

A conference co-presented by the IBA Intellectual Property and Entertainment Law Committee, the IBA Technology Law Committee and the IBA Healthcare and Life Sciences Law Committee



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9th Annual World Life Sciences Conference



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1–2 June 2023

The Kimpton Monaco Hotel
Washington, DC

Working programme

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ALL SPEAKER MATERIALS AND BIOGRAPHIES CAN BE FOUND AT
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Conference Co-Chairs

Özge Atilgan *Karakulak Gün + Partners, Istanbul; Member, Intellectual Property and Entertainment Law Committee Advisory Board*

Yuval Horn *Horn & Co, Tel Aviv; Member, IBA Technology Law Committee Advisory Board*

Jose Alejandro Luna Fandiño *Olivares, Mexico City; Co-Chair, IBA Intellectual Property and Entertainment Law Committee*

Cécile Théard-Jallu *De Gaulle Fleurance & Associates, Paris; Vice Chair, IBA Healthcare and Life Sciences Law Committee*

Host Committee Chairs

Karen Carr *ArentFox Schiff, Washington, DC*

Anne Walsh *Hyman, Phelps & McNamara, Washington, DC; Vice-Chair, IBA Healthcare and Life Sciences Law Committee*

Local Host Committee

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Mintz

Morgan, Lewis & Bockius

Nixon Peabody

Ropes & Gray

Sidley Austin

Sterne Kessler Goldstein & Fox

Wednesday 31 May

1830 – 2030 **Hosted reception**

601 Massachusetts Avenue NW, Washington, DC

Headline social event sponsor

Knobbe Martens

MOBILE TELEPHONES

Delegates are requested to ensure that mobile telephones and any other portable devices are switched to silent in working sessions.

**All working sessions will take place in the Paris Room
Breakfasts and lunches will take place in the Athens Room**

- 0730 – 1730 **Registration**
- 0730 – 0830 **Continental breakfast**
- 0830 – 0840 **Opening remarks by the Conference Co-Chairs**
- 0840 – 0910 **Keynote speaker**
Arun Rao *Deputy Assistant Attorney General, US Department of Justice, Washington, DC*
- 0910 – 0940 **Keynote speaker**
Mark Abdo *Associate Commissioner for Global Policy and Strategy, US Food and Drug Administration, Washington, DC*
- 0940 – 1225 **Roundtables**
Introduction
Yuval Horn *Horn & Co, Tel Aviv; Member, IBA Technology Law Committee Advisory Board*
- Topic one: Post-Covid-19 litigation trends**
Moderators
Shelby Buettner *Becton Dickinson, Washington, DC*
Beth Weinman *Ropes & Gray, Washington, DC*
- Topic two: Responsibility, liability and conflict of interests: risks met by compliance officers**
Moderators
Catherine Longeval *Van Bael & Bellis, Brussels; Co-Chair, IBA Healthcare and Life Sciences Law Committee*
Emily Mason *Amgen, Thousand Oaks, California*
- Topic three: Evolution of product liability rules**
Moderators
Eric Alexander *Reed Smith, Washington, DC*
Edona Vila *Borden Ladner Gervais, Toronto, Ontario; Membership Officer, IBA Product Law and Advertising Committee*
- Topic four: Evolution of telemedicine (survey conducted by the IBA Healthcare and Life Sciences Committee)**
Moderators
Renata Fialho *Veirano, São Paulo; Latin American Regional Forum Liaison Officer, IBA Healthcare and Life Sciences Law Committee*
René Quashie *Vice President, Digital Health, Consumer Technology Association, producer of CES®, Washington, DC*

Conference dinner sponsors

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Topic five: Rare diseases and the continuous challenge of marketing an orphan drug

Moderators

David Parsons *Leadiant Biosciences, Washington, DC*

Kristin Wall *Norton Rose Fullbright, Toronto, Ontario*

Topic six: Current opportunities and challenges in strategic collaborations

Moderators

Elysangela De Oliveira Rabelo Maurer *Rabelo Maurer Advocacia, São Paulo; Vice Chair, IBA Life Sciences Subcommittee*

Harry Rubin *Kramer Levin, New York*

Topic seven: The European unitary patent court system

Moderators

Christophe Ronse *Altius, Brussels; Scholarship Officer, IBA Intellectual Property and Entertainment Law Committee*

Amrish Tiwari *KNS Partners, Gurgaon, Haryana; Chair, IBA Life Sciences Subcommittee*

Topic eight: Post public health emergency

Moderator

Howard Sklamberg *Arnold & Porter Kaye Scholer, Washington, DC*

Topic nine: Patents in the US versus ROW

Moderators

Jason Jarvis Jardine *Knobbe Martens, San Diego, California; Chair, IBA Patent Law Subcommittee*

Alex Spiegler *ArentFox Schiff, New York*

Topic ten: Impact of metaverse on life sciences industry: fiction or future reality?

Moderators

Jeffrey Costellia *Nixon Peabody, Washington, DC; Website Officer, IBA Intellectual Property and Entertainment Law Committee*

Elisa Stefanini *Portolano Cavallo, Milan*

Topic eleven: Recent regulatory changes and opportunities in medical and recreational cannabis

Moderators

Ignacio Gillmore *Carey, Santiago*

Mariana Larrea *KIO Networks, Toluca*

Topic twelve: Public to private sector technology transfer: challenges and solutions

Moderator

Camila Parise *Pinheiro Neto Advogados, São Paulo*

Topic thirteen: Food labelling (octagons, symbols, difficulties) and cannabis regulations

Moderators

Ana Maria Castro *Lloreda Camacho & Co, Bogota*

Viviana Cervieri *Cervieri Monsuárez, Montevideo*

Topic fourteen: Managing market access at a global level

Moderators

Markus Schott *Baer & Karrer, Zurich*

Charlotte Tillett *Stevens & Bolton, Guildford*

Topic fifteen: Pricing of medications

Moderators

Miranda Franco *Holland & Knight, Washington, DC*

Andreas Wildi *Walder Wyss, Zurich*

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Topic sixteen: Abortion pill: medicine versus law

Moderators

John Murphy III *Chief Policy Officer, Biotechnology Innovation Organization, Washington, DC*

Eva Temkin *King & Spalding, Washington, DC*

Topic seventeen: How new players will impact traditional healthcare providers

Moderator

Gary Copelovitz *Lipa Meir & Co, Tel Aviv*

1230 – 1300

Keynote speaker

Dr Ryan Reeves *Director of Science and Technology, International Space Station US National Lab, Melbourne, Florida*

1300 – 1345

Lunch

1345 – 1445

PLENARY SESSION ONE

Technology (AI) and the engagement of physicians

Along with the rapid pace of innovation in digital health products and services, AI and other computer learning models are increasingly used in a variety of health settings in familiar and new ways. These tools are both welcomed and viewed with concern. This panel will explore several things – first, establishing a common literacy for what is meant by AI, sorting fiction from science fiction. Second, the panel will explore the ways in which AI is already deployed in health care settings, often without much fanfare, and how we can use regulations and processes to manage present risks. Finally, we will touch on what is coming and how it is the different in degree or kind from past digital health technologies.

Moderator

Jennifer Geetter *McDermott Will & Emery, Washington, DC*

Speakers

Richie Bavasso *nQ Medical, Cambridge, Massachusetts*

David Kizner *Viz.ai, Redwood City, California*

Deanne Primozić *Santesys Solutions, Washington, DC*

1445 – 1545

PLENARY SESSION TWO

From primary to secondary use of health personal data, from open data to intellectual property investment protection: is privacy opposed to data valuation?

How can we ethically and effectively share and value health data for both primary and secondary use? Join our panel of experts as they will explore the opportunities and challenges of leveraging health data to improve healthcare outcomes, drive innovation, and advance research. We'll delve into key questions such as: How can we ensure data privacy and security while promoting data sharing? What are the ethical considerations around data ownership and informed consent? Which should be the boundaries between the processing of health data, privacy and the development of innovation in health? What are the concerns and challenges for the international transfer of data between the US and EU due to the shield, Data Governance Act and European data space? Don't miss this discussion on the cutting edge of health data sharing and valuation.

Moderators

Fabio Alonso Vieira *Kestener & Vieira, São Paulo*

Cécile Théard-Jallu *De Gaulle Fleurance, Paris; Co-Chair, IBA Healthcare and Life Sciences Law Committee*

Speakers

Scott Jones *Johnson & Johnson Washington, DC*

Kim Le *Debevoise & Plimpton, San Francisco, California*

Samuli Simojoki *Borenus Attorneys, Helsinki*

1545 – 1600

Coffee/tea break

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1600 – 1700

PLENARY SESSION THREE

M&A panel on current trends in the HCLS industry

The M&A panel will focus on recent worldwide M&A activity in the life science sector, and market dynamics that are impacting levels of M&A activity. The panel will consider various types of deals as well as alternatives to M&A such as licensing and collaboration deals between biotechs and big pharma. Considerations such as the state of capital markets and regulatory developments will also be reviewed.

Moderators

Bill Whelan *Mintz, Boston, Massachusetts*

Speakers

Lorenza Ferrari Hofer *Schellenberg Wittmer, Zurich*

Pamela F Forrest *Covington & Burling, Washington, DC*

Murphy Gallagher *SVB Securities, Washington, DC*

Jabali Wells *Founding Managing Partner, Blackpoll Capital Partners, Washington, DC*

Frank Zhou *JunHe, Shanghai, Membership Officer, Healthcare and Life Sciences Law Committee*

1700 – 1800

PLENARY SESSION FOUR

The revolution of the food industry into the life sciences helm

During the past decade the food industry has been under constant transformation. From the climate crisis to consumer awareness and a pandemic, the sector faced variations that tested its resilience and innovation ability. With increased interest in plant-based options, sustainable food production and consumer health concerns with affordability, disruptive technologies are emerging.

Our panel aims to discuss how those trends and standards for increased transparency and safety will reflect in new regulatory and post-market realities.

Moderators

Karen Carr *Arent Fox Schiff, Washington, DC*

Anderson Ribeiro *Souto Correa Advogados, São Paulo*

Speakers

Kristin Bresnahan *General Counsel, Nobell Foods, New York*

Matias Cortes *Foodwit, Portland, Oregon*

Andreas Natterer *Schönherr Rechtsanwälte, Vienna*

Tony Pavel *Deputy General Counsel, Global Food Law, Perfect Day, Berkeley, California*

1900

Conference dinner

Mastro's Steakhouse, 600 13th Street, NW

As the restaurant is a short walk from the Kimpton Monaco Hotel transport will not be provided.

Places must be pre-purchased. Please enquire about availability at the registration desk.

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Breakfasts and lunches will take place in the Athens Room

0730 – 1230

Registration

0730 – 0830

Continental breakfast

0830 – 0840

Welcome remarks

Jose Alejandro Luna Fandiño *Olivares, Mexico City; Co-Chair, IBA Intellectual Property and Entertainment Law Committee*

Marc Hilber *Oppenhoff & Partner, Cologne; Co-Chair, IBA Technology Law Committee*

Catherine Longeval *Van Bael & Bellis, Brussels; Co-Chair, IBA Healthcare and Life Sciences Law Committee*

0840 – 0945

PLENARY SESSION FIVE

A global look at expedited programmes for drug and device development

Expedited programs such as accelerated approval have been a critical tool to get promising new treatments to patients more quickly, and have been the subject matter of an EU legislative proposal. However, such programs are increasingly a source of controversy, with new pressures emerging with respect to the tradeoffs associated with residual uncertainties in approvals based on certain biomarkers or clinical endpoints, the costs of such products, the speed of confirmation of effectiveness via post-market clinical trials, and the use of real-world evidence to support such confirmation. This panel will take a comparative look at such expedited programs, and examine these evolving regulatory and legal issues.

Moderators

Daniel Kracov *Arnold & Porter Kaye Scholer, Washington, DC*

Joanna Krakowiak *Wardynski & Partners, Warsaw*

Speakers

Juan Carlos Macouzet *Astellas Farma México, Mexico City*

Augusto Martínez *Janssen Mexico, Mexico City*

John Murphy III *Chief Policy Officer, Biotechnology Innovation Organization, Washington, DC*

0945 – 1100

PLENARY SESSION SIX

Significant international post-pandemic IP policies. A worldwide review.

The pandemic triggered various threats to the patent system in various jurisdictions. Some of them were temporary and unarmful but others seem to sustain trends and intimidation against innovators, especially in some fields such as biotechnology.

The panel will analyze and comment on practices including potential restrictive patentability criteria, patent backlogs, compulsory licensing, weak patent enforcement, litigation strategies, and lack of regulatory data protection.

The discussion will include the weight of the TRIPS waiver expansion and WHO pandemic treaty and the central role USTR have in determining IP policies which could have influence in the public and private sectors.

The mRNA space, especially in the context of the global rollout of the vaccines, also intersects with ongoing global IP policy issues. In many ways, pandemic, also demonstrated how innovators and governments were able to make progress together to improve global health.

Moderators

Özge Atilgan Karakulak *Gün + Partners, Istanbul; Member, Intellectual Property and Entertainment Law Committee Advisory Board*

Jose Alejandro Luna Fandiño *Olivares, Mexico City; Co-Chair, IBA Intellectual Property and Entertainment Law Committee*

Speakers

Anjam Aziz *PhRMA, Washington, DC*

Corey Salsberg *Novartis, Washington, DC*

Daniel Shores *Rothwell Figg Ernst & Manbeck, Boston, Massachusetts*

1100 – 1120

Coffee/tea break

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Criminal considerations for corporate counsel

A life sciences company in the crosshairs of a government investigation faces wide variability in the penalties that can be brought against it and any responsible individuals within the company. Learn from government and in-house lawyers around the world about the risk of criminal liability for regulatory violations. The panel will provide a comparison of the framework used in different countries for making prosecutorial decisions, and the compliance considerations that companies should consider minimising potential criminal exposure.

Moderators

Raj Pai *Sidley Austin, Washington, DC*

Anne Walsh *Hyman, Phelps & McNamara, Washington, DC; Vice Chair, IBA Healthcare and Life Sciences Law Committee*

Speakers

Martin Gantzhorn *Bech-Bruun, Copenhagen, Denmark; European Regional Forum Liaison Officer, Healthcare and Life Sciences Law Committee*

Ross Goldstein *Assistant Director, US Department of Justice, Consumer Protection Branch; Washington, DC*

Kathy Martin-Weis *Former Acting Director, US Food and Drug Administration, Office of Criminal Investigations, Washington, DC*

1230 – 1240

Final comments by the Conference Co-Chairs

1240 – 1330

Lunch

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LIFE SCIENCES

Expertise

We provide a one-stop-shop legal service for life sciences companies combining the firm's strengths in all practice areas. Our expertise cover wide range of life sciences products including pharmaceuticals, medical devices, food supplements, healthcare products and cosmetics.

We advise and represent trade organisations in the pharmaceutical and medical device sectors in relation to all local and international aspects of their field of activity and member interests, their relations with governmental organisations and peers, as well as establishing regulatory policies, position papers and the like.

We advise clients across all phases of the business cycle of life science products including clinical trials, marketing authorization procedures, pricing and reimbursement regulations, observational studies, promotional activities and ethical rules governing relations with healthcare professionals.

We advise and represent clients in life sciences sector in relation to all types of commercial transactions and contracts including licensing, technology transfer, co-marketing, co-promotion and toll manufacturing agreements, joint research, collaboration and development schemes as well as on data privacy and competition law issues.

Combining our life sciences expertise with our employment, competition and anti-corruption expertise, we support corporate clients in compliance with the FCPA and UKBA and the corresponding Turkish rules and regulations as well as offering compliance audits and training programs.

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Dispute Management
Corporate and M&A
Data Protection and Privacy
Business Crimes and Anti-Corruption
Employment
Administrative, Tax and Regulatory
Competition
Finance

INTELLECTUAL PROPERTY

Patent and Utility Models
Trademarks and Designs
Anti-Counterfeiting
Copyrights
IP Prosecution

INDUSTRIES

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Technology, Media and Telecom
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Knobbe Martens is one of the largest IP law firms in the U.S. and has consistently been recognized for having one of the preeminent life sciences IP practices in the country.

Knobbe Martens is comprised of close to 300 lawyers and scientists, with over 80 working in life science fields. The combination of law and deep technical knowledge makes Knobbe Martens attorneys uniquely qualified to represent a diverse array of clients in a broad spectrum of intellectual property matters. The firm is internationally recognized across the spectrum of life science disciplines and is considered an authority on related intellectual property issues. More information about the firm can be found at www.knobbe.com.



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