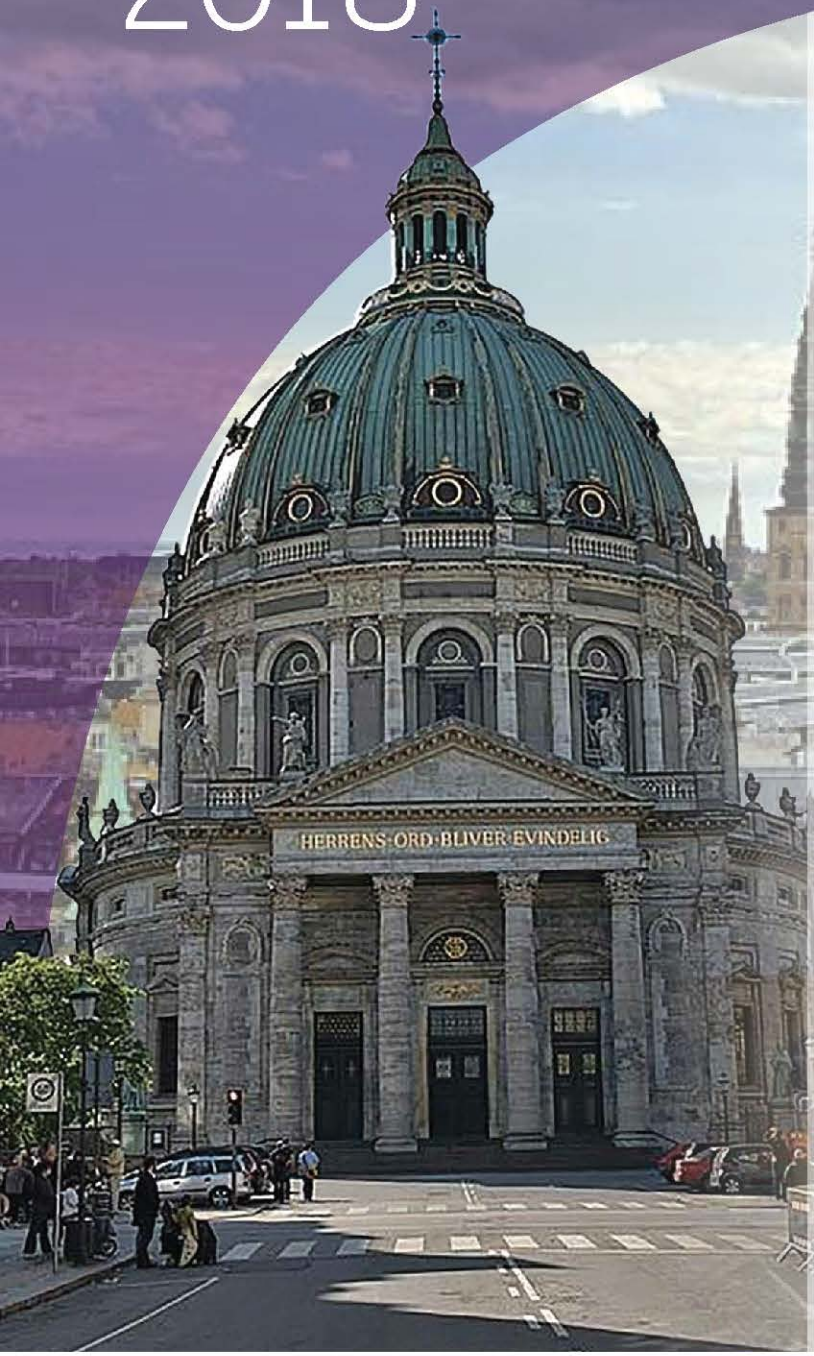
ABA Section of International Law

Lifesciences Conference 2018



- European Patent Package
- Jurisdiction in Life Sciences Litigation
- Investigations, Discovery & Privileges
- Regulatory Developments
- Trade Secrets
- Product Pricing
- Worldwide Clinical Trials
- Artificial Intelligence
- Privacy / Data Protection
- Ethics

June 10-12, 2018

Scandic, Copenhagen

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2018 LIFE SCIENCES CONFERENCE COPENHAGEN, DENMARK

Scandic Copenhagen, Vester Søgade 6, 1601 København V, Denmark

Schedule of Events

SUNDAY, JUNE 10, 2018

5:00 PM-6:30 PM — **WELCOME RECEPTION - Scandic Copenhagen**

Join us for the welcome reception at the Scandic Copenhagen. Start the conference by getting to know your colleagues and fellow attendees.

MONDAY, JUNE 11, 2018

8:00 AM – 9:00 AM — **REGISTRATION & BREAKFAST**

8:55 AM-9:00 AM — **OPENING REMARKS**

Steve Richman, Chair, Section of International Law

9:00 AM – 10:30 AM — **OPENING PLENARY SESSION**

LIFE SCIENCE REGULATION AND THE TIDAL WAVES OF CHANGE

The life science sector is amongst the fastest growing sectors – both economically and technically. It is offering and will in an ever faster accelerated pace offer patients new and better treatments through new and evolving technology advancements – more sophisticated electronic medical records (EMRs), wearable health care devices, next-generation sequencing, breakthroughs in genomics, immunotherapy, and gene therapy, and use of real-world evidence (RWE) and data analytics. But it all comes at a cost. The obvious are financial, but as medical devices are increasingly interconnected—via the Internet, hospital networks, other medical devices, smartphones, electronic health records, and third-party cloud solutions—there's also an increased risk of cybersecurity attacks and infringements of the patients' personal sphere. The opening session will give a perspective on where we are and will then focus on anticipated legal issues and possible solutions, including data protection issues, intellectual property issues, compliance issues, and whether the regulation and increasing compliance requirements are adequate and can keep up with the tides of change.

Panel Chair:
Niels Walther-Rasmussen, Mazanti-Andersen Korsø Jensen, Copenhagen, Denmark

Speakers:
Ida Sofie Jensen, CEO, The Danish Association of the Pharmaceutical Industry, Copenhagen, Denmark
Craig Rappel, Rappel Health Law Group PL, Vero Beach, FL
Stephan Rau, McDermott Will & Emery, Munich, Germany

10:30 AM – 11:00 AM — **NETWORKING BREAK - Pauseområde (Ballroom Foyer)**

11:00 AM – 12:30 PM **CONCURRENT SESSIONS**

THE EUROPEAN PATENT PACKAGE: A CONTEMPORARY PILGRIM'S PROGRESS?

In 2012, 25 of the then 27 EU member states agreed to the European Patent Package that would provide for a unitary patent among participating states, simplify the language regime and create the Unified Patent Court. This session explores the impact of this package, particularly on intellectual property lawyers, and remaining legal hurdles including the final preparations for the provisional application phase and sunset period.

Panel Chair:
Liz Cohen, Bristows LLP, London, UK

Speakers:
Ettie-Ann Alder, Ericsson, Guildford, UK
Nicolaj Bording, Kromann Reumert, Copenhagen, Denmark
James Horgan, Merck, Hertfordshire, UK
Alexander Ramsay, Unified Patent Court, Sweden

THERE'S NO PLACE LIKE HOME: CHALLENGES TO JURISDICTION IN LIFE SCIENCES LITIGATION

If electronic life sciences information is accessible from anywhere, does jurisdiction lie everywhere? In recent decisions, the U.S. Supreme Court imposed substantial limitations on forum-shopping in patent infringement and product liability litigation filed in the U.S., which should generally have a favorable impact on life sciences companies. But as we've recently seen, some federal and state court trial judges have their own view on whether they are automatically required to give up large-scale litigation in their courtrooms.
What is the extraterritorial reach of U.S. laws (such as civil RICO, wire fraud investigations, securities and antitrust) on European life sciences companies? In Europe, the introduction of the Unified Patent Court may be affected by Brexit and affect life sciences patent litigation in Europe and the UK. This panel discusses litigation strategies in light of these new developments.

Panel Chair & Moderator:
Gerald P. Schneeweis, Clark Hill LLP, San Diego, CA

Speakers:
Rachel Leninger Schweers, Novintum Biotech, Schaffhausen, Switzerland
Lisa Savitt, The Axelrod Firm PC, Washington, DC
Alexander S. Vesselinovitch, Freeborn & Peters LLP, Chicago, IL

12:30 PM – 2:00 PM **NETWORKING LUNCHEON - Grand Ballroom 12-15**

2:30 PM – 4:00 PM **SESSION**

SENSITIVE PERSONAL DATA ALERT: DATA PROTECTION, CYBERSECURITY AND ETHICAL CHALLENGES IN USES AND DISCLOSURES OF CLINICAL RESEARCH AND DATA

Patient health data, as sensitive personal information, is among the most highly regulated information in the world. Does regulation interfere with or help facilitate the development of research and new modalities of treatment, such as connected devices to monitor patients and mass data collection to assist artificial intelligence applications in diagnosis, treatment and research? In addition, whether at the hands of regulatory authorities or private parties, the company's documents and information containing patient and research subject identifiable data are frequently subject to disclosure demands. This session provides a comparison of law and practice in the US and Europe, including the General Data Protection Regulation; legal constraints on export of health data from the EU to the US Asia, Canada, Africa and other jurisdictions; disclosures of health data to governments, courts and insurance companies, and related rules of professional conduct for attorneys and medical practitioners.

Panel Chairs:
Ken Rashbaum, Barton LLP, New York, NY
Mark Anderson, Law Society of England and Wales & Anderson Law LLP, Oxford, UK

Moderator:
Mark Anderson, Law Society of England and Wales & Anderson Law LLP, Oxford, UK

Speakers:
Holger Bielesz, Wolf Theiss Rechtsanwälte GmbH & Co KG, Vienna, Austria
Susanne Kudsk, Aarhus University, Aarhus, Denmark
Ken Rashbaum, Barton LLP, New York, NY
Jorg Rehder, Schiedermair, Frankfurt, Germany
Amie Taal, Stratagem Tech Solutions Limited, London, UK

4:00 PM-4:30 PM **NETWORKING BREAK – Pauseområde (Ballroom Foyer)**

4:30 PM – 6:00 PM CONCURRENT SESSIONS

WHO LIVES, WHO DIES, WHO RECEIVES TREATMENT AND WHO GETS TO DECIDE? WHEN ADVANCES IN BIOMEDICINE LEAD TO MORE QUESTIONS AND FEWER ANSWERS

Developments in life sciences and biomedicine lead to more questions than answers about how these advances should be applied, and what is the role of government in defining how and when and if a treatment or drug may be used, not to mention who should regulate its cost and who should pay for it. The United States and European countries alike are grappling with these issues, including price regulation for new and potentially life-saving therapies, but they often come to different conclusions.
When should “experimental” or untried approaches be allowed, and who should pay for them? Should the costs of new therapies be regulated in the public interest and, if so, how? When if ever is it permissible to "pull the plug" to end life support and who should make this decision?

Panel Chair:
Monika Gattiker, Attorney-at-law, Zürich, Switzerland

Speaker:
Dr. Simone Breitkopf, Market Access EU, Berlin, Germany
Beatus Hofrichter, ConCep+, Switzerland
Dr. Andreas Natterer, Schoenherr, Vienna, Austria
Sidney D. Watson, Saint Louis University School of Law, St. Louis, MO

TRADE SECRETS: APPROACHES AND DEVELOPMENTS

Trade secrets have become increasingly important, resulting in new statutory directives in the U.S. and Europe. This is having an impact not only on businesses, but also on inventors, entrepreneurs, and regulators and their legal counsel. This session explores the new EU Trade Secrets Directive in a comparative perspective to the U.S. Defend Trade Secrets Act of 2016. Particular focus will be on the availability and practical use of enforcement instruments, including discovery proceedings and court-ordered searches.

Panel Chairs:
Frederik Kromann Jespersen, Gorrissen Federspiel, Copenhagen, Denmark
Jacob Ørndrup, Gorrissen Federspiel, Copenhagen, Denmark

Speakers:
Scott E. Davis, Klarquist, Portland, OR
Henrik Rothe, Danish Maritime and Commerical High Court

6:30 PM – 8:00 PM RECEPTION – Association of Danish Law Firms

The reception will be held at the headquarters of The Association of Danish Law Firms - a voluntary representative bar association for Danish law firms, where approx. 70% of all Danish lawyers are members. The Associations offices are situated in a 120-year-old, but newly renovated beer and dancehall “Valencia”. Over the years the dance hall has been called “Thor’s Beerhall” and the “The Moulin Rouge of Scandinavia” – and if only the walls could talk!

TUESDAY, JUNE 12, 2018

8:00 AM – 9:00 AM REGISTRATION & BREAKFAST

9:00 AM – 10:30 AM CONCURRENT SESSIONS

PRODUCT PRICING: LEGAL AND ETHICAL CONSTRAINTS

This session will explore present and likely future regulation on pricing of medicinal products, both US/EU domestically and in the context of export to developing countries. What are the mechanics of reimbursement of drug costs in the US and EU and what is their effect upon research and development of and access to new, innovative medicines?

Panel Chairs and Moderators:
Torkil Høeg, DLA-Piper, Copenhagen, Denmark
Karen Dyekjær, DLA-Piper, Copenhagen, Denmark

Speakers:
Jörn Grotjahn, Geiger & Nitz, Munich, Germany
Sharon Lamb, McDermott Will & Emergy, London, UK
Elisabeth McCuskey, University of Toledo College of Law, Toledo, OH
Ana Santos Rutschman, DePaul University College of Law, Chicago, IL

HAS THE FUTURE ARRIVED? IF SO, HOW SECURE IS ITS HEALTH INFORMATION? ARTIFICIAL INTELLIGENCE, BLOCKCHAIN AND LIFE SCIENCES DATA

Great advances have been made in the use of analytics and artificial intelligence in research and diagnosis. Some of these applications can process millions of scholarly papers and medical records in seconds and advise researchers and clinicians of answers to their questions, rated by degree of probability. How will protection of privacy be maintained? How can this information be secured? "Blockchain"—the shared repository for peer to peer distribution of information is increasingly utilized as a security tool in financial services, but what is its utility in life sciences, particularly in terms of patient security, collaboration, and delivery of and payment for treatment? This panel addresses how, and whether, the Blockchain revolution and other technical information protection platforms could transform patient consent documentation and access to patient records; how AI may revolutionize medical treatment; potential uses of robots and other forms of artificial intelligence and machine learning in diagnosis and research.

Panel Chair:
Jakob Krag Nielsen, Lundgrens, Copenhagen, Denmark

Speakers:
Gene Burd, Arnall Golden Gregory LLP, Washington, DC
Jonathan Jenkins, McKinsey & Company, UK

10:30 AM – 11:00 AM NETWORKING BREAK - Pauseområde (Ballroom Foyer)

11:00 AM – 12:30 PM CONCURRENT SESSIONS

WORLDWIDE CLINICAL TRIALS: THE CHALLENGES OF SIMULTANEOUS COMPLIANCE

Can your organization be one hundred percent compliant in one hundred percent of its business locations? That is a very high bar and one few companies can meet. Is attempting to do so feasible or even desirable? The challenges of simultaneous compliance with US, EU and other national regulations, the role of the EU 'legal representative', the differing roles of CROs, and the expectations of investigator sites in different jurisdictions and cost containment will be analyzed in the interactive discussion.

Panel Chair:
Stephan Rau, McDermott Will & Emery, Munich, Germany

Moderator:
Jana Grieb, McDermott Will & Emery, Munich, Germany

Speakers:
Autumn Dawn Lang, PhD, RAC, Clinlogix, Germany
Renata Oliveira, Veirano, Brazil
Roberta Verdesca, Amgen, Milan, Italy

QUASI-IP IN THE EU AND USA, AND ITS EFFECT ON THE LIFE SCIENCE SECTOR

How do rights granted by statute and regulation (and, in common law jurisdictions, case law) attain the qualities and aspects of intellectual property protection in the life sciences area? Regulations in multiple countries provide legal protection to those developing and commercializing life science products. These including provisions governing licenses, data exclusivity, supplementary protection certificates, orphan drug status and pediatric exemption. This session will consider the effect of these regulations on regulatory oversight, litigation, transactions and product and process development strategy in the life science sector.

Panel Chair:
Craig Rappel, Rappel Health Law Group PL. Vero Beach, FL

Moderator:
Carla Whillier, Chair of the Ontario Bar Association Health Law Section, Board Member Ontario Ministry of Health and Long-Term Care, Ontario, Canada

Speakers:
Dr. Achim Hansjürgens, Hako-Med GmbH, Karlsruhe, Germany
Bert Oosting, Hogan Lovells, Amsterdam, Netherlands

12:30 PM – 2:00 PM **NETWORKING LUNCHEON - Grand Ballroom 12-15**

2:30 PM – 3:30 PM **CLOSING PLENARY SESSION**

FUTURE OF LIFE SCIENCES: THE CONVERGENCE OF PRIVATE AND PUBLIC LAW

In our closing Plenary we will address conflict of patents versus distribution to developing countries, treaties, best practices, corporate social responsibility; developing drugs for treatment of non-profitable, prevalent disease, and the social responsibility aspect of life science.

Panel Chair:
Steven M. Richman, Clark Hill PLC, Princeton, NJ

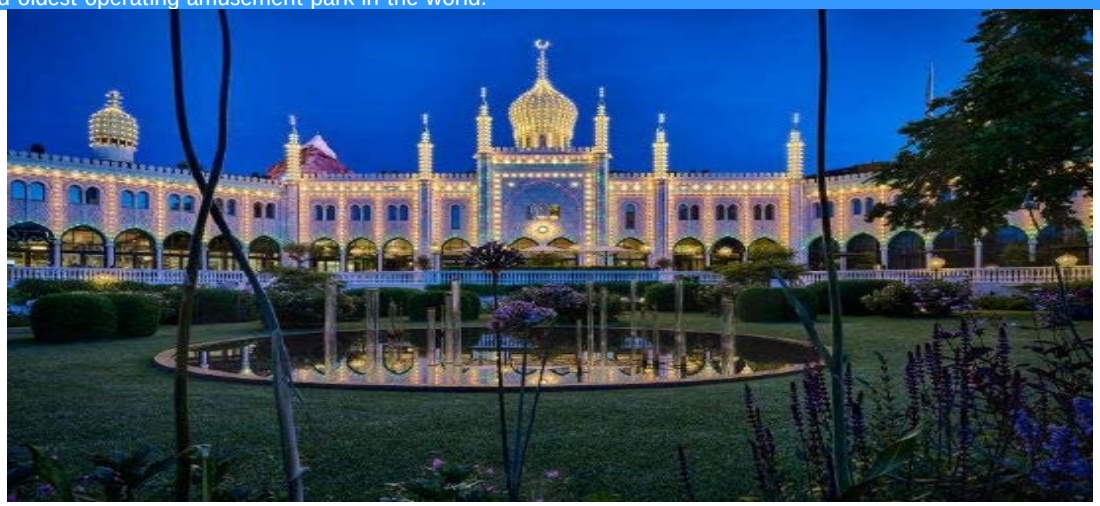
Speakers:
Andrew J. Bayne, The Bayne Law Group LLC, Princeton, NJ
Michael E. Burke, Arnall Golden Gregory LLP, Washington, DC
Megan S. Wynne, Turtle Beach Corporation, San Diego, CA

4:00 PM – 5:30 PM **RECEPTION AT TOWN HALL**

Copenhagen City Hall is the headquarters of the municipal council as well as the Lord mayor of the Copenhagen Municipality. The building is situated on The City Hall Square in central Copenhagen, and was built in the years 1892-1905. It was designed by the architect Martin Nyrop in the National Romantic style, drawing inspiration from the Siena City Hall, Italy. In recent years The City Hall has been used for scenes in Danish hit tv series like "The Killing" and "Borgen".

6:00 PM **DINNER AT MAZZOLI (includes entrance to Tivoli Gardens) Separately ticketed: $125 USD**

Tivoli Gardens is a famous amusement park and pleasure garden in Copenhagen, Denmark. The park opened on 15 August 1843 and is the second-oldest operating amusement park in the world.



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