

ROPES&GRAY | BOSTON | LAW

October 20 – 23, 2020 Zoom Webinar



Dear Guest.

We are pleased to welcome you to the 3rd annual International IP Summit, hosted by Boston College Law School's Program on Innovation and Entrepreneurship (PIE) and Ropes & Gray LLP.

The past year has brought an event that has disrupted life globally. Our online summit is one small example. This year, we are holding the summit via Zoom, as opposed to in person and on the Newton campus of Boston College. But we made the changes we needed to make, and we were able to make them because of advances in telecommunications and computer networking. These are advances for which we are grateful, as they have made it much more manageable for dealing with the pandemic. They have also shown us alternative ways to work and stay in touch. We suspect that these alternatives for work and communication will stay with us long after the pandemic has passed.

As we go forward with this year's online International IP Summit, it is worth remembering that Intellectual Property law, at its core, is supposed to support advances in science, engineering and art, and—perhaps even more to the point—the creative efforts of people who use technology and expression to improve our lives and overcome challenges, like the current pandemic. This summit will take up issues that we all face as we seek to collaborate on creative efforts that reach across disciplines and national boundaries.

We hope that you will leave here with a better understanding of the current global IP landscape and with tools you can employ to address these challenges.

Thank you for attending. We hope you enjoy the event.

Edward Kelly

Partner
Ropes & Grav LLP

Regina Sam Penti

Partner
Ropes & Gray LLP

David Olson

Associate Professor and Faculty Director for the Program on Innovation and Entrepreneurship Boston College Law School

Agenda

DAY 1 | October 20

12:00 - 12:10 PM WELCOME REMARKS

Vincent Rougeau, Dean, Boston College Law School

12:10 - 12:20 PM REMARKS BY CO-CHAIRS

12:20 - 1:00 PM KEYNOTE ADDRESS

Sandra Leung, Executive Vice President, General Counsel, Bristol Myers Squibb

Charlotte Jacobsen (moderator), Partner, Ropes & Gray LLP

1:00-1:10 PM BRFAK

1:10-2:30 PM

Legal Issues in the Development, Production and Distribution of Vaccines and Treatments for COVID-19

Companies, universities and governments are racing to produce vaccines and other treatments to address the ongoing COVID-19 pandemic. The production and distribution of these vaccines and treatments are impacted not just by regulatory frameworks imposed by the FDA and similar organizations, but also by intellectual property rights and laws. This session will explore these issues, including:

- How do we incentivize production of vaccines and therapeutics?
- How do we address compulsory licensing, without killing the incentive to produce?
- Considerations for and challenges posed by rolling out biological,
 regulated products on a massive scale in a short period of time

^{*}All times throughout this booklet are EST

Agenda

DAY 1 | October 20 continued

 Overview of regulatory changes and considerations in the United States and from around the world to address the pandemic

Julie Barnes-Weise, Executive Director, Global Healthcare Innovation Alliance Accelerator

David Halstead, Partner, Foley Hoag LLP

Shaun Ryan, Senior Vice President & Deputy General Counsel, Moderna, Inc.

Joanna Wu, General Counsel, HiFiBiO Inc.

David Olson (moderator), Professor, Boston College Law School

5:00-6:30 PM NETWORKING

Live Virtual Mixology Class and Interactive Cocktail Hour

DAY 2 | October 21

9:00-10:30 AM

Digital Health in China

The Chinese government has been promoting the development of digital health to counter the uneven distribution of health care delivery across the country. Many pharmaceutical and medtech companies have been taking advantage of AI and big data to develop new products and services that suit this new paradigm. Nevertheless, the collection, use and outbound transmission of health data by foreign companies is subject to government approval and even security review. Foreign companies must collaborate with Chinese entities in order to legitimately collect health data, and intellectual property derived from the collaboration could be subject to joint ownership.

^{*}All times throughout this booklet are EST

Agenda

DAY 2 | October 21 continued

In this session, we will discuss the IP, data and regulatory issues companies may encounter in their digital health initiatives:

- What are the emerging technology trends in the life sciences sector?
- What regulatory requirements should companies be aware of when they launch digital health initiatives in China?
- Considerations for life science companies when leveraging the power of and protecting digital health technologies

David Chen, Counsel, Ropes & Gray LLP

Serina Tang, Associate Partner, McKinsey & Company

Katherine Wang, Partner, Ropes & Gray LLP

Sally Wang Liang (moderator), Vice President of Business Development, PepLib; General Counsel, The US-China Health Summit

12:00 - 12:50 PM

Hot Topics and Emerging Trends in IP and Innovation

This panel will focus on recent intellectual property trends, including cases, legislation, and emerging trends, that will shape IP's role in innovation in the coming years. The topics will include patents, trademark, copyright, and data use rights domestically and internationally, including developments in the licensing of standard essential patents (SEPs) critical to 5G, the role of the ITC in brand protection and anti-counterfeiting in cross-border cases, emerging trends on data scraping and data use, etc.

Steven Geiszler, U.S. Chief Intellectual Property Litigation Counsel, Huawei Maria Hipps, Assistant General Counsel, Regional Legal Lead, LatAm, IQVIA Melissa Rones, Partner, Ropes & Gray LLP

Joseph Liu (moderator). Professor of Law. Boston College Law School

12:50 - 1:00 PM BRFAK

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DAY 2 | October 21 continued

1:00 - 2:00 PM

Dealmaking in Times of Escalating International Sanctions and Trade Disputes

In recent years, the United States government has embarked on a coordinated effort to ratchet up pressure on China, with significant implications on trade between China and the United States. The panel will explore risks posed by these changes, as well as strategies for dealing with those risks. Topics to be covered include:

- Political and economic implications of the U.S.-China trade war
- Implementation of the U.S.-China trade agreement and practical implications for companies conducting business in China
- CFIUS and the impact of FIRRMA on fundraising and technology transactions

Yasheng Huang, Epoch Foundation Professor of International Management, MIT Sloan School of Management

Michael Mangelson, Principal Counsel and Director for China IP, U.S. Patent and Trademark Office

Richard Sofield, Partner, Wiley Rein LLP, Former Director of the Foreign Investment Review Section, United States Department of Justice

Brendan Hanifin (moderator), Counsel, Ropes & Gray LLP

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DAY 3 | October 22

10:00 - 11:00 AM

Leading and Thriving in a Time of Disruption and Uncertainty:

A Conversation with General Counsels

Companies, particularly those in the tech and life sciences sectors, are facing an unprecedented challenge as they navigate a pandemic that has disrupted everything from supply chains to life as we know it. Many companies have been forced to make dramatic changes to their business models and to adapt to a new normal. The GCs on our panel lead legal organizations in some of the fastest-growing companies in America. In this session, they will share the challenges they face, and strategies for leading and thriving in these uncertain times.

Heidy Abreu King-Jones, Chief Legal Officer & Corporate Secretary, Provention Bio Inc.

Esther Dominguez, General Counsel, .406 Ventures

Brian Elworthy, General Counsel, Toast, Inc.

Scott Samuels, Senior Vice President, General Counsel, BeiGene, Ltd.

Duane Valz, VP & General Counsel, Insitro

Regina Sam Penti (moderator), Partner, Ropes & Gray LLP

12:00 - 12:50 PM

Life Sciences Regulatory Update: U.S., Europe and China

The life sciences industry has been one of the most dynamic and active areas in international trade relations. For U.S. companies looking for local collaboration partners or seeking market access in China and Europe (and vice versa for Chinese and European companies), navigating the complicated and ever-changing regulatory landscape presents a major challenge. This panel will explore the distinctive aspects of the regulatory regime for the life sciences industry, as well as recent updates. Topics will include:

^{*}All times throughout this booklet are EST

Agenda

DAY 3 | October 22 continued

- FDA policies during the COVID-19 pandemic
- Regulation of digital health and data
- IP landscape and regulatory exclusivity
- Considerations regarding government investigations and compliance
- Impact of regulatory regime and any roadblocks on partnerships and collaborations

Kathryn Harris, Senior Director & Compliance Counsel (Investigations), Alexion Pharmaceuticals, Inc.

Sally Wang Liang, Vice President of Business Development, PepLib; General Counsel, The US-China Health Summit

Shaun Ryan, Senior Vice President & Deputy General Counsel, Moderna, Inc.

Yang Xu, Assistant General Counsel, Intellectual Property, BeiGene, Ltd.

Kellie Combs (moderator), Partner, Ropes & Gray LLP

12:50 - 1:00 PM BRFAK

1:00 - 2:00 PM

Cross-Border IP Protection and Enforcement in a Changing Landscape

This panel will examine recent developments in multijurisdictional IP protection and enforcement, particularly in the United States, China and Europe, including:

- Safeguarding and enforcing IP (including trade secrets, branding and patented inventions) in China
- Global FRAND licensing requirements for standard essential patents after Sisvel and Unwired Planet
- Enforcement of life sciences IP and government-authorized infringement of pharmaceutical patents in the era of COVID-19

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DAY 3 | October 22 continued

Sam Brenner, Counsel, Ropes & Gray LLP

Brendan Gavin, Intellectual Property Senior Counsel, Vertex Pharmaceuticals, Inc.

Mathias Karlhuber, Patent Attorney, Equity Partner, Cohausz & Florack

Michael Mangelson, Principal Counsel and Director for China IP, U.S. Patent and Trademark Office

Charlotte Jacobsen (moderator), Partner, Ropes & Gray LLP

DAY 4 | October 23

INTERACTIVE WORKSHOP: DOING BUSINESS IN CERTAIN TIMES

12:30 - 1:00 PM OPENING & INTRODUCTORY PRESENTATION

Introductory Presentation

- Deal Making Statistics and Trends 2020
- The Need for Global Collaboration vs. Increased Segregation and Tension among Major Economics in the World
- Specific IP Issues to Watch During the Pandemic

Beibei Sun, Associate, Ropes & Gray LLP

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DAY 4 | October 23 continued

1:00 - 1:40 PM

Deal Making during a Pandemic: Experiences and Strategies

To discuss experiences and strategies of deal making in the context of the new business reality imposed by the pandemic. How has the pandemic affected the due diligence process or the negotiation process? How have the strategic priorities of the industry players shifted during this time, and what are the best practices for companies sitting on cash and considering deal making in a very uncertain environment? Have cross-border transactions been facing more challenges than domestic transactions? Any success story or best practice to share? How have existing contracts been disrupted? Experiences from different industries are welcome (e.g., life sciences, telecommunication, big data, artificial intelligence, etc.)

Minh-Chau Le, Partner, Ropes & Gray LLP

Amanda McGrady Morrison, Partner, Ropes & Gray LLP

1:40 - 1:55 PM BRFAK

1:55 - 2:35 PM

Global Collaboration and the Role of Policy to Ensure Public Access to Diagnostics, Medicines and Care

In front of this unprecedented challenge for public health, we have seen an increasing level of collaboration among government, academics, industry and international organizations (such as WHO) throughout the world to find a cure and to ensure sufficient access to diagnostics, medicines and care. This session will take a closer look into the global collaboration for vaccine development and other aspects of the combat against the pandemic. What has been the role of policies in facilitating such collaboration? What can the academics and industry do to contribute to this process? Are there any unique issues in relation to SEPs, FRAND licensing or litigation, or compulsory licenses in the context of vaccine development and global collaboration?

Julie Barnes-Weise, Executive Director, Global Healthcare Innovation Alliance Accelerator

Gillian M. Fenton, Senior Counsel, Vaccines Legal Operations - Innovation, Business Development and Strategic Partnerships, GSK

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DAY 4 | October 23 continued

2:35-3:15 PM

Rebuilding the New World Order Post-COVID and the Role of IP

We are not seeing an immediate end to the pandemic yet, but many have already realized that we will be living in a different world post-COVID. The way companies conduct businesses, the way different countries interact with each other, and the way people communicate and live their lives will all be different. As the world rebuilds itself post-pandemic, what are the changes that you see happening in the IP realm, such as IP protection and enforcement, companies' IP strategies, IP's role in the post-pandemic world trade, etc.? How can businesses better prepare themselves for this new world order in relation to IP and beyond?

Melissa Rones, Partner, Ropes & Gray LLP

Peter K. Yu, Professor of Law and Communication, Texas A&M University

3:15 - 3:30 PM CLOSING REMARKS

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Biographies

CO-CHAIR



ED KELLYPartner
Ropes & Gray LLP

EDWARD (ED) KELLY represents clients at the U.S. Patent Trial and Appeals Board, the European Patent Office and the U.S. Patent Office, handling contentious administrative proceedings such as IPR and oppositions. He also represents clients with corporate acquisitions and investments where intellectual property is a critical asset. He structures purchase agreements, licenses and joint development agreements, and delivers strategies for securing patents, trademarks and copyrights to a broad range of clients across industries, including medical devices and high technology. Ed is dual-qualified as a U.S. lawyer and a Solicitor of England & Wales, and is a registered practitioner at the U.S. and European Patent Offices.

Biographies

CO-CHAIR



DAVID OLSONProfessor
Boston College Law School

PROFESSOR OLSON teaches Patent Law and Intellectual Property. He serves as Faculty Director for the <u>Program on Innovation and Entrepreneurship</u>. Professor Olson has published articles on patents, copyrights, antitrust and music licensing. His writing has been cited by the Supreme Court and other courts. He has testified before Congress and Senate committees on patents, FDA regulation and antitrust.

Professor Olson is interested in international IP and competition law. In 2015, he served as Visiting Professor of Law at Pontifical Catholic University, Rio de Janeiro, Brazil (PUC-Rio). In June 2018, Professor Olson was appointed to the visiting faculty of Zhongyuan Technical University in Zhengzhou, Henan Province, China.

The media frequently seeks Professor Olson's insights. He has been quoted in *The Wall Street Journal*, *Associated Press* and *Reuters*, and his op-eds have appeared in the *The Chicago Tribune*, *The Washington Times* and *The Hill*.

In 2012, Professor Olson received The Professor Emil Slizewski Award for Faculty Excellence in recognition of his teaching excellence.

Biographies

CO-CHAIR



REGINA SAM PENTIPartner
Ropes & Gray LLP

REGINA SAM PENTI is a partner in the intellectual property transactions and data practice groups, with offices in Boston and London. She leads strategic transactions such as mergers, acquisitions, asset purchases, joint ventures, and licensing of technology and data. She is also an experienced legal strategist who helps clients grow, defend, commercialize and manage critical IP and technology assets. An MIT-trained engineer and computer scientist, Regina has deep experience, as well as clients across a range of industries, including financial technology (fintech), health care, artificial intelligence (AI) and semiconductor, among others.

With a dual-qualification as a U.S. lawyer and Solicitor of England & Wales, Regina is frequently invited to comment on global intellectual property and technology law issues. She is a guest lecturer on patent law at the MIT Sloan School of Business. She is co-chair of the Internet and Technology Law Committee of the Boston Bar Association and the International IP Summit, an annual symposium for leading legal and business executives.

Regina also co-chairs Ropes & Gray's global Diversity Committee and maintains a *pro bono* practice focused on gender and immigration matters.

Biographies

WELCOME REMARKS



VINCENT ROUGEAU
Dean
Boston College Law School

Boston College Law School Dean **VINCENT ROUGEAU** is the president-elect of the American Association of Law Schools. Over the past decade, he has led a reorganization in leadership structure at BC Law that supports a more holistic approach to student services, expands the school's recruitment of a diverse student body, and enhances the school's commitment to experiential learning and global engagement. BC Law's Center for Experiential Learning brings the school's hands-on training programs together, while the Global Practice Program is launching new opportunities for students in Dublin, Germany, Chile, France and other locations around the globe. In addition to his leadership at BC Law, Dean Rougeau was recently named the inaugural director of the new Boston College Forum on Racial Justice in America.

An expert in Catholic social thought, Dean Rougeau's current research and writing consider the relationship between religious identity and citizenship and membership in highly mobile and increasingly multicultural democratic societies. Before entering the legal academy, Dean Rougeau practiced law at Morrison & Foerster and then served as a professor at Loyola University Chicago and professor and Associate Dean for Academic Affairs at Notre Dame. He also serves as Senior Fellow at the Centre for Theology and Community in London.

Biographies

KEYNOTE SPEAKER



SANDRA LEUNGExecutive Vice President, General Counsel *Bristol Myers Squibb*

SANDRA LEUNG serves as legal advisor to the Bristol Myers Squibb Board of Directors and company executives, and is responsible for shaping the company's legal strategy. Sandy is also responsible for Environment, Health & Safety & Sustainability, Corporate Security and Philanthropy.

Sandy joined Bristol Myers Squibb in 1992 as a staff attorney in the litigation department. In 1996, she became assistant counsel and, one year later, was named associate counsel. In 1999, Sandy was appointed to the position of counsel and corporate secretary. In 2006, she was appointed acting general counsel, and in 2007, she was named general counsel. In 2014, Sandy was named executive vice president.

Prior to joining the company, Sandy was a prosecutor in the Manhattan District Attorney's Office. Sandy earned her law degree from Boston College of Law and her bachelor's degree from Tufts University.

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JULIE BARNES-WEISE
Executive Director
Global Healthcare Innovation Alliance Accelerator

JULIE BARNES-WEISE, J.D., CLP, Executive Director of the Global Healthcare Innovation Alliance Accelerator, co-founded the non-profit GHIAA in the spring of 2016 as a spin-out of her work at Duke University as a Visiting Associate Professor of the Practice at Duke's Sanford School of Public Policy, and Director of the Sanford Innovation, Technology Policy project. The GHIAA MAPGuide, a guide to global health agreements, was launched in August 2020: www.ghiaa.org.

She is a lawyer, board member, business development executive and Certified Licensing Professional, and has been a member of the Licensing Executive Society since 1986. In October she will become a board member of LES.

Julie has been a Senior Business Development and Legal Consultant to the Coalition for Epidemic Preparedness Innovations (CEPI) for over three years. She has also been a consultant on partnering for the Pandemic Preparedness Framework initiative of the WHO, during which time she co-authored a paper on the success and failures of the Ebola Outbreak 2014 consortia and created a system for monitoring potential Priority Pathogen development partner matching.

Julie is also a Consultant and lecturer for the Duke Law School Access to Medicines course and a Board Member of the Medical University of South Carolina Foundation for Research and Development.

She is a former Director of Business Development at Glaxo Wellcome (now GSK), an attorney at SAS Institute, and founder and consultant for BioMatch, LLC for many years. She has decades of experience negotiating IP licenses and alliance agreements and advising health care companies and institutions on partnering strategies. She has consulted with both U.S. and European start-up companies and initiatives, including developing business development plans for venture capitalist-backed spin-out companies.

Biographies

PANELISTS



SAM BRENNERCounsel
Ropes & Gray LLP

SAMUEL BRENNER, PH.D., is counsel in Ropes & Gray's intellectual property litigation group. Sam is an experienced trial and appellate lawyer, patent litigator, and ITC and PTAB practitioner who focuses his practice on intellectual property and complex commercial litigation, and who has represented leading companies in a variety of technical fields, including telecommunications, electronics, software and hardware, pharmaceuticals, and semiconductors. Sam has significant experience counseling clients in matters involving litigation and licensing strategy, and also has significant experience litigating Standard Essential Patents and RAND/FRAND issues. Before joining Ropes & Gray, Sam served as a law clerk for Judge Kim McLane Wardlaw of the U.S. Court of Appeals for the Ninth Circuit and Judge David McKeague of the U.S. Court of Appeals for the Sixth Circuit. Sam lectures and publishes regularly, and has taught at the University of New Hampshire School of Law, the University of Michigan, Brown University and the University of Rhode Island.

Biographies

PANELISTS



DAVID CHENCounsel
Ropes & Gray LLP

DAVID CHEN is an IP transactions and data privacy counsel based in Ropes & Gray's Shanghai office. He regularly advises clients in the life sciences and technology industries on strategic collaborations, intellectual property transactions, general commercial matters and data monetization, protection and privacy matters. He also frequently advises private equity funds and other financial institutions on investment and financing transactions, mergers and acquisitions, and foreign direct investments in the APAC region. He often counsels clients on protecting and leveraging their data, patents, trade secrets, copyrights, trademarks and other intellectual property rights in China.

David specializes in advising pharmaceutical, biotech, digital health and medical device companies on their transactions encompassing the entire value chain, including on early-stage collaboration on drug discovery, in-licensing and out-licensing of drug candidates, CMO and CRO arrangements, supply, distribution, promotion, and cross-industry digital health initiatives.

David also regularly advises mobile app, mobile gaming, digital media and data-driven companies on their transactions involving mobile app, mobile game and content development, distribution and data sharing.

Biographies

PANELISTS



KELLIE COMBSPartner
Ropes & Gray LLP

KELLIE COMBS provides legal and strategic advice to pharmaceutical, biotechnology, medical device, food and cosmetic manufacturers, as well as hospitals and academic institutions, on a broad range of issues under the Food, Drug, and Cosmetic Act and the Public Health Service Act. She is a partner in the FDA regulatory practice group and is also a co-chair of Ropes & Gray's cross-practice Digital Health Initiative. Kellie is currently advising a number of clients on issues related to the COVID-19 pandemic, including the deployment of digital health and telemedicine tools, the manufacture and distribution of personal protective equipment, and the 3D printing of medical devices and components. She has extensive experience handling matters implicating FDA promotional rules and the First Amendment and also routinely advises clients on lifecycle management, regulation of clinical research and post-approval compliance. In addition, Kellie conducts regulatory due diligence in connection with transactions involving drug, device, dietary supplement, cosmetic and other consumer product manufacturers, and she has advised on a number of government investigations of FDA-regulated companies.

Biographies

PANELISTS



ESTHER DOMINGUEZGeneral Counsel
.406 Ventures

ESTHER DOMINGUEZ is General Counsel at .406 Ventures, a venture capital firm that has raised over \$1 billion for investment in Cybersecurity, Digital Health, and Data and Cloud. Esther also works directly with select early-stage .406 portfolio companies in need of an experienced GC. Prior to her time at .406, Esther was General Counsel at Telerik Corporation, a venture-backed software company, which was sold to Progress Software in 2014. Esther is a 1997 graduate of NYU Law. She started her career at Testa, Hurwitz & Thibeault, a Boston-based firm representing venture capital funds and start-ups that was a powerhouse during Boston's technology boom.

Biographies

PANELISTS



BRIAN ELWORTHY General Counsel Toast, Inc.

BRIAN ELWORTHY is General Counsel at Toast, where he is responsible for managing all of the company's legal affairs. Before joining Toast, he served as Assistant General Counsel at inVentiv Health, a global provider of commercial and clinical solutions to the pharma industry. Brian began his legal career at Ropes & Gray, spending six years practicing in the private equity/M&A groups. Brian earned his J.D. from Georgetown University and his B.A. from Middlebury College.

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GILLIAN FENTONSenior Counsel, Vaccines Legal Operations - Innovation, Business Development and Strategic Partnerships *GSK*

GILLIAN M. FENTON, ESQ., CLP is presently Senior Counsel at GSK Vaccines, where she is the sole North American attorney for significant business development transactions (acquisitions, in-licenses, collaborations, out-licenses and asset divestments). Gillian's practice also includes a wide variety of collaborations and R&D funding agreements with U.S. Government entities (NIH/NIAID, BARDA and DARPA). Prior to joining GSK, Gillian was Chief Intellectual Property Counsel at Emergent BioSolutions Inc., where she founded the IP department and oversaw all IP activities in support of Emergent's IPO and subsequent growth through M&A. Prior to joining EBS, while in-house counsel at Biogen Inc., Gillian led all IP activities in support of market launch of a new biotherapeutic product and secured a favorable outcome in a precedential patent interference proceeding. She is currently the President-Elect and Chair-Elect of the Licensing Executives Society (U.S.A. and Canada). Education: J.D. cum laude, Suffolk University Law School; B.Sc. Biochemistry, Trinity College. Admissions: MA, MD, DC

Biographies

PANELISTS



BRENDAN GAVIN
Intellectual Property Senior Counsel
Vertex Pharmaceuticals, Inc.

BRENDAN GAVIN is a patent attorney and recent addition to the Intellectual Property Group at Vertex Pharmaceuticals Incorporated. He has worked for more than 12 years in the field of patent law, with a focus on life science subject matter. Brendan has experience working on a variety of intellectual property issues, including worldwide patent portfolio development, freedom-to-operate analysis, patent prosecution, due diligence and litigation support. All views expressed by Brendan during the panel discussion are his own and do not necessarily represent the opinions of any entity with which he has been, is now or will be associated.

Biographies

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STEVEN GEISZLERU.S. Chief Intellectual Property
Litigation Counsel
Huawei

STEVEN GEISZLER is U.S. Chief Intellectual Property Litigation Counsel for Huawei, one of the world's largest technology companies. Before going in-house, Steven practiced for 15 years at international law firms in Dallas, handling complex patent litigation in venues including the Eastern District of Texas, District of Delaware and U.S. International Trade Commission. Steven has received recognition from *Chambers USA* and *Best Lawyers in America*, and he has been quoted in publications such as *Corporate Counsel, Managing IP* and *Law.com*.

Steven has appeared as counsel of record in more than 150 U.S. patent litigation cases and has helped manage more than 60 cases for Huawei, including SEP/FRAND licensing disputes. Drawing on his science background, including three years as a biomedical researcher, Steven is a proponent of data analytics in the legal profession. He lectures on litigation management at Baylor Law School.

Biographies

PANELISTS



DAVID HALSTEADPartner
Foley Hoag LLP

DAVID HALSTEAD is a partner in Foley Hoag's Intellectual Property Department. David works with clients in the biotechnology, chemical and pharmaceutical industries on a wide range of intellectual property issues. He assists clients with obtaining robust and enforceable patents and navigating the existing patent landscape. Using his experience working with patents and applications in many foreign countries, David also helps clients devise effective global patent strategies designed to satisfy the idiosyncratic requirements of foreign patent offices.

David works with clients to create and manage their relationships with business partners. He evaluates the intellectual property portfolios of target companies to identify strengths, weaknesses and opportunities to create value by revising patent strategies and addressing latent issues. Using his understanding of the regulatory environment for pharmaceutical and biotech products, David also advises clients regarding product life-cycle management, including Hatch-Waxman and Orange Book issues.

Before beginning his legal career, David obtained his Ph.D. in Organic Chemistry from Harvard University, where he studied the synthesis of complex organic molecules and completed the total synthesis of discodermolide in the laboratory of Professor David A. Evans.

Biographies

PANELISTS



BRENDAN HANIFINCounsel
Ropes & Gray LLP

BRENDAN HANIFIN advises clients on international risk compliance matters, as well as the Committee on Foreign Investment in the United States (CFIUS) review process.

Brendan has represented clients in the energy, financial, health care, investment management, life sciences, manufacturing, and transportation and logistics industries in internal and governmental investigations of potential violations of economic sanctions, export control laws, customs regulations, anti-corruption laws and anti-boycott laws. He regularly advises private equity sponsors and venture capital firms on economic sanctions, money laundering, export control, and corruption risks related to international transactions and investments. Brendan also represents clients in national security reviews before CFIUS, and he assists U.S. and non-U.S. clients in managing CFIUS risk in connection with fundraising and investment activities.

Brendan has assisted clients across a broad range of industries to develop or enhance their compliance programs. He has particular experience helping U.S. investment advisors develop risk-based anti-money laundering and economic sanctions programs.

A member of *Law360*'s International Trade Editorial Advisory Board, Brendan writes frequently on CFIUS, economic sanctions and other international risk compliance matters.

Biographies

PANELISTS



KATHRYN HARRISSenior Director & Compliance Counsel (Investigations)

Alexion Pharmaceuticals, Inc.

KATHRYN HARRIS is Senior Director and Compliance Counsel at Alexion Pharmaceuticals. In that role, Kathryn assesses allegations of compliance-related misconduct and conducts internal investigations across all geographies and business units. Before joining Alexion, Kathryn was a senior associate in the Litigation and Enforcement group at Ropes & Gray. At Ropes, Kathryn represented pharmaceutical clients in complex matters, including government investigations into alleged misstatements in securities filings, off-label marketing practices, HIPAA violations, anti-kickback violations and other health care-related fraud. Kathryn has a B.A. in Political Science from Boston College and a J.D. from Boston College Law School. After law school, Kathryn spent a year clerking in federal district court in New Hampshire.

Biographies

PANELISTS



MARIA HIPPS
Assistant General Counsel,
Regional Legal Lead, LatAm
IQVIA

MARIA MIRABAL HIPPS currently serves as Assistant General Counsel at IQVIA Inc., a global industry leader in the advanced analytics, technology solutions and clinical research services to the life sciences industry. María is responsible for managing IQVIA's Latin America Business Unit, which is comprised of 13 countries with annual revenue of over \$150MM. She tackles a diverse range of complex legal issues, including data and technology licensing, M&A, internal investigations, litigation, privacy, and more. Maria is a true generalist, with the added advantage of being a native Spanish speaker. Prior to joining IQVIA, Maria worked as an Associate Attorney at Thelan Reid (formally Brown Raysman Millstein Felder & Steiner) where she honed her corporate transactional and litigation skills. Maria earned a B.A. from Wesleyan University in 1997 and J.D. from American University, Washington College of Law in 2001. Maria resides in New Jersey with her husband and three children. Her passions include writing, documentaries, immigration & criminal justice reform, and diversity, equity and inclusion issues. Maria is licensed in New Jersey and New York.

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PANELISTS



YASHENG HUANG
Epoch Foundation Professor of
International Management
MIT Sloan School of Management

YASHENG HUANG is Epoch Foundation Professor of International Management and faculty director of action learning at MIT's Sloan School of Management. From 2013 to 2017, he served as an associate dean in charge of MIT Sloan's global partnership programs and its action learning initiatives. His previous appointments include faculty positions at the University of Michigan and at Harvard Business School.

Professor Huang is the author of 11 books in both English and Chinese and numerous academic papers and news commentaries. He is currently a co-Pl in a large-scale cross-disciplinary research project on food safety in China. His current book is on the rise and the fall of technologies in ancient and contemporary China.

At MIT Sloan School, Professor Huang founded and runs China Lab and India Lab, which have provided low-cost consulting services to over 360 small and medium enterprises in China and India. From 2015 to 2018, he ran a program in Yunnan province to train women entrepreneurs (funded by Goldman Sachs Foundation). He has held or received prestigious fellowships such as National Fellowship at Stanford University and Social Science Research Council-MacArthur Fellowship. National Asia Research Program named him one of the most outstanding scholars in the United States conducting research on issues of policy importance to the United States. He is or has been a fellow at the Center for China in the World Economy at Tsinghua University, a research fellow at Shanghai University of Finance and Economics, a fellow at William Davidson Institute at Michigan Business School, and a World Economic Forum Fellow. He has served as a consultant at the World Bank, Asian Development Bank and OECD, and serves on advisory and corporate boards of non-profit and for-profit organizations.

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PANELISTS



CHARLOTTE JACOBSEN
Partner
Ropes & Gray LLP

charlotte Jacobsen, MS, LLM, is a first-chair litigator with over 15 years of experience litigating complex patent disputes concerning biotechnology, pharmaceuticals and the chemical arts, with an emphasis on litigation under the Hatch-Waxman Act and BPCIA. She has argued before the PTAB, in federal district courts and in patent appeals before the Federal Circuit. Charlotte is technically astute and has handled cases spanning a broad range of technologies related to pharmaceuticals and biologics. Charlotte started her career as a barrister in the United Kingdom. She has experience with oppositions before the European Patent Office and executing global litigation strategies. Charlotte has been recognized for her work by *The Legal 500* and as a leading life sciences lawyer by *LMG Life Sciences*. Charlotte has an M.Sc. in Forensic Science from King's College, London, an M.A. in Natural Sciences from Cambridge University and an LL.M. from Columbia University.

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MATHIAS KARLHUBERPatent Attorney, Equity Partner
Cohausz & Florack

MATHIAS KARLHUBER completed his studies in mechanical engineering, specializing in design technology, at the Technical Universities in Munich and Hamburg-Harburg and the Rush Presbyterian Saint Luke's Medical Center in Chicago, IL, graduating in 1995 as a Dipl.-Ing.

He was trained in IP law at patent law firms in Hamburg and Berlin, the German Patent and Trademark Office, the Federal Patent Court, and the District Court in Munich. In 1999, he was admitted as a German patent attorney and accredited for representation before the European Patent Office (EPO) and the European Union Intellectual Property Office (EUIPO). Mathias joined COHAUSZ & FLORACK in 2001 and became a partner in 2005. Since 2015, he is the Patent Rapporteur of the IP Commission of the International Chamber of Commerce (ICC).

Mathias is mainly involved in obtaining and defending technical IP rights in the field of electronic program guides, data security, medical devices, semiconductor lithography systems and railway technology (vehicle dynamics, crash safety and aerodynamics).

Mathias speaks German, English and French.

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HEIDY ABREU KING-JONES
Chief Legal Officer & Corporate Secretary
Provention Bio Inc.

HEIDY ABREU KING-JONES is the Chief Legal Officer of Provention Bio, Inc., a clinical-stage biopharmaceutical company developing novel therapeutics aimed at intercepting and preventing immune-mediated diseases. She has nearly 12 years of corporate counsel and law firm experience in the biotechnology and pharmaceutical sectors. As CLO, Heidy supports Provention Bio's commitment to upholding the best practices of compliance, corporate governance, and legal and enterprise risk management. Previously, she served as General Counsel of Axcella Health Inc., where she was a key advisor to the executive team and board on company strategy and a key contributor to the achievement of key milestones, such as the company's first interactions with the FDA and completion of the company's initial public offering. Prior to joining Axcella, Heidy managed the Corporate and Commercial Law Department at Sarepta Therapeutics, Inc. She was also the corporate legal lead in Sarepta's efforts to expand globally. Heidy was previously an associate at Ropes & Gray LLP, where she focused on representing public companies in corporate matters.

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MINH-CHAU LE Partner Ropes & Gray LLP

MINH-CHAU LE practices primarily in Ropes & Gray's private equity group, representing private equity funds, strategic investors, and public and private companies in mergers and acquisitions, leveraged buyouts, and other strategic transactions. Chau regularly advises private equity firms and their portfolio companies on acquisitions, divestitures and general corporate governance matters.

Chau Le was named one of *The Deal*'s "Top 21 New M&A Law Partners" of 2019.

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SALLY WANG LIANG
Vice President of Business Development
PepLib
General Counsel
The U.S.-China Health Summit

SALLY WANG LIANG is a biopharma & health tech business executive and a multidisciplinary IP & Regulatory lawyer, often working at the intersection of the U.S. and China health care industries. She is currently VP of Business Development, heading the Global Business Unit at PepLib, an innovative Chinese biotech company at the forefront of peptide drug discovery. She was CEO and Co-founder of an international telemedicine company that bridges American and Chinese health care. She also serves as General Counsel of the U.S.-China Health Summit. Previously, she was Chief Strategy Officer and EVP of IP and Regulatory of a leading digital therapeutics company, Click Therapeutics. She practiced patent litigation and IP licensing at Venable-Fitzpatrick, and clerked for the Honorable Charles S. Haight at the Southern District of New York. She advised many of the world's largest pharmaceutical companies and top biotech firms on business strategy as a management consultant at Clarion Healthcare. She was a legal-policy fellow at the Food and Drug Administration and the US Senate Health Education Labor Pension Committee Health Office. Sally received a B.A. in Biology from Harvard College, a J.D. from Harvard Law School, and an M.P.H from the Harvard T.H. Chan School of Public Health.

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JOSEPH LIU
Professor of Law
Boston College Law School

JOSEPH LIU is a Professor at Boston College Law School. Professor Liu writes and teaches in the areas of copyright, trademark and internet law, with a particular focus on how digital technology is changing the way consumers interact with copyrighted works. Prior to Boston College, Professor Liu served as V.P. and General Counsel to a venture-backed internet startup and practiced at Foley, Hoag & Eliot. He clerked for the Honorable Levin H. Campbell of the U.S. Court of Appeals for the First Circuit. He is a graduate of Yale College and Columbia Law School, where he was Editor in Chief of the Columbia Law Review

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MICHAEL MANGELSON
Principal Counsel and Director for China IP
U.S. Patent and Trademark Office

MICHAEL MANGELSON joined the USPTO as Principal Counsel and Director for China IP in 2020 after serving one year as Senior Counsel for China IP and five years as the U.S. IP Attaché in Shanghai. Michael leads a team in advocating U.S. IP interests, policies and initiatives in China, and works closely with right holders on IP protection and enforcement issues. He advises and coordinates with U.S. government agencies and China counterparts to resolve IP issues, promote U.S. IP policy, encourage effective IP protection and enforcement in China, and secure high IP standards in trade agreements and China IP laws.

Michael joined the public sector with over 20 years of experience as a nationally recognized IP practitioner, strategist and former head of the China Practice group and Technology & Intellectual Property group for U.S. law firm Stoel Rives in Salt Lake City, and previously with Morrison & Foerster in Los Angeles and Hong Kong, and Jones Day in Taiwan. Michael holds a Juris Doctor degree from BYU Law School and is fluent in Mandarin Chinese, with a US Foreign Service ILR rating of 4/4 (Full Professional Proficiency).

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AMANDA MCGRADY MORRISON Partner Ropes & Gray LLP

AMANDA MCGRADY MORRISON advises a broad range of clients on M&A transactions. She is co-head of Ropes & Gray's private equity industry group and has significant experience leading leveraged buyouts and dispositions of companies, as well as guiding direct investments and recapitalizations. Amanda frequently represents investment management firms in connection with strategic transactions. She also assists clients with corporate governance matters. Amanda serves as co-chair of the Ropes & Gray Women's Forum, which sponsors a wide range of initiatives aimed at promoting and supporting the firm's female attorneys and clients.

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MELISSA RONESPartner
Ropes & Gray LLP

MELISSA RONES counsels life sciences clients on a wide range of intellectual property issues, including patent portfolio strategy and life cycle management, licensing and monetization strategy, and the risks associated with third-party intellectual property. She also performs due diligence investigations and advises clients on strengths, weaknesses and opportunities to mitigate risk and remedy issues related to intellectual property in the context of a range of transactions, including private financings and capital markets transactions, license agreements, collaborations, joint ventures, and mergers and acquisitions.

Prior to joining Ropes & Gray, Melissa completed a Ph.D. in Cell and Develop-mental Biology from Harvard University. Her graduate work focused on examining signaling events involved during the patterning of tissues to generate complex organs and helped define specific roles for Notch signaling in both cardiogenesis and nephrogenesis.

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SHAUN RYANSenior Vice President & Deputy General Counsel *Moderna, Inc.*

SHAUN RYAN is SVP & Deputy GC at Moderna, Inc., the Cambridge-based developer of mRNA-based vaccines and therapeutics. During his almost seven years at Moderna, he has worked with the board of directors, senior executives and other leaders to define and execute on the company's objectives. He has been the lead attorney for structuring and negotiating a range of development collaborations, government partnerships, technology licenses, and supply chain and manufacturing arrangements. Since February, Shaun has been primarily focused on the company's efforts to develop and ultimately distribute an mRNA-based vaccine to prevent SARS-CoV-2 infection. Prior to joining Moderna, Shaun was at Goodwin Procter, where he represented biotech companies (including Moderna) in connection with their financing and partnership activities.

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SCOTT SAMUELSSenior Vice President, General Counsel *BeiGene*, *Ltd.*

SCOTT SAMUELS, ESQ., has served as Senior Vice President, General Counsel at BeiGene, Ltd. since May 2017. Prior to joining BeiGene, Mr. Samuels served as Assistant General Counsel and Acting General Counsel and Secretary at ARIAD Pharmaceuticals, Inc., from 2016 through its acquisition in 2017 by Takeda Pharmaceuticals. Previously, Mr. Samuels spent 17 years in private practice at the law firm Mintz Levin, including nine years as a partner in the firm's life sciences practice, where he specialized in securities law, corporate governance, and business development and corporate financing transactions. Mr. Samuels began his career as a law clerk in the U.S. District Court in Philadelphia. Mr. Samuels received his J.D. from George Mason University and his B.A. in Philosophy from Cornell University.

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RICHARD SOFIELD
Partner, Wiley Rein LLP
Former Director of the Foreign
Investment Review Section
United States Department of Justice

RICK SOFIELD has more than 25 years of experience in U.S. national security legal and public policy matters in both the public and private sectors, working closely with the Federal Bureau of Investigation, the National Intelligence Council, the Federal Communications Commission, the National Security Council, the Executive Office of the President and the U.S. Departments of Treasury, Defense, Homeland Security, State, Commerce and Energy, as well as other agencies evaluating foreign investment-related issues. He represents clients in matters involving U.S. national security issues, crossborder transactions and government investigations. Prior to joining Wiley, Rick was the Director of the Foreign Investment Review Section for the National Security Division at the U.S. Department of Justice (DOJ), where he oversaw the DOJ's participation in the Committee on Foreign Investment in the United States (CFIUS), including the review of over 1,000 acquisitions and efforts to prohibit multiple transactions on national security grounds. He also served as Chair of Team Telecom, which evaluates certain applications before the FCC to determine whether they raise law enforcement or national security concerns.

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BEIBEI SUNAssociate
Ropes & Gray LLP

BEIBEI SUN advises public and private companies, investors and institutions in the life sciences and technology industries on transactions involving corporate and intellectual property matters, including licensing and collaboration, mergers and acquisitions, joint ventures, technology transfer, equity financing, and other strategic commercial transactions. Beibei is a native Chinese (Mandarin) speaker and regularly advises her clients on China-related transactions.

Prior to joining Ropes & Gray, Beibei interned with the Patent Cooperation Treaty Division of World Intellectual Property Organization (WIPO) in Geneva, Switzerland. Beibei was a leading member of the legal team at Creative Commons China Mainland. She is currently a board member of Global Healthcare Innovation Alliance Accelerator (GHIAA), a think tank institute based in Durham, NC, which aims to facilitate global health care consortium formation and find legal solutions to most effectively confront public health crises.

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SERINA TANG
Associate Partner
McKinsey & Company

SERINA TANG is an associate partner at McKinsey & Company, based in the Shanghai office. She is a co-leader of the McKinsey Pharmaceutical and Medical Products practice and focuses on driving innovation and supporting growth initiatives for biopharmaceutical clients in China. Over the past 10 years, Serina has served leading biopharmaceutical companies on a wide range of topics, including digital transformation, commercial and business model innovation, ecosystem partnership, and corporate strategy. She has co-authored several publications on the China health care market, including "Bridges to Innovation," "McKinsey Quarterly: China biopharma at a crossroads" and "CPA-McKinsey China Hospital Pharmaceuticals Report." Serina holds a B.S. in Biological Sciences from Peking University and a Master of Public Health from Yale University.

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DUANE VALZVP & General Counsel *Insitro*

DUANE VALZ has led the legal and IP functions at prominent Silicon Valley companies operating at a variety of scales and growth stages. He has been broadly recognized over the past 10 years as one of the world's leading IP strategists. Duane is currently VP & General Counsel of Insitro, a venturebacked company applying machine learning and automation to disease target identification and new drug development. Prior to Insitro, he was VP & General Counsel of Zymergen Inc., a molecular technology growth company operating at the intersection of biology, chemistry, automation and machine learning. Duane was previously a senior member of the Patent Team at Google, where he led strategic IP initiatives bearing on mobile, cloud, web and open source technologies. He was also previously Associate General Counsel in charge of patent development at Yahoo! Duane began his career at Howard Rice Nemerovski Canady Falk & Rabkin (now combined with Arnold & Porter LLP). Duane serves on the Board of Directors for SMASH.org, is an advisory board member for UCOP's MESA program, and is on the advisory Board for the National Society of Black Physicistsall organizations focused on supporting underrepresented students in the pursuit of education and careers in STEM fields.

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KATHERINE WANGPartner
Ropes & Gray LLP

KATHERINE WANG is a partner in Ropes & Gray's life sciences group. Widely regarded as a leading life sciences regulatory lawyer in China, Katherine assists pharmaceutical, biotechnology and medical device companies on a wide range of matters, including early-stage discovery, product registration, regulatory/GxP compliance, pricing, reimbursement, clinical studies, promotional practices and product safety issues. Katherine provides dayto-day counseling on issues that life sciences companies face in relation to their interaction with agencies, including the National Medical Products Administration (NMPA, formerly the CFDA), the National Health Commission (NHC), the State Administration of Market Regulation (SAMR) and the Human Genetic Resources Administration of China (HGRAC), among others. She also assists institutional investors and corporate clients in structuring transactions and conducting regulatory due diligence, including good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP) and pharmacovigilance, on investment targets and prospective business partners in China.

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JOANNA WU General Counsel HiFiBiO Inc.

XUQIONG (JOANNA) WU is the General Counsel at HiFiBiO Therapeutics. She is an accomplished lawyer and scientist with more than 15 years of experience advising life sciences and biotechnology companies.

Previously, she held various in-house counsel positions at three organizations, including a global leader of machinery and engineering, a cutting-edge provider of patient-specific surgical instruments and orthopedic implants, and an emerging biotechnology company. Prior to those positions, Dr. Wu worked at the Boston office of Ropes & Gray LLP, where she advised a variety of clients in the life science industry on intellectual property and regulatory matters.

Dr. Wu received her Juris Doctor (JD) from the law school at the University of California at Berkeley with a certificate in Law & Technology. During law school, she was an editor for the *Berkeley Technology Law Journal* and the *California Law Review*, and worked as a law clerk for an intellectual property law firm in San Francisco. Before law school, she received her Ph.D. in Physiology from the University of Virginia and conducted research at the Lawrence Berkeley National Laboratory as a recipient of the Alexander Hollaender Distinguished Postdoctoral Fellowship awarded by the U.S. Department of Energy.

Biographies

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YANG XUAssistant General Counsel, Intellectual Property *BeiGene, Ltd.*

YANG XU is the Assistant General Counsel, Intellectual Property of BeiGene, Ltd. Prior to BeiGene, Yang worked as a patent attorney in pharmaceutical companies and law firms in the United States and China. His practice includes patent strategy, patent procurement, patent due diligence, IP litigation, IP policy and licensing transactions.

Yang received his J.D. degree from the University of Texas Law School, his Ph.D. degree in Biochemistry and Molecular Biology from the University of Chicago, and his B.S. degree from Beijing University. Yang is registered to practice before the USPTO, and is admitted to practice in Massachusetts.

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PETER K. YUProfessor of Law and Communication *Texas A&M University*

PETER K. YU (余家明) is Professor of Law, Professor of Communication and Director of the Center for Law and Intellectual Property at Texas A&M University. He previously held the Kern Family Chair in Intellectual Property Law at Drake University Law School and was Wenlan Scholar Chair Professor at Zhongnan University of Economics and Law in Wuhan, China. He served as a visiting professor of law at Bocconi University, Hanken School of Economics, Hokkaido University, the University of Haifa, the University of Helsinki, the University of Hong Kong and the University of Strasbourg.

Born and raised in Hong Kong, Professor Yu is a leading expert in international intellectual property and communications law. A prolific scholar and an award-winning teacher, he is the author or editor of seven books and more than 180 law review articles and book chapters. He is the Co-Director of Studies of the American Branch of the International Law Association and has served as the general editor of *The WIPO Journal*. He is a member of the American Law Institute.

Ropes & Gray's International Practice

Ropes & Gray is a preeminent global law firm with more than 1,400 lawyers and legal professionals worldwide. The firm has consistently been recognized by leading ranking publications such as *Chambers* and *The Legal 500* for its practices in many areas, including intellectual property, private equity, M&A, litigation, finance, investment management, hedge funds, real estate, tax, life sciences, health care, government enforcement, privacy & cybersecurity, and business restructuring. The firm was ranked #2 on *The American Lawyer*'s 2020 "A-List," marking the fourth straight year Ropes & Gray has earned a top-three ranking and the tenth consecutive year the firm has been recognized on the elite list.

Ropes & Gray's global IP practice can handle any deal or dispute anywhere in the world, including patent, trademark, advertising and trade secret disputes; technology licenses and joint development agreements; and data protection and privacy counseling and advice. Our IP practice includes individuals who have graduated from the world's top science and engineering programs, and our team boasts more than 75 technical degrees. Encompassing every significant patent venue, our practice includes PTAB work at the U.S. Patent Office, opposition work at the European Patent Office, and representation at the International Trade Commission.

Our practice works closely with our firm's life sciences group, which has attorneys with deep experience in the industry and a team of regulatory attorneys who have a broad view of the commercial and regulatory forces affecting life sciences companies. Our regulatory attorneys advise clients on regulatory counseling and administrative litigation, government enforcement investigations, compliance program design and implementation, and FDA-related IP issues.

The Boston College Law School Program on Innovation and Entrepreneurship

The Boston College Law School Program on Innovation and Entrepreneurship (PIE) draws upon the intellectual capital of its faculty and the energy of its talented students to develop activities designed to build strong bridges between BC Law and the innovation and entrepreneurship communities in Boston and beyond. PIE hosts speakers, discussions, conferences and symposia at BC Law, in Greater Boston and in other cities, in partnership with collaborators in the innovation and entrepreneurship space. PIE also supports experiential opportunities, academic research and student work related to innovation and entrepreneurship.

PIE builds on and extends BC Law's existing academic strengths in areas such as intellectual property, entrepreneurship, business law and experiential learning. The program supports academic research and exchange, and allows students to participate in externships in the legal departments of innovative and entrepreneurial companies and law firms. PIE also provides opportunities for students to work directly with the program on events, workshops and legal research.



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