HYBRID EVENT

EU Pharmaceutical Law Forum

CELEBRATING 32 YEARS

TUESDAY 23RD - THURSDAY 25TH MAY 2023
The Steigenberger Wiltcher's Hotel, Brussels

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EU Pharmaceutical Law Forum

CELEBRATING 32 YEARS

IN-PERSON EXPERIENCE – 23 - 25 MAY
BRUSSELS

Reconnect with fellow legal professionals and the big names in industry to celebrate the 32nd year of EU Pharmaceutical Law Forum. Packed with keynote presentations, vibrant discussions and numerous networking opportunities, this is a great time to exchange views and discuss the latest challenges within the legal pharmaceutical industry.

- 3 full days of in-person content from the EU Commission, EMA and leading in-house counsel
- Evening drinks reception
- Customised breakout opportunities for tailored learning
- Partnering and meeting opportunities through the ConnectMe App
- Everything included in the digital experience and on-demand library

DIGITAL EXPERIENCE
ONLINE

For any reason you're unable to join us in person you can still connect with us digitally and experience the same content-rich programme on-demand.

- Live streamed from Brussels, plus, view all of the recorded presentations from the main in-person conference on-demand from Tuesday 30th May for 10 working days.
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- Explore the partnering and meeting opportunities through the ConnectMe Platform
- ConnectMe Platform with dynamic features including: attendee and company profiles, advanced search capabilities to identify opportunities and potential partners, easy-to-use technology to enable virtual networking, seamless scheduling tools to establish meeting times

AGENDA
COMPETITION LAW AND PATENT LITIGATION: TUESDAY 23 MAY 2023

All live presentation times listed are in Central European Time (CET)

9:00 Opening Remarks from Morning Chair
Mélanie Thill - Tayara, Antitrust/Competition Partner, **Dechert LLP**

9:10 **KEYNOTE Update from EU Commission on Competition Law Enforcement**
- Recent updates on competition law enforcement in the EU pharmaceutical sector
- Current and future focus for 2023 and beyond

Paul Csiszár, Director, DG Competition, **European Commission**

9:45 **PANEL: Merger Control and Expanded Jurisdictional Reach: Lessons from Illumina/Grail Case**
- Experience in the Illumina / Grail case: examining the procedural aspects and merits of the case, and the on-going gun jumping investigation
- Are the theories of harm damaging innovation?
- Commercial implications precautionary advice from the Illumina/Grail case
- Review of wider merger control cases

Paul Csiszár, Director, DG Competition, **European Commission**
Julia Wahl, Partner, **Copenhagen Economics**
Héctor Armengod, Partner, **Latham & Watkins LLP**
Michael Frese, Associate, **Skadden, Arps, Slate, Meagher & Flom LLP**
Noel Watson-Doig, Senior Counsel Global Pharma Competition Law and Legal Operations, UK & Ireland Pharma, **GSK**

11:00 - 11:30 - Networking Break

11:30 **PANEL: Competition Developments Involving Promotional Strategies and Disparagement**
- Product denigration and disparagement in the Vifor Pharma case
- Implications for the industry: repercussions of an innovator vs. innovator dispute and potential consequences for dispute resolution solutions regularly applied to advertising and promotions
- Wider strategies employed for preventing competition involving regulatory processes

Alexis Brunelle, Case Handler, **Autorité de la Concurrence**
Michael Clancy, Partner, **Van Bael & Bellis LLP**
Angélique de Brousse, Head of Competition Law and Policy Group EMEA, **Johnson & Johnson**
Blaz Visnar, Deputy Head of Unit, DG Competition, **European Commission**

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12.30 **DUAL DIALOGUE: Antitrust Developments for Patent Procedures**

- Update on judgment and implications of the Servier case
- Implications of the EU Commission's Statement of Objections on the Teva Copaxone case and examining the theory of harm in the Novartis case

James Killick, Partner, **White & Case LLP**

Blaz Visnar, Deputy Head of Unit, DG Competition, **European Commission**

13:10 - 14:30 - Networking Lunch

14.30 **ENFORCERS' ROUNDTABLE: Recent Trends in the Pharmaceutical Sector**

- Active enforcement and progress of investigations in the pharmaceutical sector
- The Netherland's investigations into excessive pricing
- Belgium Authority scrutiny into biosimilars

Pablo Amador Sanchez, Senior Case Handler, **Netherlands Authority for Consumers and Markets (ACM)**

Damien Gerard, Prosecutor General, **Belgium Competition Authority**

Claudia Desogus, Officer, **Italian Antitrust Authority**

15.15 **DUAL DIALOGUE: Recent Developments for Supplementary Protection Certificates (SPCs)**

- Scope and rules of procedure of unitary SPCs
- Managing SPC protection in territories not covered by a MA
- Article 3(a) of the SPC Regulation: recent diverging case law and its implications
- Pending CJEU decisions on SPCs and the potential impact

James Horgan, Assistant Managing Counsel, **MSD**

Edward Oates, Partner, **Carpmaels & Ransford**

15:55 - 16:30 - Networking Break

16.30 **DUAL DIALOGUE: The Unified Patent Court (UPC) and Implications for your Approach to Litigation**

- Current experience, practicalities, challenges and opt out options of the UPC
- Practical considerations and management of future filings
- Trends and predictions on how to innovators, generics and biosimilar companies can utilise the UPC

Shohta Ueno, Director, Dispute Resolution, **Regeneron Pharmaceutical Inc**

Tess Waldron, Partner, Powell, **Gilbert LLP**

17.00 **DUAL DIALOGUE: IP Round-Up: Key Developments in Patent Litigation and Impact on Patent Strategies**

- Latest developments on compulsory licensing and their implications for the industry
- Updates on second medical use patents
- Review of decisions on divisional strategies for IP
- Recent patent litigation in France and the implications
- IP implications of interchangeability of biosimilars

Nicolás Vincent Ruiz, Global Intellectual Property Head, **Esteve**

Rafi Allos, Partner, **Allen & Overy**

17.40 **Close of Day Followed by Networking Drinks Reception**

8.50 Opening Remarks by the Morning Chairperson
Eveline Van Keymeulen, Partner, **Latham & Watkins**

9.00 **KEYNOTE EU Commission Update on the Regulatory Landscape**
- The revision of the EU pharmaceutical legislation
- New developments for pharmaceutical incentives and rewards
- Incentives to invest in new antimicrobials to combat resistance

Olga Solomon, Head of Unit Medicines: Policy, Authorisation and Monitoring, DG Sante, **European Commission**

9.30 **KEYNOTE PANEL: Industry Impact the EU Pharmaceutical Legislation Revision**
- Assessing new legislation against its objectives for innovation and availability of medicines
- Industry perspective on incentives for investment in R&D in the European Union
- How do you define unmet medical needs? Definition(s), implications, and risks
- Will the revisions stimulate the development in areas of high need, such as rare childhood diseases? And to combat anti-microbial resistance?**Elise Melon,** Legal Chief of Staff, Head of IP Policy & Operations, **UCB**

Eveline Van Keymeulen, Partner, **Latham & Watkins**
Stefano Marino, Head of Legal Services, **European Medicines Agency**
Olga Solomon, Head of Unit Medicines: Policy, Authorisation and Monitoring, DG Sante, **European Commission**
Kristine Peers, General Counsel, **European Federation of Pharmaceutical Industries and Associations (EFPIA)**

10:30 - 11:00 - Networking Break

11.00 **KEYNOTE PANEL: Detailed Review of Proposals for Incentivising R&D in Unmet Medical Needs: General Pharmaceutical Legislation, Orphan, and Paediatric Regulations**
Peter Bogaert, Partner, **Covington & Burling LLP**
Georgia Gavriilidou, Associate General Counsel, **Amgen**
Victoria Kitcatt, VP & Assistant General Counsel, **Pfizer**
Elise Melon, Legal Chief of Staff, Head of IP Policy & Operations, **UCB**

12.00 **DUAL DIALOGUE: New Obligations and Liability for your Supply Chain**
- Legal requirement and obligations for your supply chain
- Supply chain resilience and sustainability requirements and considerations
- Sanctions and crisis management frameworks for your supply chain

Evi Mathiou, Legal, Compliance & Quality Director, **Novo Nordisk**
Peter L'ecluse, Partner, **Van Bael & Bellis**

12:40 - 14:00 - Networking Lunch

14.00 Opening Remarks by the Morning Chairperson
Christian Jervelund, Partner, **Copenhagen Economics, Belgium**

14.10 **PANEL: New HTA Regulations and Evolving Pharmaceutical Market Access Frameworks**

- How can accelerated regulatory pathways be brought closer to market access pathways?
- Implementation of EU Joint HTA processes and the interaction with national EU processes
- Synergy between HTA and regulatory approval: will faster marketing authorizations lead to faster reimbursement?
- Upcoming changes to member state regulations and implications to reference pricing
- Ilap: new market access pathway in the UK

Ansgar Hebborn, Head, European Access Policy Affairs, **Roche**
Christian Jervelund, Partner, **Copenhagen Economics, Belgium**
Matthias Heck, Attorney-at-Law, Senior Director, International TA Policy Strategy, **AstraZeneca**
Adela Williams, Partner, **Arnold & Porter**

15.10 **DUAL DIALOGUE: Regulatory Frameworks for Healthcare Systems Solutions and Market Access Strategies**

- How are market access initiatives evolving and how can legal teams help support this?
- How can pharma be a partner in healthcare systems solutions?
- New approaches examined: from public-private partnerships and research collaborations to registries and early access schemes

Ilja Moree, Head Legal Oncology Region Europe, **Novartis AG**
Kirsten Broeckers, Vice President, Head Legal Affairs EMEA, **Novartis Gene Therapies GmbH**
Jordi Faus, Founding Partner, **Faus Moliner**

15:50 - 16:20 - Networking Break

16.20 **DUAL DIALOGUE: The IVDR and its Impact on Clinical Trials using IVDs**

- The IVDR from a pharmaceutical company perspective - biomarkers and CDx
- Using IVDs in Clinical Trials - how to ensure compliance
- Validating and CE marking IVDss

Hilary Jones, Senior Director, Legal Pharmaceutical Regulation, **BioNTech UK Limited**
Sophie Pelé, Partner, **Dechert LLP**
Amelie Chollet, Legal Regulatory Counsel, EMEA, **Abbott**

17.00 **DUAL DIALOGUE: Reshaping Clinical Research with Health Data**

- Update on European Health Data Space, EU Data Act and Data Governance Act
- Protecting the value of your data asset in light of EMA access to raw patient level data for marketing authorisation and post-authorisation applications submissions
- EMA transparency provisions: implications of Policy 43 and Policy 70
- EU Clinical Trials Regulation & CTIS transparency requirements
- Consistency between data protection legislative initiatives and regulatory constraints

Martijn ten Bloemendal, Global Privacy Counsel, **AbbVie**
Tine Carmeliet, Senior Associate, **Allen & Overy**

17.40 **Close of Day Followed by Networking Drinks Reception**

	HEALTHCARE DATA AND PRIVACY AND COMPLIANCE:	COMMERCIAL TRANSACTIONS:
8.50	Opening Remarks from Chair **Caroline Stockwell,** VP, Head of Legal, International, **Amicus Therapeutics**	Opening Remarks from Chair **Laetitia Szaller,** General Counsel and VP Business Development, **AM Pharma**
9.00	**KEYNOTE PANEL: New Developments for Healthcare Data and Legal Implications** • Examining key legal frameworks shaping clinical research including the European Health Data Space, Digital Data Act and upcoming Data Act • Commonalities and differences between French and Finnish systems • How does the existing legal framework serve as a basis for innovation, what needs to change? • Do the new proposals provide adequate coverage and encourage clinical research and innovative use of clinical/nonclinical data? Legal frameworks for sharing digital patient data amongst multiple partners • Industry considerations for potential opportunities, challenges and pitfalls **Kristof Van Quathem,** Partner, **Covington & Burling LLP** **Daniele Nardi,** Legal Officer, **European Data Protection Supervisor** **Chris Foreman,** Deputy Chief Privacy Officer, **Merck Sharp & Dohme** **Guillaume Byk,** Legislative, **Officer, DG SANTE, EU Commission**	**Transaction Trends and Deal Landscape in the Life Sciences Sector** • Expected deal trends for 2023/2024 in light of current market conditions • Hot areas for investment in the life science sector • Update on deal structures **Elizabeth-Anne Larsen,** Senior Associate, **CMS** **Hannah Curtis,** Partner, **CMS**
9.50	**DUAL DIALOGUE: Concerns and Conflicts Surrounding the Secondary Use of Clinical Research Data** • Outline of the latest developments and on-going challenges for secondary use • Potential implications for Marketing Authorisations and possible additional conditions set out by Member States • IP considerations: data used for patents, IP rights and trade secrets • Clarity on the provision for regulators to enforce the turning over of data **Florian Zabel,** Chief Privacy Officer Roche Group, **F. Hoffmann-La Roche Ltd** **Alexander Roussanov,** Partner, **Arnold & Porter**	9:30 - **DUAL DIALOGUE: Growth of Foreign Direct Investment Screening: Impact on Licensing and M&A** • New Developments in protectionist policies in US and across EU and their impact for pharmaceutical commercial transactions and collaborations • Examining potential scenarios and how to manage the resulting delays and costs **Orion Berg,** Partner, **White & Case**
	10:30 - 11:00 - Networking Break	10:10 - 10:40 - Networking Break

11.00 **Evolving International Data Transfers and Data Residency Requirement**

- Update on the adoption of new standard contractual clauses
- Assessment of the negotiations on privacy shield and adequacy determinations
- Snapshot of data residency requirements across the globe and a focus on China
- How can pharmaceutical companies navigate the increasingly complex landscape and continue to share data?

Olivier Proust, Partner, **Fieldfisher**

11.30 **Key Updates on for Behavioural Advertising though the Internet: New Developments for Cookies and Google Analytics**

- Legal frameworks compliance: ePrivacy Regulations, GDPR consistency and online consent requirements
- Latest developments and implications for the pharma industry from the IAB Europe case

Cristiana Spontoni, Partner, **Jones Day LLP**

10:40 - 11:20 - **DUAL DIALOGUE: Transactional Realities: Practical Tips on Getting Clearance on M&A, Full Function JVs and Implications from Illumina Grail**

- Practical insight on how to apply for clearance or approval of a transaction
- Examining collaboration agreements between competitors
- Practical commercial implications for transactions and filings from rising antitrust risk
- Delving into the detail from drafting deal terms and condition precedent, to closing dates and timings

Sylvie Vanden Bruel, Associate General Counsel, Business Development, M&A, Antitrust, **UCB**

Jenny Leahy, Senior Associate, Antitrust, Competition and Trade, **Freshfields Bruckhaus Deringer**

11:20 - 12:10 **PANEL: Data Sharing Antitrust Risks in Collaborations and Transactions**

- Risks and strategies to share information in collaborations and commercial transactions
- How to balance antitrust considerations with commercial reasons to share information?
- Practical strategies to manage the exchange of information pre, during and post deals

Laetitia Szaller, General Counsel and VP Business Development, **AM Pharma**

Nicolas Pourbaix, Associate General Counsel, Executive Director, **Amgen**

Michael Gavey, Partner, **Simmons & Simmons LLP**

Adam McArthur, Assistant General Counsel, Digital, IT and Operations, **AstraZeneca**

12:10 - 13:20 - Networking Lunch

HEALTHCARE DATA AND PRIVACY AND COMPLIANCE:

13.20 **PANEL: Preventative and Reactive Steps to Manage a Cybersecurity Crisis**

- Understanding the legal frameworks: Network and Information Security (NIS) Directive and European Cyber Resilience Act
- Development of security and privacy policies, best practices and procedures
- Guide to cybersecurity incidents: investigation, containment and remediation of sophisticated data breaches and cybersecurity incidents
- Best practice for regulatory response and litigation

Janice Carling, Region Europe Privacy & Cybersecurity Counsel, **Teva**

Dan Whitehead, Counsel, **Hogan Lovell**

Paul Tumelty, Mandiant Regional Leader, UKI & Practice Leader EMEA Government, **Google Cloud**

COMMERCIAL TRANSACTIONS:

13:20 - 14:00 - **DUAL DIALOGUE: Structuring Licensing Deals for Platform Technologies**

- Hottest trends for (bio)pharma licensing: mRNA, cell & gene therapy
- Constructing value for platform technology in IP licensing negotiations
- Carving up platform technologies and considering future potential of your investment/IP
- How to get best value from in and out licensing agreements

Kirsten Broeckers, Vice President, Head Legal Affairs EMEA, **Novartis Gene Therapies GmbH**

Olivia Bernardeau-Paupe, Partner, **Dechert**

14:10 **DUAL DIALOGUE: Strategic & Statutory Priority of Environmental, Social, and Governance (ESG)**

- Approach for ESGs to be meaningfully integrated into your business in the Life Science sector
- The role of General Counsel and legal departments in this evolving area
- Updates on Swiss reporting requirements on ESGs and the EU Corporate Sustainability Reporting Directive (CSRD)
- ESGs as part of a wider suite of transparency and trust activities

Arianna Greco, Senior Vice President, Head of Global Commercial Legal, **Alnylam Pharmaceuticals**

Xisca Borrás, Partner, **Bristows**

14:50 - 15:20 - Networking Break

15.20 **Omnichannel Engagement: Compliant Health Care Professional (HCP) and Public/Patient Communication**

- Interpretation of relevant rules related to omnichannel strategies & execution
- Which authority has jurisdiction over a promotional event that occurs online?
- Delving into uncertainty and grey areas for communication and marketing compliance
- Examining legal parameter and areas of risk: from privacy and consumer tracking to direct marketing rules and consent

Martin Dræbye Gantzhorn, Partner, **Bech-Bruun**

15.50 **DUAL DIALOGUE: Compliance Concerns for Advocacy Activates: Product Ambassadors and Social Media Personalities**

- Developments in pharmaceutical regulations and industry codes of conduct
- Legal considerations for emerging advocacy activities including early engagement with product ambassadors, patient advocates and engagement with social media personalities

Marie Manley, Partner, **Sidley Austin LLP**

Michele Boggiani, Director, Global Legal Lead, **Galderma**

14:00 - 14:40 - **DUAL DIALOGUE: Success Factors for Licensing Life Science Deals**

- Discussing the more challenging, yet common risks in license collaboration, true JVs, M&A and investment deals
- Key market insight: what are killing commercial deals? Changing case law and emerging risks
- Areas of risk: operational behaviour preceding the deal and practical things that crop up during and after the deals

Andres Liivak, Partner, **White & Case LLP**

Oliver Kronenberg, General Counsel, **CSL Vifor**

14:40 - 15:10 - Networking Break

15:10 - 15:50 - **DUAL DIALOGUE: WNew Developments and Risk Management in Digital Data Deals**

- When data and technology meet pharma: aligning expectations
- Managing risks in a changing landscape
- Consideration models in data deals
- Approaches to monetising data as if it was IP

Alejandro Bes, Head Legal - Engagement, Platforms and Data, **Novartis**

Daniel Pavin, Partner, **Covington & Burling LLP**

DUAL DIALOGUE: New EC Vertical Block Exemptions and Guidelines; and Draft Horizontal Collaboration Guidelines

- Beyond just collaboration: distribution issues, parallel imports and cross border distributions
- Dual distributions, information exchange and online sales
- Practical advice on adapting practices and structuring contracts to minimise risk for R&D agreements and licensing of IP

Jim Back, Senior Director, General Counsel, EU Antitrust, **Teva Pharmaceuticals**

Marta Giner Asins, Partner, **Norton Rose Fulbright LLP**

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Angélique de Brousse
Head of Competition Law and Policy Group EMEA
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Chris Foreman
Deputy Chief Privacy Officer
Merck Sharp & Dohme

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Amgen

Damien Gerard
Prosecutor General
Belgium Competition Authority

Arianna Greco
Senior Vice President, Head of Global Commercial Legal
Alnylam Pharmaceuticals

Ansgar Hebborn
Head, European Access Policy Affairs
Roche

Matthias Heck
Attorney-at-Law, Senior Director, International TA Policy Strategy
AstraZeneca

James Horgan
Assistant Managing Counsel
MSD

Farhad Jalinous
Partner
White & Case LLP

Christian Jervelund
Partner
Copenhagen Economics, Belgium

Hilary Jones
Senior Director, Legal Pharmaceutical Regulation
BioNTech UK Limited

James Killick
Partner
White and Case LLP

Victoria Kitcatt
VP & Assistant General Counsel
Pfizer

Oliver Kronenberg
General Counsel
CSL Vifor

Peter L'ecluse
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Jordi Faus,
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Head of Legal Services
European Medicines Agency

Evi Mathiou
Legal, Compliance & Quality Director
Novo Nordisk

Elise Melon
Legal Chief of Staff, Head of IP Policy & Operations
UCB

Ilja Moree
Head Legal Oncology Region Europe
Novartis AG

Daniele Nardi
Legal Officer
European Data Protection Supervisor

Mélanie Thill-Tayara
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Sophie Pelé
Partner
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Intellectual Property Head
Esteve

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Head of Unit Medicines: Policy, Authorisation and Monitoring, DG Sante
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