Arti K. Rai

Elvin R. Latty Professor
Faculty Director, Center for Innovation Policy
Duke Law School
Faculty, Duke-Margolis Center for Health Policy

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EDUCATION

HARVARD LAW SCHOOL, J.D., *cum laude*, 1991
Best Brief and Team, Harvard (Ames) Moot Court Competition
Instructor, first-year Legal Methods course

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 link between apolipoprotein E2 homozygosity and retinitis pigmentosa (resulted in publication)

SELECTED GRANTS/HONORS

Principal Investigator, Greenwall Foundation award to study intersection of trade secrecy and explainability in AI-enabled health care delivery (2019)
Co-Investigator, Kauffman Foundation Award to study decline in U.S. research investment (2016-2018)
Faculty, Duke-Margolis Center for Health Policy (2016-present)
Duke Innovation and Entrepreneurship Research Fellow (2015-present)
Principal Investigator, National Institutes of Health research grant to study "genomics as information" (2010-2015)
Principal Investigator, National Institutes of Health/Department of Energy research grant to study collaborative R&D models in genomics research (focus on bioinformatics and 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, National Advisory Council on Human Genome Research (2012-2016)
Member, American Law Institute (2013-present)
Public Member, Administrative Conference of the United States (2013-2017)

Member, Institute of Medicine Committee, Strategies for Responsible Sharing of Clinical Study Trial Data (2013-2015)
Member, Institute of Medicine Committee, Countering the Problem of Falsified and Substandard Drugs (2012)
Referee (selected journals): SCIENCE; RESEARCH POLICY; MANAGEMENT STUDIES; HEALTH AFFAIRS; JOURNAL OF LEGAL STUDIES; NEW ENGLAND JOURNAL OF MEDICINE; National Academy of Sciences studies on patent system reform and IP rights in genomics and proteomics; National Institutes of Health/National Human Genome Research Institute study sections

EMPLOYMENT

2008-Present **DUKE LAW SCHOOL**
Elvin R. Latty Professor
Faculty Director, Duke Law Center for Innovation Policy (2013-present)
Faculty, Duke-Margolis Center for Health Policy

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 PTO 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.

MONOGRAPHS **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 AND ESSAYS *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)

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

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

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)

COMMENTARIES

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)

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

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)

ADMINISTRATIVE LEADERSHIP POSITIONS (SELECTED)

Co-chair, ABA, Administrative Law Section, Intellectual Property Committee (2007-present)
Chair, Duke University Patent Policy Committee (2008-2009)
Member, Duke Office of Licensing Ventures (OLV) Board (2016-present)
Chair, Duke Law Lateral Appointments Committee (2016-2017); Member (2011-present)