

Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaboration: the Role of Intellectual Property

September 23, 2020, 1:00-5:00 PM (EDT)

September 24, 2020, 12:30-5:20 PM (EDT)

Webinar

Day One: Wednesday, September 23, 2020

How Patents and Copyrights Impact Collaboration and Innovation for Business Development in Life Science Technologies

Masters of Ceremony

Nyeemah A. Grazier, Patent Attorney, Office of Policy and International Affairs (OPIA),
United States Patent and Trademark Office (USPTO)

Brian T. Yeh, Attorney-Advisor, OPIA, USPTO

1:00 – 1:05 p.m.

Introductions

Nyeemah A. Grazier, Patent Attorney, OPIA, USPTO

1:05 – 1:15 p.m.

Opening Remarks

Andrei Iancu, Under Secretary of Commerce for Intellectual Property and
Director of the USPTO

1:15 – 1:35 p.m.

Session I: The role of patents in research and development of therapeutics, diagnostics, and vaccines, particularly during pandemics

In this session, we will explore the link between patents and innovation, and the value of innovation in the diagnostic and therapeutic arena in improving public health.

Presenter: Ms. Genia Long, Senior Advisor, Analysis Group

1:35 – 2:00p.m.

Session II: Update on USPTO guidance on patentability of life science inventions

In this session, we will discuss the agency's most recent guidance to examiners on the analysis of claims in this area for compliance with subject matter eligibility and disclosure requirements under the patent law.

Presenter: Mr. Ali R. Salimi, Senior Legal Advisor, Office of Patent Legal
Administration (OPLA), USPTO

2:00 – 2:30 p.m.

Session III: Life science patents in practice

In this session, the speakers will share their experience with ways that the patent system protects inventions in the life sciences, promotes innovation and facilitates collaboration in life sciences. Topics include, for example, the importance of new use claims and other examples of incremental innovation, and the role that subject matter eligibility plays in life sciences-related inventions.

Presenters: David E. Korn, Vice President, Intellectual Property and Law,
Pharmaceutical Research and Manufacturers of America (PhRMA)

Dr. Gaby Longworth, Director, Sterne Kessler Goldstein & Fox

2:30 – 2:40 p.m.

Coffee/Tea Break

- 2:40 – 3:40 p.m. Panel Discussion I: Are changes to US patent law needed to better support innovation in life sciences and the development of COVID-19 solutions?**
Using the COVID pandemic to exemplify and emphasize the importance of innovation, the panelists will exchange ideas about whether changes are needed to support innovation in the life sciences sector and to support collaboration. In this session, the panelists, representing academia, pharmaceutical corporations, and private practice, will provide their experience and unique perspective on this topic.
Moderator: Andrei Iancu, Under Secretary of Commerce for Intellectual Property and Director of the USPTO
Panelists: The Honorable Paul R. Michel, Chief Judge, US Court of Appeals for the Federal Circuit (Ret.)
Steven Caltrider, Vice President and General Patent Counsel, Eli Lilly & Co.
Karin Hessler, Assistant General Counsel, Association for Accessible Medicines (AAM)
Arti Rai, Elvin R. Latty Professor of Law and Co-Director of the Center for Innovation Policy, Duke, School of Law
Corey Salsberg, Vice President and Global Head of IP Affairs, Novartis
Hans Sauer, Deputy General Counsel and Vice President for Intellectual Property, Biotechnology Innovation Organization
Hiba Zarour, Head of IP Department – Global Division, Hikma Pharmaceuticals
- 3:40 – 3:50 p.m. Coffee/Tea Break**
- 3:50 – 4:15 p.m. Session IV: Copyright and innovation in the life sciences**
This series of presentations will provide an overview of copyright in the life sciences and how it encourages innovation. Topics will include digital technologies such as artificial intelligence, open access, and publishing in the life sciences sector.
Presenters: Michael W. Carroll, Professor of Law and Faculty Director, Program on Information Justice and Intellectual Property (PIJIP), American University Washington College of Law (WCL)
Mark Seeley, Consultant, SciPubLaw LLC and Adjunct Faculty, Suffolk University Law School
Bhamati Viswanathan, Affiliate Professor, Emerson College
- 4:15 – 4:50 p.m. Panel Discussion II: Copyright discussion: Enhancing access to life science: How copyright can create incentives or barriers to building data or information pools, and related licensing**
In this session, the panelists will discuss copyright's integral role in supporting the dissemination of information and facilitating different licensing models.
Moderator: Susan Allen, Attorney-Advisor, OPIA, USPTO
Panelists: Michael W. Carroll, Professor of Law and Faculty Director, PIJIP, WCL
Mark Seeley, Consultant, SciPubLaw LLC and Adjunct Faculty, Suffolk University Law School
Bhamati Viswanathan, Affiliate Professor, Emerson College

- 4:50 – 5:00 p.m. **Closing Remarks**
5:00 p.m. **End of Day 1**

Day Two: Thursday, September 24, 2020
Competition, Collaboration and Licensing to Promote Access
to Therapeutics, Diagnostics and Vaccines

Master of Ceremony

Jennifer Dixton, Special Counsel for Policy & Intellectual Property,
Antitrust Division, U.S. Department of Justice

12:30 – 12:40 p.m. Welcome Remarks

Makan Delrahim, Assistant Attorney General, Antitrust Division,
U.S. Department of Justice

12:40 – 1:10 p.m. Fireside Chat

Moderator: The Honorable Kathleen O'Malley, Circuit Judge, US Court of Appeals
for the Federal Circuit

Speakers: Andrei Iancu, Under Secretary of Commerce for Intellectual Property
and Director of the USPTO

Makan Delrahim, Assistant Attorney General for the Antitrust Division,
United States Department of Justice (USDOJ)

1:10 – 1:15 p.m. Program Overview

David Lawrence, Chief, Competition Policy & Advocacy Section,
U.S. Department of Justice

1:15 – 2:10 p.m. Session V: Collaboration and Licensing Strategies

*In this session, panelists will discuss partnerships that facilitate the development of
therapeutics and vaccines from research through the market-ready stage. Panelists will
consider public-private partnerships; private partnerships; exclusive versus non-exclusive
licensing; ownership rights; and information pooling. Panelists will also discuss how these
partnerships and licensing strategies apply in addressing the current pandemic.*

Moderator: Brian Pandya, Deputy Associate Attorney General, U.S. Department of Justice

Presenters: Laura A. Coruzzi, Senior Vice President, Intellectual Property, Regenxbio

Lauren Foster, Associate Director, Technology Licensing Office,
Massachusetts Institute of Technology

Sheridan Miyamoto, Assistant Professor, Principal Investigator, SAFE-T
Center, Penn State University

Mita Mukherjee, Associate General Counsel, Intellectual Property, Emergent
BioSolutions

Mark Rohrbaugh, Senior Advisor for Technology Transfer, National
Institutes of Health

Dick Wilder, General Counsel, Coalition for Epidemic Preparedness
Innovations

2:10 – 2:15 p.m. Coffee/Tea Break

- 2:15 – 3:05 p.m. Session VI: How Do Regulation and Antitrust Enforcement Impact Competition and Incentives for Innovation?**
In this session, panelists will discuss the extent to which regulation and antitrust enforcement are necessary to maintain competition among safe and effective products, which can impact the incentives for innovation. What are the tradeoffs of antitrust enforcement and regulation in terms of the incentives for innovation during a pandemic?
Moderator: Alexander Okuliar, Deputy Assistant Attorney General, Antitrust Division, U.S. Department of Justice
Presenters: Alden Abbott, General Counsel, Federal Trade Commission
Ernst Berndt, Louis E. Seley Professor in Applied Economics, Emeritus, Alfred P. Sloan School of Management, MIT
David J. Kappos, Partner, Cravath, Swaine & Moore, LLP
William Kovacic, Global Competition Professor of Law and Policy, George Washington University Law School
Dick Wilder, General Counsel, Coalition for Epidemic Preparedness Innovations
- 3:05 – 3:10 p.m. Coffee/Tea Break**
- 3:10 – 3:55 p.m. Session VII: Competition and Collaboration: Examining Competitive Effects and Antitrust Risks Associated with Collaborations**
In this session, panelists will discuss what makes a collaboration or partnership successful and procompetitive; antitrust concerns that can arise; and potential safeguards that reduce antitrust risk, including guidance from the DOJ-FTC Collaboration Guidelines and DOJ's recent expedited business review letters.
Moderator: Jennifer Dixon, Special Counsel for Policy & Intellectual Property, Antitrust Division, U.S. Department of Justice
Presenters: William Diaz, Senior Counsel, Amgen
Andrew Finch, Partner, Paul Weiss
Luba Greenwood, Lecturer in Engineering Sciences, Harvard University
Chuck Loughlin, Partner, Hogan Lovells
- 3:55 – 4:00 p.m. Coffee/Tea Break**
- 4:00 – 4:30 p.m. Keynote Speech**
Dr. Elias A. Zerhouni, Emeritus Professor of Radiology and Biomedical Engineering and Senior Advisor, John Hopkins Medicine
- 4:30 – 5:15 p.m. Session VIII: Academics' and Economists' Views on Collaboration and Competition**
In this session, panelists will discuss collaboration versus competition and how they can affect innovation incentives. In addition, panelists will consider how reducing risk and uncertainty from regulation or enforcement impacts innovation. Finally, panelists will discuss both the short-term and long-term risks to markets from collaboration that enable anticompetitive behavior.
Moderator: Patrick Greenlee, Economist, Antitrust Division, U.S. Department of Justice

Presenters: Rena Conti, Associate Research Director, Biopharma and Public Policy,
Associate Professor, Questrom School of Business, Boston University
Scott Hemphill, Moses H. Grossman Professor of Law, New York University
Richard Manning, Partner, Bates White Economic Consulting
Joanna M. Shepherd, Vice Dean and Thomas Simmons Professor of
Law, Emory Law School

5:15 – 5:20 p.m. **Closing Remarks**
Rene Augustine, Deputy Assistant Attorney General, Antitrust Division

5:20 p.m. **End of Day 2**