

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

## RECENT EMPLOYMENT

2008-Present

### DUKE LAW SCHOOL

Elvin R. Latty Distinguished Professor

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

- Principal Investigator, Arnold Ventures grant on drug manufacturing processes, patents, standardization, and access (2024-2025)
- Principal Investigator, Arnold Ventures grant on innovation incentives and drug pricing (2020-2021)
- Principal Investigator, Greenwall Foundation grant on innovation and accountability in health-related machine learning software (2019-2020)

Core Faculty, Duke-Margolis Institute for Health Policy

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

3/2021-12/2021

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

Senior Advisor

- Advised on 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)

Consultant, White House Office of the National Cybersecurity Director (2024)

Consultant, Administrative Conference of the United States (2021-2022)

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, NSF and Kauffman Foundation 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 National Academies studies; National Institutes of  
Health/National Human Genome Research Institute study sections; top 10 law reviews

## ARTICLES

*Molecular Diagnostics Patenting After Mayo v. Prometheus: An Empirical  
Analysis*, 23 JOURNAL OF EMPIRICAL LEGAL STUDIES \_\_\_\_ (2025) (forthcoming)

*Introducing Biosimilar Competition for Cell And Gene Therapy Products*, 11  
JOURNAL OF LAW & THE BIOSCIENCES (2024) (with co-authors)

*Four Decades of Orphan Drugs and Priorities for the Future*, 391 NEW  
ENGLAND JOURNAL OF MEDICINE 100 (2024)

*Access to Biomedical Innovation: Inside the Legal Labyrinth*, 388 NEW  
ENGLAND JOURNAL OF MEDICINE 1537 (2023)

*Cryptic Patent Reform Through the Inflation Reduction Act*, 37(1) HARVARD  
JOURNAL OF LAW & TECHNOLOGY 1 (2023) (with  
Nicholson Price and Rachel Sachs)

*Orange Book Over-Declaration Of Pharmaceutical Patents: The Advantages Of  
Ex Ante Over Ex Post Review*, HEALTH AFFAIRS FOREFRONT (2023) (with  
Jorge Contreras)

*Has the PTAB Made a Difference in Drug Settlements and Generic Entry*, 40(12)  
NATURE BIOTECHNOLOGY 1569 (2022) (with Erik Hovenkamp, Jorge Lemus,  
and Saurabh Vishnubhakat)

*Post-Grant Adjudication of Drug Patents: Agency and/or Court*, 36 BERKELEY  
TECHNOLOGY LAW JOURNAL 139 (2022) (with Saurabh Vishnubhakat, Jorge  
Lemus, and Erik Hovenkamp)

*An Administrative Fix for Manufacturing Process Patent Thickets*, 39(1) NATURE  
BIOTECHNOLOGY 20 (2021) (with W. Nicholson Price II)

*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)

*Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 SCIENCE 912

(2020) (with W. Nicholson Price II and Timo Minssen)

*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 InformationTechnology 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 Uhler, 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 21<sup>st</sup> 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)

## MONOGRAPHS

**TRUST BUT VERIFY: INFORMATIONAL CHALLENGES SURROUNDING AI-ENABLED CLINICAL DECISION SOFTWARE** (2020) (Duke Law Center for Innovation Policy and Duke-Margolis Institute 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 Institute 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)

## BOOK CHAPTERS

*Patent Institutions* in RESEARCH HANDBOOK ON THE LAW AND ECONOMICS OF INTELLECTUAL PROPERTY, VOLUME I: 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 21<sup>ST</sup> 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, 3<sup>rd</sup> 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

*What does ‘bona fide competition’ actually mean in the biologics market?* STAT First Opinion, September 6, 2023

*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)

## **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
- Focused on administrative law. Briefed and argued cases involving  
the Administrative Procedure Act, Federal Advisory Committee Act, Medicare, and  
Medicaid.
- 1992-1994           **JENNER & BLOCK, Washington D.C.**  
Associate
- Wrote briefs in U.S. Supreme Court cases as well as federal appellate and district  
court cases. Focused on patent litigation.
- 1991-1992           **JUDGE MARILYN HALL PATEL, UNITED STATES DISTRICT COURT FOR THE  
NORTHERN DISTRICT OF CALIFORNIA, San Francisco, CA**  
Law Clerk
- Drafted opinions on cases, including numerous patent cases.

**SELECTED LECTURES AND PRESENTATIONS, 2019-2024** (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; 2021-2023)

Oversight Committee, Duke Office of Translation and Commercialization (2017-2021; 2023-present)