUAL PROPERTY, VOLUME 1: THEORY (Peter Menell & Ben Depoorter, eds.) (Cambridge University Press, 2019)

The USPTO's Patent Trial and Appeal Board in RESEARCH HANDBOOK ON THE LAW AND ECONOMICS OF INTELLECTUAL PROPERTY: VOLUME II: EMPIRICS (Peter Menell & David Schwartz, eds.) (Cambridge University Press, 2019)

The "Follow-on" Challenge: Statutory Exclusivities and Patent Dances, in FDA IN THE 21ST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES (Holly Fernandez Lynch & I. Glenn Cohen, eds.) (Columbia University Press 2015)

U.S. Executive Branch Patent Policy, Global and Domestic, in PATENT LAW IN GLOBAL PERSPECTIVE 85-96 (Ruth L. Okediji & Margo A. Bagley, eds., 2014)

"Open and Collaborative" Biomedical Research: Theory and Evidence, in BRIAN KAHIN AND DOMINIQUE FORAY, EDS., ADVANCING KNOWLEDGE AND THE KNOWLEDGE ECONOMY (MIT Press 2006)

Open and Collaborative Research: A New Model for Biomedicine? in ROBERT HAHN, ED., INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES: SOFTWARE AND BIOTECH (AEI-Brookings Press 2005)

Proprietary Rights and Collective Action: The Case of Biotechnology Research with Low Commercial Value, in JEROME REICHMAN AND KEITH MASKUS, EDs., INTERNATIONAL PUBLIC GOODS AND TECHNOLOGY TRANSFER IN A GLOBALIZED INTELLECTUAL PROPERTY REGIME (Cambridge University Press 2005)

“Patenting Organisms and Basic Research” and “Private Ownership of Inventions” entries in ENCYCLOPEDIA OF BIOETHICS, 3rd ed. (Macmillan 2004)

Proprietary Considerations, in ROBERT LANZA, ED., HANDBOOK OF STEM CELLS, VOL.2: EMBRYONIC STEM CELLS (Elsevier Press 2004) (with Rebecca Eisenberg)

The Increasingly Proprietary Nature of Publicly Funded Biomedical Research: Benefits and Threats, in DONALD G. STEIN, ED., BUYING IN OR SELLING OUT? THE COMMERCIALIZATION OF THE AMERICAN UNIVERSITY (Rutgers University Press 2004)

COMMENTARY

Acknowledging the Public Role in Private Drug Development: Lessons from Remdesivir, STAT, March 8, 2020 (with Justin Hughes)

Competing with the "Patent Court": A Newly Robust Ecosystem, 13 CHICAGO-KENT JOURNAL OF INTELLECTUAL PROPERTY 386-393 (2014)

Diagnostic Patents at the Supreme Court, 18 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW 1 (2014)

Biomedical Patents at the Supreme Court: A Path Forward, 66 STANFORD LAW REVIEW ONLINE 111 (2013)

Who's Afraid of the Federal Circuit?, 121 YALE L.J. ONLINE 335 (2011)

Unstandard Standardization: The Case of Biology, COMMUNICATIONS OF THE ACM 37 (2010)

Is Bayh-Dole Good for Developing Countries?: Lessons from the U.S. Experience, 6 PLOS BIOLOGY e262 (2008) (with co-authors)

Patenting Human Organisms: An Ethical and Legal Analysis (working draft of paper prepared for President's Council on Bioethics) (2002)

Gene Patenting: A Case Study in Patenting Research Tools, 77 ACADEMIC MEDICINE 1368 (2002)

Genetic Interventions: (Yet) Another Challenge to Allocating Health Care, 39 SAN DIEGO LAW REVIEW 657 (2002)

Locating Gene Patents Within the Patent System, 2 AMERICAN JOURNAL OF BIOETHICS 18 (2002)

Health Care Fraud and Abuse: A Tale of Behavior Induced by Payment Structure, 30 JOURNAL OF LEGAL STUDIES 579 (2002)

Evolving Research Norms and the Public Domain: A Reply to Professor Kieff, 95 NORTHWESTERN UNIVERSITY LAW REVIEW 707 (2001)

The Physician as a Health Care Proxy, 29 HASTINGS CENTER REPORT 14 (September/October 1999) (with Drs. Mark Siegler and John Lantos)

Reflective Choice in Health Care: Using Information Technology to Present Allocation Options, in *Symposium Issue, Electronic Medical Information: Privacy, Liability, & Quality Issues*, 25 AMERICAN JOURNAL OF LAW & MEDICINE 387 (1999)

SELECTED LECTURES AND PRESENTATIONS, 2019-2022 (in person and virtual)

Harvard Medical School (Program on Regulation, Therapeutics, and Law); Stanford Medical School (health AI conferences); Stanford Law School; Yale Law School; NYU Law School; USC Law School; U.S. Future of Technology Commission; University of Pennsylvania Law School; Washington University Law School; Cambridge University Law School; multiple NASEM conferences (AI, federally funded research); Northwestern Kellogg School of Management; USC IP Institute

RECENT ADMINISTRATIVE SERVICE

ABA Administrative Law Section Council (2020-present)

Duke Law Laterals Appointment Committee, Chair and/or Member (2015-2019; 2021-Present)

Oversight Committee, Duke Office of Translation and Commercialization (2017-2021)