Abstracts of papers presented
at the special Cold Spring Harbor Laboratory
conference on Patenting in the Life Sciences

GENES & DIAGNOSTICS: A MYRIAD OF ISSUES IN BIOTECH IP

March 10–March 13, 2013

Cold Spring Harbor Laboratory
Cold Spring Harbor, New York

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GENES & DIAGNOSTICS: A MYRIAD OF ISSUES IN BIOTECH IP

March 10–March 13, 2013

Arranged by

Salim Mamajiwalla, *In(sci)te IP, Markham, Canada*
Rochelle K. Seide, *RKS Consulting, Boca Raton, Florida, USA*

Cold Spring Harbor Laboratory
Cold Spring Harbor, New York

Generous support for this conference provided by:

- **Bereskin & Parr LLP**
- **Baker Botts LLP**
- **Biotechnology Industry Organization (BIO)**
- **Genentech**
- **Jones Day**

Cover: DNA double helix sculpture on the grounds of Cold Spring Harbor Laboratory (Charles Jencks).

Special CSHL Conference on Patenting in the Life Sciences

GENES & DIAGNOSTICS:
A MYRIAD OF ISSUES IN BIOTECH IP

Sunday, March 10 – Wednesday, March 13, 2013

Sunday	1:30 pm	*Optional Pre-Conference Workshops* **IP101** and **BIOTECH101**
Sunday	7:30 pm	*Welcome, Introduction and Overview* **Keynote Address**
Monday	9:00 am	**Session 1:** Patenting Genes and Diagnostics: The Judiciary's View
Monday	1:00 pm	**Session 2:** A Global Perspective on Patentable Subject Matter, Patentability, and Enforceability
Monday	5:00 pm	Concert
Monday	7:30 pm	**Special Evening Session:** Patenting and Biotechnology at Cold Spring Harbor Laboratory
Tuesday	9:00 am	**Session 3:** Are Gene and Diagnostic Patents a Hindrance or Help to Industry?
Tuesday	2:00 pm	**Session 4:** The Impact of Prometheus on Personalized Medicine
Tuesday	5:30 pm 6:30 pm	Cocktails Banquet
Wednesday	9:00 am	**Session 5:** Patenting Genes and Diagnostics: Policy and Ethics
Wednesday	12:15 pm	**Session 6:** Where to Next?

Mealtimes at Blackford Hall are as follows:

Breakfast 7:30 am-9:00 am
Lunch 11:30 am-1:30 pm
Dinner 5:30 pm-7:00 pm
Bar is open from 5:00 pm until late

Printed on 100% recycled paper.

PROGRAM

SUNDAY, March 10—1:30 PM

PRE-CONFERENCE WORKSHOPS

IP 101: Aimed at scientists, entrepreneurs, venture capitalists, and investors

Tom Irving
Finnegan Henderson LLP, Washington DC

BIOTECH 101: Aimed at patent practioners, venture capitalists, and investors

Cold Spring Harbor Scientists

SUNDAY, March 10—7:30 PM

Welcoming Remarks

Bruce Stillman
President of Cold Spring Harbor Laboratory

INTRODUCTION AND OVERVIEW

Salim Mamajiwalla
In(sci)te IP, Markham, Canada

Rochelle K. Seide
RKS Consulting, Boca Raton, Florida

KEYNOTE ADDRESS

Timothy Caulfield
Faculty of Law, University of Alberta, Edmonton, Canada

"Reexamining the promise and perils of personalized medicine—Patents and beyond" 1

MONDAY, March 11—5:00 PM

CONCERT
Grace Auditorium

MONDAY, March 11—7:30 PM

SPECIAL EVENING SESSION:

PATENTING AND BIOTECHNOLOGY at
COLD SPRING HARBOR LABORATORY

Chairperson: **Salim Mamajiwalla,** In(sci)te IP, Markham, Canada

TUESDAY, March 12—9:00 AM

SESSION 3: ARE GENE AND DIAGNOSTIC PATENTS A HINDRANCE OR HELP TO INDUSTRY?

Chairperson: **Michele Wales,** Human Genome Sciences, Rockville, Maryland

Panel – follow up discussion of session

TUESDAY, March 12—2:00 PM

SESSION 4: THE IMPACT OF PROMETHEUS ON PERSONALIZED MEDICINE

Chairperson: **Warren Woessner,** Schwegman Lundberg Woessner LLP, Minneapolis, Minnesota

Panel – Follow up discussion of session

TUESDAY, March 12—5:30 PM

BANQUET

Cocktails 5:30 PM Dinner 6:30 PM

Timothy Caulfield, Canada Research Chair in Heath Law and Policy; Professor, Faculty of Law and School of Public Health; Research Director, Health Law and Science Policy Group, University of Alberta, Edmonton, Canada

Timothy Caulfield is a Canada Research Chair in Health Law and Policy and a Professor in the Faculty of Law and the School of Public Health at the University of Alberta. He was the Research Director of the Health Law Institute at the University of Alberta from 1993 to 2011 and is now leading the Faculty of Law's Health Law and Science Policy Group (HeaLS). Over the past several years he has been involved in a variety of interdisciplinary research endeavours that have allowed him to publish over 250 articles and book chapters. He is a Health Senior Scholar with the Alberta Heritage Foundation for Medical Research and the Principal Investigator for a number of large interdisciplinary projects that explore the ethical, legal and health policy issues associated with a range of topics, including stem cell research, genetics, patient safety, the prevention of chronic disease, obesity policy, the commercialization of research, complementary and alternative medicine and access to health care. Professor Caulfield is and has been involved with a number of national and international policy and research ethics committees, including Canadian Biotechnology Advisory Committee, Genome Canada's Science Advisory Committee, and the Federal Panel on Research Ethics. He is a Fellow of the Royal Society of Canada and the Canadian Academy of Health Sciences. He writes frequently for the popular press and is the author of *The Cure for Everything: Untangling the Twisted Messages about Health, Fitness and Happiness.*

THE VALUE PARADOX: REEXAMINING THE PROMISE AND PERILS OF PERSONALIZED MEDICINE

Much has been made about the potential to use genomic information to personalize treatment and prevention. While the area has great promise, the limitations of the field, particularly in the context of public health and the preventions of common chronic diseases, are often underplayed. Indeed, while the popular press continues to refer to the personalized medicine as a "revolutionary" approach, significant scientific and translation challenges remain. This reality has implications for both the value of personalized medicine to the improvement of population health and the nature and severity of the related legal, ethical and social issues (ELSI). In this presentation, I will outline some of the key challenges associated with personalized medicine. I will argue that the scientific and clinical limitations of the field necessitate a re-thinking of the key ELSI concerns, including 1) the application of patent law; 2) the idea that genetic information is uniquely sensitive; and 3) concept of genetic discrimination.

Honourable Ian Binnie, Lenczner Slaght LLP, Toronto, Canada

One of Canada's most respected advocates, the Honourable Ian Binnie served for nearly 14 years as a Justice of the Supreme Court of Canada. When he retired in 2011 he was described by The Globe and Mail as "*arguably the country's premier judge*" and by La Presse as "*peut-être le juge le plus influent au Canada dans la dernière décennie*."

During his time on the country's top court (as only the second modern Justice appointed directly from the bar) Ian authored more than 170 opinions, including on landmark cases involving issues of patent interpretation and validity, protection of trade-marks, media law, commercial disputes, punitive damages, expert evidence and many aspects of constitutional, criminal and administrative law. Almost a third of the Supreme Court docket in a typical year comes from Quebec, of which about 30% engage in the Quebec Civil Code (the others being criminal and other public law cases). Accordingly, the judges of the Court work in both official languages and, on a day-to-day basis, in the civil law system as well as the common law.

In his role as Counsel with Lenczner Slaght, Ian shares strategic and practical advice, as well as his dispute resolution expertise, with his colleagues and the firm's clients. In doing so he draws not only on his judicial insights, but also his wealth of courtroom experience as one of Canada's top litigators. Over the course of three decades, he argued cases in most of the common law provinces and appeared regularly before the Supreme Court on a range of constitutional, civil and criminal matters.

Throughout his career as a litigator, Ian has often taken on public service roles as well. In the early 1980s he served for four years as Canada's Associate Deputy Minister of Justice. He was later appointed Special Parliamentary Counsel to the Joint Committee of the Senate and the House of Commons on the Meech Lake Accord. An elected member of the International Commission of Jurists, he has appeared before the International Court of Justice and various international tribunals in governmental litigation matters, and has acted as Canadian representative in high-profile disputes involving France and the U.S.

The U.S. Supreme Court will soon decide whether genes are patent-eligible inventions or mere "products of nature", and, like the heat of the sun and the quality of metals, are not eligible for patent protection. In *Myriad Genetics*, now on appeal, the Court of Appeals for the Federal Circuit tied itself in quasi-scientific knots to characterize the "invention". Is isolating DNA from a genome more like genetically modifying bacteria, converting tungsten oxide to pure tungsten, or snapping a leaf from a tree? When Thomas Jefferson wrote out the definition of patent-eligible subject matter in the United States *Patent Act* in 1793, he cannot have imagined such arcane debates.

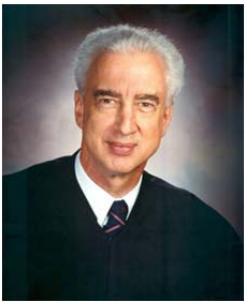
Navigation of the difficult terrain between "product of nature" and invention requires a solid understanding of the underlying science. Are courts properly equipped to deal with the subject matter? The medical research industry says it needs gene patents to sustain the costs of bringing new medicines to market, but what are the public, researchers and downstream inventors actually getting in exchange for the grant of the patent monopoly? This speech will discuss from a legal perspective the implications of privatizing the rights to life's instruction book.

Honourable Mr. Justice Sir Richard Arnold, High Court Patents, England & Wales

The Hon Mr Justice (Richard) Arnold was called to the Bar of England and Wales in 1985 and became a QC in 2000. At the Bar he specialised in intellectual property law, entertainment and media law and information technology law. He was Chairman of the Code of Practice for the Promotion of Animal Medicines Committee from 2002 to 2008, an Appointed Person hearing trade mark appeals from 2003 to 2008 and a Deputy High Court Judge from 2004 to 2008. He was appointed to the High Court, Chancery Division in October 2008. He is the author of *Performers' Rights* (4th ed, Sweet & Maxwell, 2008), the editor of the *Halsbury's Laws* title on trade marks (4th ed, Butterworths, 2007 reissue), was editor of *Entertainment and Media Law Reports* from 1993 to 2004 inclusive and has published numerous articles in legal journals.

RECENT EUROPEAN AND ENGLISH CASE LAW ON PATENTING GENES AND DIAGNOSTICS

This talk will survey recent European and English case law on patenting genes and diagnostics, with particular attention to the decision of the UK Supreme Court in *Human Genome Sciences Inc v Eli Lilly and Co*.



Honourable Paul R. Michel, Chief Circuit Judge (Ret.)

Paul R. Michel was appointed to the United States Court of Appeals for the Federal Circuit in March of 1988. On December 25, 2004, he assumed the duties of Chief Judge. After his elevation to Chief Judge, he served as one of 27 judges on the Judicial Conference of the United States, the governing body of the Judicial Branch. In 2005 he was appointed by Chief Justice Rehnquist to also serve on the Judicial Conference's seven-judge Executive Committee. On May 31, 2010, Chief Judge Michel stepped down from the bench after serving more than 22 years on the court.

In his years on the bench Judge Michel judged thousands of appeals and wrote over 800 opinions, approximately one-third of which were in patent cases. Prior to his appointment to the bench, Judge Michel served in the executive and legislative branches for 22 years. Following graduation from Williams College in 1963 and the University of Virginia Law School in 1966, Michel served as Assistant District Attorney and then Deputy District Attorney for Investigations under Arlen Specter in Philadelphia; as Assistant Special Watergate Prosecutor in 1974-1975; from 1975 to 1976 he was an assistant counsel for the Senate Select Committee on Intelligence; from 1976-1978, he served as Deputy Chief of the Justice Department's Public Integrity Section, where he directed the "Koreagate" investigation; in 1978 he was appointed as an Associate Deputy Attorney General; in 1980 he served as Acting Deputy Attorney General; and from 1981 until 1988, he served on Senator Arlen Specter's staff, including as Counsel and Chief of Staff.

Judge Michel has been named one of the 50 Most Influential People in the world in intellectual property by *Managing Intellectual Property* magazine. In 2008 Chief Judge Michel was awarded the first annual Lifetime Achievement Award by the Richard Linn American Inn of Court; the Sedona Conference Lifetime Achievement Award; the first "Outstanding Achievement in the Area of Intellectual Property Law" award given by the Philadelphia Intellectual Property Law Association; and the annual Judicial Honoree Award by the Bar Association of the District of Columbia. In 2010 he received the U.S. Patent and Trademark Offices' Federico Award for "outstanding contribution to the Patent and Trademark Systems of the United States of America"; the North American Lifetime Achievement Award by *Managing Intellectual Property* Magazine; the Distinguished Intellectual Property Professional Award from the Intellectual Property Owners Education Foundation; the career achievement award of the American Intellectual Property Law Association (AIPLA); and was one of five global figures inducted into *Intellectual Asset Management* magazine's Intellectual Property Hall of Fame. He has been a Member of Honor of FICPI since 2001.

Since retiring from the court, Judge Michel continues to share knowledge gained during his 22 years on the court by speaking out on issues related to the courts and the patent system. He also provides mediation, arbitration, and case evaluation services to private clients.

Judge Michel is also serving as an advisor to a number of organizations. In June 2010, Judge Michel was elected a member of the Board of Directors of the Intellectual Property Owners (IPO) Education Foundation and became a Distinguished Scholar in Residence there. He also serves as Special Advisor to the Patent Reform Task Force and the Council of the Section on Intellectual Property of the American Bar Association, and is a member of the AIPLA Committee on Public Appointments. Most recently he was invited to join the Advisory Committee of the World Intellectual Property Organization's Networked Innovation project and the Advisory Committee of the Manufacturing Initiative of the U.S. Council on Competitiveness.

Dr. Laura Coruzzi, Partner, Jones Day

Dr. Laura Coruzzi has represented clients in biotechnology and pharmaceuticals for close to 30 years. Prior to joining Jones Day, she practiced at Pennie & Edmonds LLP and was one of the first members of that firm's biotechnology group founded by S. Leslie Misrock, affectionately known as the "father of biotechnology patent law." Laura's practice has evolved with the patent laws and matured with the needs of the biotechnology and pharmaceutical industries. Her practice involves all aspects of patent law as it relates to a variety of disciplines in the life sciences, including genetic engineering, molecular biology, virology, vaccines, immunology, therapeutic antibodies, biologic and small molecule therapeutics, diagnostics, drug discovery, and drug delivery.

Laura's patent procurement practice focuses on strategic planning and management of patent portfolios designed to protect emerging new technologies as well as mature biologic and pharmaceutical therapeutics and diagnostics. She counsels clients on portfolio evaluation, due diligence investigations, patent prosecution and interferences, European oppositions, and licensing. Laura's practice also encompasses patent litigation and appeals before the USPTO Board of Appeals and the Federal Circuit. She is a member of the Jones Day team representing Myriad in *Association for Molecular Pathology v. Myriad Genetics* (2011) upholding the patent-eligibility of isolated human genes. Prior to joining Jones Day, she and her team won reversal of an $18 million jury verdict in 2000 for Cadus Pharmaceutical Corporation in a case involving cell-based assays for drug screening.

Jennifer Gordon, Baker Botts L.L.P., New York, New York

Jennifer Gordon is a partner in the New York of office of Baker Botts L.L.P. and head of the firm's Life Sciences Intellectual Property practice. For over 30 years, the focus of her practice has been biotechnology patent litigation, counseling and procurement. Her cases have involved stem cell technologies, nucleic acid amplification technologies (PCR), recombinantly-produced proteins (including antibodies, immunoadhesins, enzymes and hormones), animal vaccines, other biologics, pharmaceuticals and medical diagnostics. She has appeared before United States Federal District Courts and the U.S. Court of Appeals for the Federal Circuit. She has also participated in oppositions and trials in Europe, Japan, Australia and India.

Dr. Gordon is a graduate of the Massachusetts Institute of Technology, where she was awarded an S.B. degree in Life Sciences in 1975 and a Ph.D. degree in Biochemical Engineering in 1981. She attended Fordham University School of Law where she graduated with a J.D. degree, *cum laude*, in 1985.

PATENTING GENES, BIOMARKERS AND CORRELATION-BASED METHODS: THE EVOLVING U.S. LEGAL LANDSCAPE

After decades of patenting all kinds of biological subject matter, including isolated DNA molecules, highly purified proteins and diagnostic methodologies based on natural correlations, we are now witnessing unprecedented--and sometimes successful--challenges to such patents on eligibility grounds. Surprisingly, 35 U.S.C. § 101 has become a potent weapon against life science-related patents, particularly medically-related ones. Recent developments in case law, including the U.S. Supreme Court's keen interest in this area, will be discussed, as will the way forward.

Dr. Malathi Lakshmikumaran, Lakshmikumaran & Sridharan Attorneys, New Delhi, India

Dr. Malathi Lakshmikumaran has more than 25 years of experience in the field of Plant Molecular Biology. She has expertise in plant genomics, DNA fingerprinting and genetic transformation. She has successfully supervised several Ph.D. students in the area of Plant Molecular Biology. She has more than 100 publications to her credit in various International and Indian journals.

At present, she is working in the IP division of the law firm Lakshmi Kumaran & Sridharan. She is actively engaged in preparing, filing and prosecution of Patent Applications, both in India and abroad. She is mainly working on biotechnological, pharmaceutical patent applications and is also involved in plant variety protection. She is also actively involved in the area of Traditional knowledge. She has delivered several seminars on IPR issues at different forums such as National Law School University of India, MSSRF, TERI, TIFAC, AUSBIOTECH, Indian Patent Office, CII, and FICCI etc. She has several publications on IP.

Dr. Malathi has been a high achiever througout her academic life.

- She was awarded the NTSE Scholarship and was the Science Talent Fellowship Holder from Graduate to Doctoral Level for the years 1972-1980.
- She was awarded the UNESCO fellowship as a visiting scientist for three months in 1992 at University of Perpignan, France in the laboratory of Dr. Michel Delseny
- She was awarded the best ongoing and completed project by DST Committee on Plant Sciences in 1990 and 1991 on the project entitled "Genome organisation and RFLP studies in Brassica"
- She was also awarded the First National Women Bioscientist Award in March 2000 by the Department of Biotechnology
- Dr. Malathi conducted her research in the area of Plant Molecular Biology. She has worked on assessment of genetic diversity of 'amla', *Brassica*, poplars, 'neem', tea and *Withania* using RAPD, ISSR and AFLP markers. She has also worked on cloning and characterisation of repetitive elements in poplars and *Brassica.*
- She was recognized as a guide for MSc and PhD students by the Poona University. She has successfully supervised 10 PhD students in Plant Molecular Biology.
- She has worked as an expert on the award panels of Jawaharlal Nehru Award by ICAR and DBT Overseas Fellowship
- She has served as an expert member on DBT Task Force on Biodiversity in 1994.
- She was an expert member of DBT Task Force on Women and Rural Development (1997-2000)
- She is an expert member of DBT Task Force on Plant Biotechnology (2000 – till date)
- She is also an expert member of DST Task Force on Women in Science (2006 –To date)

Micheline Gravelle, Bereskin & Parr L.L.P., Toronto, Canada

Micheline is a partner with Bereskin & Parr and heads the firm's biotechnology and pharmaceutical practice group.

Micheline is a patent agent registered to act before the Canadian and United States Patent Offices. Micheline has B.Sc. in Biochemistry and an M.Sc. in Immunology. Her practice includes including assessing new technologies, preparing and prosecuting patent applications worldwide and conducting due diligence analysis on patent portfolios.

Micheline is consistently ranked by the Canadian Legal Lexpert Directory as a leading biotechnology practitioner and is listed in the IAM Patent 1000- The World's Leading Patent Practitioners and the Lexpert/American Lawyer Guide to the Leading 500 Lawyers in Canada.

PATENTING GENES AND DIAGNOSTIC METHODS IN CANADA

This session will explore the patentability of genes and diagnostic methods in Canada. The session will include a discussion on whether genes and diagnostic methods are considered patent eligible subject matter based on recent court decisions as well as Patent Office guidelines. The session will also discuss the scope of claims currently being issued by the Canadian Patent Office and the level of support needed to obtain such claims. The session will also address the scope and status of the Canadian Myriad and Prometheus patents.

Friederike Stolzenburg, Vossius & Partner, Munich, Germany

After completing her studies of biology at the Julius Maximilian University of Würzburg, Dr. Friederike Stolzenburg received her doctorate at the Institute of Biochemistry in the field of DNA replication in mammalian cells. She was then awarded a research fellowship sponsored by the European Community at the "Service de Biochimie et Génétique Moléculaire" in the Centre D'Etudes de Saclay in Paris in the field of RNA polymerases of Saccharomyces cerevisiae. From 1993 to 1995, she was employed by the research institution "Institut für Genbiologische Forschung Berlin", which was specialized in plant biotechnology, where she dealt with patent applications. In 1995, she joined the firm of VOSSIUS & PARTNER and she was admitted to practice as a European Patent Attorney in 1997, and as a German Patent Attorney (Patentanwalt) and European Trademark Attorney in 1999. Dr. Stolzenburg is a partner in the firm of VOSSIUS & PARTNER since 2000. She handles prosecution and opposition cases concerning biotechnological inventions at the European Patent Office as well as nullity and litigation cases before the national German courts.

DNA INVENTIONS AND DNA-BASED DIAGNOSTICS: THE EUROPEAN PERSPECTIVE

The presentation will address issues regarding patentability, validity and enforceability of patents relating to DNA inventions and DNA-based diagnostics from a European perspective, in particular the practice at the European Patent Office (EPO). In general, the European Patent Office has a rather liberal attitude as regards the patentability of DNA inventions and DNA based diagnostics and, thus, (so far) allows obtaining protection for basically every aspect in this field. The talk will provide an overview over the history, typical cases, examples for possible claims and the limits of obtaining protection for DNA related inventions at the EPO and their enforceability.

Jan Witkowski, Ph.D.

Jan Witkowski is the Executive Director of the Banbury Center at Cold Spring Harbor Laboratory (CSHL) and a Professor in the Watson School of Biological Sciences, the graduate school program at CSHL. The Banbury Center is a small conference center that holds scientific meetings recognized internationally as being amongst the world's best discussion workshops for topics in molecular biology, molecular genetics, human genetics, neuroscience, and science policy (http://www.cshl.edu/banbury).

Dr. Witkowski was educated at Handsworth Grammar School in Birmingham, UK, obtained his B.Sc. in Zoology at the University of Southampton, UK, and earned his Ph.D. in biochemistry at the National Institute for Medical Research, London, UK. He carried out postdoctoral research on Duchenne muscular dystrophy at the Royal Postgraduate Medical School, Hammersmith Hospital, London, as well as at the Mayo Clinic in Minnesota. In 1984, Dr. Witkowski moved to the Imperial Cancer Research Fund in London to pursue research on oncogenes. In 1986, he was invited to join the Institute for Molecular Genetics at the Baylor College of Medicine in Houston, where he ran a laboratory performing DNA-based diagnosis of human genetic diseases.

Dr. Witkowski moved to his present position at Cold Spring Harbor Laboratory in 1987. As director of the Banbury Center, he is responsible for the organization of some twenty scientific meetings each year. Dr. Witkowski is also an editor on the *Image Archive on the American Eugenics Movement* and *DNA from the Beginning* projects. Dr. Witkowski is on the Faculty of the Watson School of Biological Sciences, a former member of its Executive Committee (1999-2004), and a former instructor of the Scientific Ethics and Exposition course. He is a member of the Scientific Advisory Council of the James A. Baker Veterinary Research Institute (Cornell University) and Editor-in-Chief of the journal *Trends in Biochemical Sciences.*

Dr. Witkowski's special interests are human molecular genetics, the interaction of science and society, and the history of modern experimental biology. He has published many papers on these topics and was a co-author with Dr. James D. Watson, co-discoverer of the DNA double helix, of the second and third editions of the textbook *Recombinant DNA.* Most recently, he was co-editor with Alex Gann of a new edition of Watson's classic book *The Double Helix;* Witkowski and Gann have added over 250 illustrations, a similar number of annotations, five appendices, and an index to create *The Annotated and Illustrated Double Helix (Simon & Schuster, November 2012).*

Pavel Osten, M.D., Ph.D.

Pavel Osten is an Associate Professor of Neuroscience at Cold Spring Harbor Laboratory (CSHL) and a founder of the drug screening company Certerra, Inc., currently located in Cold Spring Harbor, New York.

Born in Czechoslovakia, Dr. Osten received his M.D. from Charles University in Prague. After moving to the United States, he obtained a Ph.D. in neurophysiology from the State University of New York in Brooklyn, and he trained in molecular neurobiology with Dr. Edward Ziff at New York University. In 1999, Dr. Osten accepted a group leader position at the Max Planck Institute for Medical Research in Heidelberg, Germany, where his laboratory pioneered the use of viral vectors, *in vivo* two-photon microscopy, and *in vivo* electrophysiology in the study of cortical circuits in the rodent brain. Before coming to CSHL in 2008, Dr. Osten held an Assistant Professor position in the Department of Physiology at Northwestern University in Chicago.

Dr. Osten's research at CSHL focuses on the study of brain circuit deficits in genetic mouse models of autism and schizophrenia. Dr. Osten's laboratory has developed an automated three-dimensional microscopy called serial two-photon (STP) tomography, which enables high-resolution imaging and analysis of neural circuits in the whole mouse brain. Application of STP tomography to the study of genetic mouse models promises to identify brain circuit-based targets for the development of therapeutic approaches in autism, schizophrenia, and other cognitive disorders. Dr. Osten was the recipient of Wellcome Trust Senior Fellowship in 2005 and the McKnight Technological Innovations in Neuroscience Award in 2009.

Prem K. Premsrirut, Ph.D., Co-founder, President and CEO of Mirimus, Inc. launched in September of 2010

Dr. Premsrirut is an expert in the development and use of RNAi transgenic mice. She was an inventor of technological advancements that lead to the development of a high-throughput platform for rapid and efficient generation of conditional RNAi transgenic mice. She pioneered a novel approach for the generation of "speedy" chimeric GEMMs based on rederivation of mouse embryonic stem cells (ESCs) from existing mouse strains with a predisposition to cancer. The feasibility of her approach will transform research using GEMMs by enabling fast and flexible validation of candidate genes and drug targets in vivo.

Dr. Premsrirut received a Ph.D. in genetics following her training in the laboratory of Dr. Scott Lowe at Cold Spring Harbor Laboratory. Her work focused on the development of transgenic mouse models to study the effects of tumor maintenance on lung cancer using RNA interference. She received a B.A. in Molecular Cell Biology and Biochemistry from UC Berkeley. She previously worked in the lab of Dr. Ravi Iyengar at Mount Sinai School of Medicine, where she studied the downstream effects heterotrimeric G-proteins coupled to muscarinic, dopamine and adrenergic receptors in order to gain an understanding of the signal transduction pathways that play a role in opioid addiction and neuronal development. Dr. Premsrirut was also an MSTP fellow at Stony Brook School of Medicine, where she began her medical training

Katherine J. Strandburg, New York University School of Law

Katherine Strandburg is Professor of Law at New York University School of Law. She concentrates her teaching and research in the areas of intellectual property law and information law. She is particularly interested in understanding how the law in these areas might accommodate and reflect the importance of collaborative and emergent collective behavior. Current projects include an institutional theory of patentable subject matter, studies of medical innovation by physicians and its relationship to patenting, and a study of an NIH initiative to promote collaborative research into rare diseases.

Professor Strandburg has authored several amicus briefs to the Supreme Court and Federal Circuit Court of Appeals dealing with patent law issues. Most recently, she represented a group of medical associations in amicus briefing in the Mayo v. Prometheus case dealing with the patentability of certain medical diagnostic procedures. She spent six years in litigation practice in Chicago before entering legal academia and is licensed to practice before the United States Patent and Trademark Office.

Professor Strandburg obtained her law degree from the University of Chicago Law School with high honors in 1995 and then served as a law clerk to the Honorable Richard D. Cudahy of the U.S. Court of Appeals for the Seventh Circuit. Prior to her legal career, Professor Strandburg received a Ph.D. in physics (Cornell U. 1984) and was a physicist at Argonne National Laboratory for several years. She was a visiting faculty member of the physics department at Northwestern University from 1990-1992.

GENE AND DIAGNOSTIC PATENTS AT THE INTERFACE BETWEEN INDUSTRY, ACADEMIA, AND MEDICAL PRACTICE

This presentation will discuss the roles and contributions of industry, academic and nonprofit scientists, and medical practitioners as providers and innovators in medical diagnostics. I will argue that gene and diagnostic patents are not simply means of technology transfer, but play a larger role in determining the characteristics of the commercial enterprises that develop at the boundaries of academic research and medical practice and in shaping interactions between industry, academia, and the medical profession. Moving the line between patentable and unpatentable subject matter, for example, shifts the focus of commercialization activity. If genetic sequences patentable, business models arise to exploit exclusive rights in those sequences. If they are not patentable, different business models will arise. In this sense, the question is not whether gene and diagnostic patents are a hindrance or help to industry, but what kind of industry (and what kind of academic research and medical practice) develops in the presence (or absence) of such patents.

Michele Wales, founder, InHouse Patent Counsel

Michele is the founder and principal of InHouse Patent Counsel. Before starting InHouse Patent Counsel, Michele was the department head of Litigation and Intellectual Property at Human Genome Sciences (HGS). She created and managed all aspects of HGS' extensive IP portfolio in the U.S. and abroad, which had been repeatedly recognized by the Wall Street Journal as one of the "Top 10 Biotech Portfolios" in the industry and covered over 10,000 human genes, proteins and antibodies. She was at HGS from the beginning when their focus was solely on patent protection. As the company progressed, she participated in the drug development process of multiple lead clinical candidates and was involved in bringing HGS' first approved drug to market.

At HGS she also directed all phases of HGS' litigations and internal investigations, developed cross- functional processes, and evaluated numerous third party portfolios, freedom to operate analysis and litigation risks. Notably, she successfully managed the team that established the Utility Standard for gene based patents at the United Kingdom's Supreme Court and the European Patent Office. This team was also nominated in 2012 by the International Law Office as "In-House Litigation Team of the Year."

With experience running one of the most complex genomic portfolios in the biotech industry, Michele has an invaluable understanding of how a biotech company works. She also understands how to work with large pharmaceutical companies and how to match IP protection with a company's business needs. She can readily help a company license, enforce licensing provisions and evaluate product and M&A due diligence. She can analyze freedom to operate risks on complex third party biotechnology portfolios and develop and implement strategies to minimize potential litigation and present this analysis to a company's board of directors. When avoidance of litigation is not possible, Michele can develop successful litigation strategies consistent with a company's business needs and effectively manage teams to carry out those strategies.

PATENTS ENCOURAGE INNOVATION IN BIOTECHNOLOGY

One of the reasons that the United States is the global leader in biotechnology is for its strong patent system. Even Abraham Lincoln recognized that patents "added the fuel of interest to the fire of genius." A patent encourages innovation by rewarding inventors who obtain a patent with the legal right, for a limited time, to exclude others from copying the invention and selling it themselves but only if the inventor first discloses the invention to the public.

New biological therapeutics typically takes over ten years from discovery to market. The average cost of bringing a biological product to market exceeds $1.2 billion dollars, after considering costs for preclinical research, clinical trials, and post-approval testing. Moreover, not every product makes it. For every successful therapeutic, numerous candidate therapeutics fail, often only after large investments of time and capital have been made. If failures are included in drug development costs, then the costs associated for bringing a single drug to market can be as much as $4 billion dollars.

In light of the clear risk in drug development, raising the necessary funds to support biotechnology research and development requires the expectation that reasonable financial returns will flow from those therapeutics that do indeed make it to market. Human Genome Sciences is an example of a company initially funded on such an expectation. Without the ability to patent human products, HGS would not have been able to bring to market, after failing with other products, the first Lupus approved drug in 50 years.

John T. Aquino, Esq., Legal Editor, Life Sciences Law Industry Report, Bloomberg BNA

John T. Aquino has a B.A. and M.A. in English from the Catholic University of *America in Washington, D.C., and a J.D. from the Columbus School of Law, the Catholic University of America. He is an IP law attorney, a journalist, and* an author. He is a member of the D.C. and Maryland bars, the bars of the U.S. District Court for the District of Maryland, the U.S. Court of Appeals for the District of Columbia, and the U.S. Supreme Court, and of the National Press Club. He has been with Bloomberg BNA since 2007. He is a legal editor for its *Life Sciences Law & Industry* and *Medical Research Law & Policy Report* and has written over 800 bylined articles for BNA. His coverage includes court proceedings congressional hearings, conferences, regulatory affairs, and interviews.

TENSIONS BETWEEN IP AND BUSINESS DEVELOPMENT: LEARNING HOW TO TALK THE SAME LANGUAGE

BNA contacted intellectual property patent attorneys who work for or with life sciences companies and discussed whether or not there is a tension between IP and business development in these companies. The majority of the attorneys said that they believe there is often a tension between the business side and the intellectual property side in assessing which of its own products a company wants to market and in assessing what products developed by another company it wants to license or acquire. They suggested that the IP people tend to be focused on the IP and on the likelihood that the patent will be found valid or invalid or limited in scope by a court, while the business people may acknowledge problems with the patent but argue that patent should be pursued because the improved technology it covers fits in very well with the company's business plan. They ask if there is an acceptable risk in developing or licensing the patent, and the IP people may respond that the only acceptable risk is zero risk. These attorneys who feel there is a tension between the IP and business people suggested that there may be a linguistic tension as well as a tension that exists between the actual jobs of IP and business people. Getting the deal done is what business people do; it's how they are judged and how they are compensated. Other suggested that there is a budgetary tension, with the IP attorneys wanting to file patent applications that may be broader and deeper in scope than might appear necessary, and the business people lacking the expertise to ask if this is really worth the cost. However, some attorneys contacted by BNA felt that there really is no tension between the business and IP sides, or at least not any more. They suggested that what people describe as a tension is really the learning curve that any attorney experiences when he or she enters a new law firm or any new corporate legal environment. But whether there is a tension or it's a learning curve, there was a consensus that there is a need for and indeed evidence of a new breed of life sciences attorneys who are business-savvy and who talk in business terms, who know that the goal is to make decisions that promote the value of the business and that to advocate decisions that are the safest or the easiest may be to denigrate that value. The solution often comes down to ***compromise***. If nothing else, the company needs to obtain the freedom to operate in the particular space. If it doesn't have the freedom, that will break the deal. There was also a consensus that when academia works with life sciences companies in partnership, the mix of IP perspectives becomes even more complicated.

Jennifer Elliott, Associate General Counsel, Director of Law, Genentech, South San Francisco, California

Jennifer Elliott is an Associate General Counsel, Director of Law at Genentech in South San Francisco, leading the neuroscience intellectual property practice group. Her practice includes patent prosecution, IP diligence, providing IP guidance in business decisions, and transactional work. She was formerly an Associate at the Palo Alto office of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, and a Technical Specialist at the Boston firm Lahive & Cockfield. Jennifer received her J.D. from Stanford Law School, and her Ph.D. in Microbiology and Molecular Genetics from Harvard University, studying anthrax toxin biochemistry under R. John Collier. She is a graduate of Williams College.

It is challenging to even discuss the biotechnology industry without discussing genes. The identification, use and manipulation of genetic material have been integral to developments in most biotechnology programs. Identification of therapeutic targets, screening, improvements to production strains, and identification of patient populations all routinely involve genetic engineering and detection. Some are even exploring the use of nucleic acids themselves as therapeutics.

When some estimates place the cost of developing a single new biotech therapeutic in the billions of dollars, meaningful intellectual property protection is a business necessity for making such an investment in the first instance. But is patent protection for all aspects of gene/genetic material use during such therapeutic development necessary for such 'meaningful intellectual property protection' of the therapeutic, particularly a protein therapeutic? This talk explores one perspective on the relative importance of patent protection for genes to the business of targeted therapeutic biotechnology.

Ben Jackson, Myriad Genetics, Salt Lake City, Utah

Ben Jackson has been with Myriad for seven years, advancing from a law student clerk to his current position as Senior Director of Legal Affairs. In this role, Ben oversees Myriad's IP portfolio and a significant portion of Myriad's commercial legal matters. He is also intimately involved in Myriad's current litigation relating to the BRCA genes (often referred to as *ACLU v. Myriad*) and he co-authored Myriad's *amicus* briefs at the U.S. Supreme Court and the Court of Appeals for the Federal Circuit in *Prometheus v. Mayo*, *Akamai v. Limelight*, and *McKesson v. Epic Systems*. Ben graduated from UCLA with a bachelor's degree in microbiology, immunology, and molecular genetics and received his J.D. from the J. Reuben Clark Law School at BYU.

HOW PATENTS DRIVE INDUSTRY: ACROSS SYNDROMES AND ACROSS CONTINENTS

Patents promote innovation. This fact is the basis of all modern patent systems and, until quite recently, it was essentially unquestioned. Spurred mainly by perceived problems caused by patents in the software and e-commerce sectors, some have begun to challenge this axiom. But this opposition has expanded to sectors such as medical diagnostics, where the value and importance of patents is clear.

Originally, objections to medical diagnostic patents generally and so-called "gene patents" specifically were philosophical or even visceral ("It's just wrong"). More recently, gene patent opponents have adopted the tactics used by those who challenge software patents, arguing gene patents are not necessary to spur innovation, inhibit advances, and hurt the public.

There is no evidence that gene patents, or any other patents, have a net negative effect on the creation or delivery to patients of innovative diagnostic products. Patents present freedom-to-operate obstacles in diagnostics as in every other industry. On balance, however, gene and other patents have played a critical role in driving innovation and in delivering quality genetic diagnostic testing to patients.

Complementing the lack of evidence of negative effect is the story of BRCA testing, which, especially when compared with Lynch syndrome or when US BRCA testing statistics are compared to those for Europe, provides compelling evidence of the positive impact of patents in diagnostics. Based on the limited period of exclusivity promised by the patents, Myriad has invested hundreds of millions of dollars in developing its assays and in building medical society, physician and patient awareness and insurance coverage. Unfortunately for patients, the lack of incentives inherent in an exclusive position has meant that Lynch Syndrome and BRCA testing in Europe have lacked such a standard-bearer.

Blair Elizabeth Taylor, Ventana Medical Systems, Inc.

Dr. Blair Elizabeth Taylor is the Senior Director of Patents for Ventana Medical Systems, Inc. ("Ventana"), the headquarters for the Roche Tissue Diagnostics business unit. In this role, Dr. Taylor supervises a team of attorneys and expert support staff who craft and implement strategic plans for securing patents, trademarks and other types of intellectual property that enable Ventana and its parent company Roche to remain a market leader in the field of cancer diagnostics. Ventana's patent attorneys also evaluate the intellectual property of competitors to minimize the risks associated with launching new products. In addition, Dr. Taylor advises Ventana on licensing and enforcement matters related to intellectual property rights. Prior to joining Ventana, Dr. Taylor was in private legal practice in Washington D.C., where she gained years of experience in intellectual property matters serving as a litigator, conducting patent prosecution, and advising on transactional matters. She clerked with Judge Randall Rader of the U.S. Court of Appeals for the Federal Circuit, and currently serves that court as a member of its Advisory Council. Dr. Taylor holds a Bachelor's degree in Microbiology, a Master's degree in Chemistry, a Doctorate in Pharmacology, and a Juris Doctorate.

Ventana Medical Systems, Inc. (Ventana), headquarters for Roche's tissue diagnostics business, is one of the world's leading cancer diagnostic companies and is an innovator of tissue-based tests that enable the delivery of personalized healthcare to cancer patients. Ventana develops and manufactures medical diagnostic instruments and reagent systems that provide leading-edge automation technology for use in slide-based tissue diagnosis of cancer and infectious disease. In addition, the company offers premier workflow solutions designed to improve laboratory workflow efficiency, providing automated safeguards to enhance the quality of patient healthcare worldwide. Ventana products and solutions are used globally in the world's most advanced hospital-based histology laboratories, independent reference laboratories, medical research centers, and pharmaceutical companies. Underpinning Ventana's success is an intellectual property portfolio composed of patents, trademarks, copyrights, and trade secrets. These assets, particularly the patent portfolio, are tools that enable Ventana to maintain a robust licensing program that is a key component of companion diagnostic collaborations with partners within Roche and across the biomedical industry. The shifting landscape of what constitutes patent eligible subject matter in the United States has required Ventana to adopt a flexible approach to its business strategies, which will be explored in this discussion.

Warren D. Woessner, Schwegman, Lundberg & Woessner, P.A., Minneapolis, Minnesota

Warren D. Woessner is a registered patent attorney and a founding shareholder of Schwegman, Lundberg & Woessner, P.A. His practice focuses on chemical patent law, including biotechnology, pharmaceuticals, vaccines, medical treatments, diagnostics, and biofuels and agricultural chemistry, including related opinion and licensing matters. Warren received his B.A. in chemistry (1966) from Cornell University, his Ph.D. (organic chemistry, 1971) and his law degree (J.D., *cum laude*, 1981) from the University of Wisconsin - Madison. From 1972-1978 he worked for Miles Laboratories in new drug research. He has published and spoken widely on legal topics, was the 1993-1995 chair of the Chemical Practice Committee of the American Intellectual Property Law Association, chaired the Biotechnology Committee (2003-2005) and served two terms as a member of the Amicus Committee. He is a member of LES and a certified Licensing Professional.

BIOMARKERS—MARKING YOUR IP SPACE

Kathleen Determann, Associate General Counsel, Genomic Health, Inc., Redwood City, California.

Kathleen Determann is Vice President and Associate General Counsel at Genomic Health, Inc., a molecular diagnostics company specializing in oncology. Specifically, Genomic Health is focused on improving the quality of cancer treatment decisions through the research, development and commercialization of genomic-based clinical laboratory services. The company is an industry leader in conducting genomic research to develop clinically-validated molecular diagnostics which provide individualized information on response to certain types of therapy, as well as the likelihood of disease recurrence. Kathleen joined Genomic Health in 2008 to manage the company's increasingly complex intellectual property portfolio, including patent prosecution, litigation, and freedom to operate analyses.

Kathleen started her career as a complex commercial and intellectual property litigator. She then transitioned into IP transactions, patent prosecution, and regulatory counseling. In these roles, she has developed an understanding of the business and legal hurdles that the life sciences industry faces, including the need for an IP strategy that balances a reasonable and time-limited monopoly of certain technology (*e.g.*, patents) to allow an innovator to recoup the massive costs of R&D and commercialization of new products, with the need to share data for the benefit of patients and improvements in healthcare. This is the balance that Congress and the courts have sought to achieve through implementation and enforcement of patent laws, to greater and lesser effect. If this balance is disrupted, industry will no longer be able to support breakthrough research or ensure global patient access. Though some view certain patents and commercialization of healthcare products with suspicion, it is clear that industry, academia, and healthcare providers must all work cooperatively to continue advancing technologies, techniques, and understanding in the area of medicine.

Jeffrey N. Peterson, Target Discovery, Inc., Palo Alto, California

Jeffrey N. Peterson is the CEO of Target Discovery, Inc. (Palo Alto, CA), a Personalized Medicine Diagnostics, initially focusing on high-value cancer treatment guidance applications. TDI is developing and applying proprietary proteomics tools, to identify and leverage the "missing link" in biochemical pathway control and biomarker utility: the specific modification states of proteins (isoforms). Mr. Peterson serves as Chairman of TDI's majority-owned subsidiary company Veritomyx, Inc., developing breakthrough tools in accurate peptide, protein, isoform and metabolite identification and characterization.

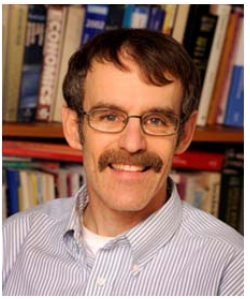
Mr. Peterson serves as Chairman of the Board of Pressure Biosciences, Inc. (OTCQB: PBIO), an innovative platform technology company utilizing extreme pressure cycling to control bio-molecular interactions, to optimize sample preparation across the range of life science R&D and diagnostic applications.

Mr. Peterson brings broad executive general management, multi-functional, multi-business and international experience to these roles. Prior to Target Discovery, he served as CEO of Sharpe, Peterson, Ocheltree & Associates, an international business development consulting firm assisting Fortune 500 and many smaller firms in business expansion and strategy. He spent 9 years in key management roles in Abbott Laboratories' Diagnostics and International (Pharmaceuticals, Hospital Products, Nutritionals, Consumer) businesses, last serving as CEO and General Manager of Abbott South Africa, where he doubled the sales and tripled the income of this 50 year-old business in 3.5 years, during the tumult of South Africa's political transition. He played an earlier pivotal management role in Abbott's successful introduction and support of multiple new diagnostics instrument and reagent systems in the history-making X-System series, including the IMx (the highest global sales diagnostic system in history).

Mr. Peterson's experience prior to Abbott included 11 years with General Electric's Engineered Materials and Plastics businesses, spanning roles in strategic planning, business development, technology licensing, marketing/sales, operations/quality and R&D. He holds BSChE and MSChE (Chemical Engineering) degrees from MIT.

Mr. Peterson is Chair Emeritus of the BayBio Institute, a non-profit organization serving the regional life science community, and serves on the Board of BayBio, the trade association for the life sciences industry in Northern California. He is a co-founder of the Coalition for 21st Century Medicine, and of BIO's Personalized Medicine & Diagnostics Group.

Mr. Peterson has lived and worked overseas for 18 years, in the Middle East, Europe and Africa. Amongst many interests outside of his profession, Mr. Peterson is Chair Emeritus of the American International School of Johannesburg. He has served on the Board and continues to assist SanGlobal Ed Corp. (dba MyVerse and Zimron), a teen and collegiate personal and professional development resource, enabled with social media on web and mobile platforms.



David B. Resnik, National Institute of Environmental Health Sciences, National Institutes of Health

David B. Resnik is a Bioethicist at the National Institute of Environmental Health Sciences, National Institutes of Health. He has an MA and PhD in philosophy from the University of North Carolina at Chapel Hill and JD from Concord University. He received his BA in philosophy from Davidson College. Dr. Resnik was an Associate and Full Professor of Medical Humanities at the Brody School of Medicine at East Carolina University (ECU) from 1998-2004, and an Associate Director of the Bioethics Center at ECU and University Health Systems from 1998-2004. Dr. Resnik was Assistant and Associate Professor of Philosophy at the University of Wyoming (UW) from 1990-1998, and Director of the Center for the Advancement of Ethics at UW from 1995-1998. Dr. Resnik has published over 200 articles on various topics in philosophy and bioethics and is the author of 8 books. He serves on several editorial boards and is an Associate Editor of the journal Accountability in Research. Resnik is also Chair of the NIEHS Institutional Review Board, which reviews and oversees research involving human participants.

DNA PATENTS AND HUMAN DIGNITY

One of the main moral arguments against patents on human DNA, including patents on DNA used as a diagnostic tool, is that they violate human dignity by treating people as property. This presentation will review these arguments against patenting human DNA. It will argue that patenting DNA does not violate human dignity because it does not treat whole human beings as property. Nevertheless, DNA patenting may threaten human dignity by partially commodifying people. However, this threat is not more significant than other threats to human dignity that most people would regard as morally acceptable, such as selling one's hair, gametes, or image, or modeling for pay.

Arti Rai, Elvin R. Latty Professor, Duke Law School and Duke Center for Public Genomics

Arti Rai, Elvin R. Latty Professor of Law, is an internationally recognized expert in intellectual property (IP) law, administrative law, and health policy. Rai has also taught at Harvard, Yale, and the University of Pennsylvania law schools. Rai's research on IP law and policy in biotechnology, pharmaceuticals, and software has been funded by NIH and the Kauffman Foundation. She has published over 50 articles, essays, and book chapters on IP law, administrative law, and health policy. She is the editor of *Intellectual Property Law and Biotechnology: Critical Concepts* (Edward Elgar, 2011), the co-author of a 2012 Kauffman Foundation monograph on cost-effective health care innovation, and the co-author of a casebook on law and the mental health system. From 2009-2010, Rai served as the Administrator of the Office of External Affairs at the U.S. Patent and Trademark Office (USPTO). As External Affairs Administrator, Rai led policy analysis of the patent reform legislation that ultimately became the America Invents Act and worked to establish the USPTO's Office of the Chief Economist. Rai studied biochemistry and history at Harvard College, was a student at Harvard Medical School, and received her law degree from Harvard Law School.

MARKETS AND MEDICINE IN A JUST SOCIETY: THE CASE OF GENETIC DIAGNOSTIC PATENTS

Medical care is a particular flash point in the combustible mixture of patents and non-market considerations confronting U.S. policymakers. The market-oriented patent jurisprudence dominant in the U.S. has a very limited vocabulary for addressing some of the non-market considerations (e.g. distributive justice, liberty) raised by biomedical patents. One typical response calls for demand-side institutions, such as a health insurance system supported in significant part by public subsidies, to address non-market considerations. Health insurance is clearly part of the answer. However, even expanded versions of these insurance subsidies may not provide a complete answer.

Professor Rai will discuss this public policy conundrum in the context of genetic diagnostic patents. Such patents raise particularly interesting questions at the public/private divide. Much of the research that has led to these patents has been publicly funded. The rationale for allowing patents on publicly funded research is that, absent such patents, and broad exclusive licensing thereof, we would not see the private sector investing in the further development necessary to translate the research into commercial products. For diagnostic testing, this rationale is less ironclad that in other contexts. For example, exclusive licenses could be restricted to sales of diagnostic kits, thereby preserving opportunities for in-house and research use. In fact, in statements like "In the Public Interest: Nine Points to Consider in Licensing University Technologies," many academic institutions have themselves recognized these principles. The problem is adherence by outliers and also the legacy of past licensing practices.

Richard Gold, Professor, Faculty of Law, McGill University, Montreal, Canada

Dr. Richard Gold is a James McGill Professor at McGill University's Faculty of Law where he was the founding Director of the Centre for Intellectual Property Policy. He teaches in the area of comparative intellectual property and innovation. His research centers on the nexus between innovation, development and commerce, with an emphasis on the life sciences. Professor Gold has provided advice to Health Canada, Industry Canada, the Canadian Biotechnology Advisory Committee, the Ontario Ministry of Health and Long-Term Care, the Organisation for Economic Cooperation and Development (where he was the lead author of the OECD Guidelines on the Licensing of Genetic Inventions and a report on Collaborative Mechanisms in Life Science Intellectual Property), the World Health Organization, the World Intellectual Property Organization and UNITAID. His research has been published in high-impact journals in science, law, philosophy and international relations including Nature Biotechnology, The Lancet, PLoS Medicine, the McGill Law Journal, Public Affairs Quarterly and the European Journal for International Relations.

This presentation will highlight the international dimensions of the gene patent debate. Gene patents – essentially claims covering DNA and RNA sequences and methods of diagnosis – are controversial not only in the United States, but internationally. When Myriad Genetics entered the Canadian market in 2001 with its breast and ovarian genetic tests, it did what no federal government could do: bring together all Canadian provinces, including a separatist government in Quebec, to call for the limitation of these patents. In Europe, Myriad's threatened entry led governments, hospitals and research institutions to band together not only to fight – and significantly decrease the scope of – Myriad's patents, but to limit the scope of gene patents in France and Germany more generally and to bring forth a new compulsory licensing regime over diagnostics. In Myriad's wake, Australia continues to struggle with the question of gene patents with government commissioned studies and legislation introduced into the Senate. The OECD developed guidelines on the licensing of genetic inventions that, in a rare move, made it all the way to the OECD Council, its governing body. While governments have become less active as of late after these developments, the next wave of genetic tests is already causing stir, uniting those opposed to gene patents and likely to lead to judicial developments not only in the US, but internationally.

Hans Sauer, Biotechnology Industry Organization (BIO), Washington, D.C.

Hans Sauer, PhD, JD is Deputy General Counsel for Intellectual Property for the Biotechnology Industry Organization (BIO), a major trade association representing over 1,100 biotechnology companies from the medical, agricultural, environmental, and industrial sectors. Few industries are as dependent on patent rights as the biotech industry. Biotech companies need patents for business formation, access to capital, and for the partnering and investment decisions without which investigational products could not advance through the decade-long process from conception to regulatory approval. But despite great legislative reforms to U.S. patent law, the patentability of biotech inventions has never been as uncertain as it is today. Dr. Sauer participated in key negotiations of the 2011 America Invents Act on behalf of BIO, and advises the organization's board of directors, amicus committee, and various staff committees on patent and other intellectual property-related matters. Prior to his current position, Dr. Sauer was Chief Patent Counsel for MGI Pharma, Inc. and Senior Patent Counsel for Guilford Pharmaceuticals Inc. Dr. Sauer has 13 years of professional in-house experience in the biotechnology industry. He has an M.S. in Biology from the University of Ulm in his native Germany, a Ph.D. in Neuroscience from the University of Lund, Sweden, and a J.D. from Georgetown University. He did his postdoctoral work at Genentech, Inc. in South an Francisco and currently serves as adjunct professor at Georgetown University Law Center in Washington, D.C.

Daniel J. Kevles, Yale University

Daniel J. Kevles is the Stanley Woodward Professor of History at Yale University. His research interests center on the history of science and technology in America, including their relationship with national security, politics, economics, and law. His publications include *The Physicists: The History of a Scientific Community in Modern America* (1978); *In the Name of Eugenics: Genetics and the Uses of Human Heredity* (1985), and *The Baltimore Case: A Trial of Politics, Science, and Character* (1998), a study of accusations of scientific fraud. He is also a coauthor of *Inventing America: A History of the United States*, and a co-editor with Leroy Hood of *The Code of Codes: Scientific and Social Issues in the Human Genome Project* (1992). He is currently working on a history of innovation and intellectual property protection in plants, animals, and people since the eighteenth century.

GENES, RAILROADS, AND REGULATION: INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST

Railroads are huge and genes are tiny, but the processes by which they came to figure in the American economy are marked by significant similarities. In the latter third of the nineteenth century, the transcontinental railroad system was developed with munificent federal patronage in the form of grants of rights of way and tracts of land along them to private railroad companies. Operating in an otherwise laissez-faire environment, the companies built the transcontinental railroads and served the day's national interest by joining East and West in a system of rapid transport of people and goods. In the late twentieth century, the field of molecular biology grew and flourished in no small part as a result of federal patronage, notably through the National Institutes of Health. Research in the field produced increasing knowledge of human genes, especially after the creation of the Human Genome Project, which was eventually fostered by the National Human Genome Research Institute and the Department of Energy. Particularly important progress was made in identifying genes responsible for or at least implicated in disease. Patents on these genes were sought and many obtained, not least as a result of the Bayh-Dole Act, in 1980, which strongly encouraged the patenting of innovations arising from federally sponsored research. Patented genes formed the principal capital basis of a number of start-up biotechnology companies and thus figured significantly in the rise of the biotechnology industry.

The biotechnology industry, particularly the branch of it that rests on human genes, may be on the same course that led to state regulation of the railroad industry. The profit-maximizing policies and practices of the railroad companies disadvantaged small farmers and other suppliers of freight. Thus diverging from the service of an equitable public interest, increasing demands were raised for regulation of the railroads. The companies objected, insisting that such regulation would interfere with their private property, but the demands were sufficient to result in the passage of the state Granger Laws and then, in 1887of the federal Interstate Commerce Act. While the biotechnology industry, like the railroad industry before it, serves an essential public interest in the areas of medicine and food, some companies are exploiting their intellectual property rights in human genes in ways that run counter to sound medical practice and the progress of research. This paper argues that, despite objections raised by the biotechnology industry, the time has come to regulate the property rights represented by patents in human genes, just as society established regulation of property rights in railroads more than a century ago.

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VISITOR INFORMATION

EMERGENCY	CSHL	BANBURY
Fire	**(9) 742-3300**	**(9) 692-4747**
Ambulance	**(9) 742-3300**	**(9) 692-4747**
Poison	**(9) 542-2323**	**(9) 542-2323**
Police	**(9) 911**	**(9) 549-8800**
Safety-Security	**Extension 8870**	

Emergency Room **Huntington Hospital** 270 Park Avenue, Huntington	**631-351-2300** **(1037)**
Dentists Dr. William Berg Dr. Robert Zeman	 **631-271-2310** **631-271-8090**
Doctor MediCenter 234 W. Jericho Tpke., Huntington Station	**631-423-5400** (**1034**)
Drugs - 24 hours, 7 days Rite-Aid 391 W. Main Street, Huntington	**631-549-9400** (**1039**)

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Photocopiers, Journals, Periodicals, Books, Newspapers
Photocopying – Main Library
Hours: 8:00 a.m. – 9:00 p.m. Mon-Fri
10:00 a.m. – 6:00 p.m. Saturday
***Helpful tips* – Use PIN# 50115** to enter Library after hours.
See Library staff for photocopier code.

Computers, E-mail, Internet access
Grace Auditorium
Upper level: E-mail only
Lower level: Word processing and printing.
STMP server address: mail.optonline.net
To access your E-mail, you must know the name of your home server.

Dining, Bar
Blackford Hall
Breakfast 7:30–9:00, Lunch 11:30–1:30, Dinner 5:30–7:00
Bar 5:00 p.m. until late
Helpful tip - If there is a line at the upper dining area, try the lower dining room

Messages, Mail, Faxes
Message Board, Grace, lower level

Swimming, Tennis, Jogging, Hiking

June–Sept. Lifeguard on duty at the beach. 12:00 noon–6:00 p.m. Two tennis courts open daily.

Russell Fitness Center

Dolan Hall, east wing, lower level
PIN#: **Press 50115 (then enter #)**

Concierge

On duty daily at Meetings & Courses Office.
After hours – From tan house phones, dial x8870 for assistance

Pay Phones, House Phones

Grace, lower level; Cabin Complex; Blackford Hall; Dolan Hall, foyer

CSHL's Green Campus

Cold Spring Harbor Laboratory is pledged to operate in an environmentally responsible fashion wherever possible. In the past, we have removed underground oil tanks, remediated asbestos in historic buildings, and taken substantial measures to ensure the pristine quality of the waters of the harbor. Water used for irrigation comes from natural springs and wells on the property itself. Lawns, trees, and planting beds are managed organically whenever possible. And trees are planted to replace those felled for construction projects.

Two areas in which the Laboratory has focused recent efforts have been those of waste management and energy conservation. The Laboratory currently recycles most waste. Scrap metal, electronics, construction debris, batteries, fluorescent light bulbs, toner cartridges, and waste oil are all recycled. For general waste, the Laboratory uses a "single stream waste management" system, removing recyclable materials and sending the remaining combustible trash to a cogeneration plant where it is burned to provide electricity, an approach considered among the most energy efficient, while providing a high yield of recyclable materials.

Equal attention has been paid to energy conservation. Most lighting fixtures have been replaced with high efficiency fluorescent fixtures, and thousands of incandescent bulbs throughout campus have been replaced with compact fluorescents. The Laboratory has also embarked on a project that will replace all building management systems on campus, reducing heating and cooling costs by as much as twenty-five per cent.

Cold Spring Harbor Laboratory continues to explore new ways in which we can reduce our environmental footprint, including encouraging our visitors and employees to use reusable containers, conserve energy, and suggest areas in which the Laboratory's efforts can be improved. This book, for example, is printed on recycled paper.

1-800 Access Numbers

AT&T	**9-1-800-321-0288**
MCI	**9-1-800-674-7000**

Local Interest

Fish Hatchery	631-692-6768
Sagamore Hill	516-922-4447
Whaling Museum	631-367-3418
Heckscher Museum	631-351-3250
CSHL DNA Learning Center	x 5170

New York City

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Take Syosset Taxi to Syosset Train Station
($9.00 per person, 15 minute ride), then catch Long Island Railroad to Penn Station (33rd Street & 7th Avenue).
Train ride about one hour.

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To head west of CSHL - Syosset train station	
Syosset Taxi	516-921-2141 (**1030**)
To head east of CSHL - Huntington Village	
Orange & White Taxi	631-271-3600 (**1032**)
Executive Limo	631-696-8000 (**1047**)

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Long Island Rail Road	822-LIRR
Schedules available from the Meetings & Courses Office.	
Amtrak	800-872-7245
MetroNorth	800-638-7646
New Jersey Transit	201-762-5100

Ferries

Bridgeport / Port Jefferson	631-473-0286 **(1036)**
Orient Point/ New London	631-323-2525 **(1038)**

Car Rentals

Avis	631-271-9300
Enterprise	631-424-8300
Hertz	631-427-6106

Airlines

American	800-433-7300
America West	800-237-9292
British Airways	800-247-9297
Continental	800-525-0280
Delta	800-221-1212
Japan Airlines	800-525-3663
Jet Blue	800-538-2583
KLM	800-374-7747
Lufthansa	800-645-3880
Northwest	800-225-2525
United	800-241-6522
US Airways	800-428-4322


Building Directory
1. Axinn Laboratory
2. Beckman Laboratory
3. Blackford Hall/ Racker
4. Bush Lecture Hall
5. Cairns Laboratory
6. Carnegie Library
7. Delbrück/ Page Laboratory
8. DeMatteis Laboratory
9. Demerec Laboratory
10. Dolan Hall
11. Freeman Laboratory
12. Grace Auditorium
13. Harris
14. Hershey Building
15. James/ Sambrook Laboratory
16. Jones Laboratory
17. Koch Laboratory
18. Lindsay Child Care Center
19. Luke Building
20. Marks Laboratory
21. Matheson Laboratory
22. McClintock Laboratory
23. Nichols Building
24. Osterhout
25. Quick Laboratory
26. Richards Building
27. Urey Cottage
28. Wawepex Building
29. Wendt Laboratory
30. Williams House
N
Olmsted House
Ballybung
Garden House
Darrell House
Gale House
De Forest Road
Tiffany House
Airslie House
Beach path
Tennis Courts
Garden
Volleyball Courts
Ridge Road
Olney
Yellow House
Firehouse
Gazebo
Inner Harbor
Williams House
Hooper House
Upper/Lower Beckman Course Labs
Cole Cottage
Dock
Hillside Parking
Boyer Cabin
Zinder Cabin
Wendt Cabin
Stent Cabin
Alumni Cabin
Luria Cabin
Glass Cabin
Pall Cabin
Maniatis Cabin
Eagle Cabin
Stahl Cabin
Dolan Hall
Blackford Hall
Grace Auditorium
Davenport
Shipping/ Receiving
West Entrance
East Entrance
25A (Northern Blvd)
to Banbury and Huntington Village
Lawrence Hill Road
Fish Hatchery
Route 108
Scale [Approximate] 10" = 1 mile
0 0.1 mile
0.16 kilometer
Map design by Graphic Arts Department