EU Pharmaceutical Law Forum

MAY 21-23, 2024
Steigenberger Wiltcher's, Brussels

Elevate Your Edge At EU Pharma Law Forum: Where Pharmaceutical Law Expertise Meets Networking Excellence

Boost Your Understanding on Key Legal Developments. Discover Innovative Strategies to Bolster Your Business. Forge Connections With Legal Leaders and Grow Your Network.

Authority Insights Direct From the EU Commission, EMA, European Parliament Rapporteurs, and Leading Pharmaceutical Stakeholders.

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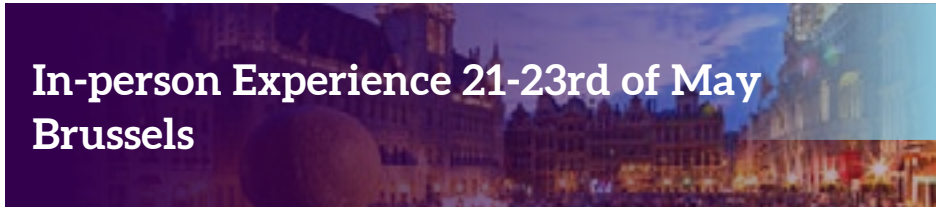
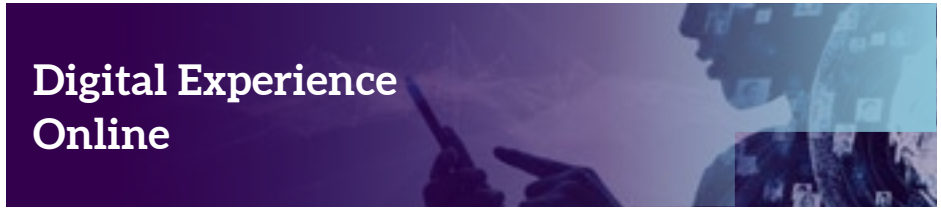
EU Pharmaceutical Law Forum



In-person Experience 21-23rd of May Brussels

Reunite with fellow legal experts and industry titans at the 33rd EU Pharmaceutical Law Forum. Immerse yourself in a program brimming with impactful keynote presentations, dynamic discussions, and an abundance of networking prospects. This presents an excellent opportunity to share perspectives, delve into the latest challenges shaping the legal pharmaceutical sector, and engage in meaningful discourse within the industry.

- Three full days of in-person content from the EU Commission, EMA, a European Parliament Rapporteur, and leading in-house counsel
- Evening drinks receptions and networking lunches
- 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

If 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 on our ConnectMe platform.

- Watch the main in-person conference in real time live streamed from Brussels.
- View all the recorded presentations from the main in-person conference on demand for 10 working days post-event.
- Explore the partnering and meeting opportunities through the ConnectMe Platform
- Utilise the other dynamic platform features such as: 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 - Day 1
Competition Law, Patents & SPCs - Tuesday, 21 May 2024

9:00 Opening Remarks from Morning Chair

- Recent developments and global antitrust trends
- Influence of EU antitrust thinking on US approach

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 2024 and beyond

Anna Vernet, Head of Unit, DG Competition, European Commission

9:45 **PANEL Merger Control and Expanded Jurisdictional Reach Developments and Strategy**

- Review of recent pharmaceutical merger control cases and authority approach
- Article 22: the latest on Illumina/ Grail and implications for merger control strategy
- Review of wider merger control cases: Pfizer/ Seagen and implications of Towercast judgments
- Comparison of EU developments to global trends in merger control
- How does merger control fit into overall regulatory scrutiny of the pharmaceutical industry?
- Practical commercial implications when planning for commercial deals

Ulla Schwager, Head of Unit, DG Competition, European Commission

Hiram Andrews, Head Legal Antitrust, Novartis

Héctor Armengod, Partner, Latham & Watkins LLP

Julia Sabine Wahl, Partner, Copenhagen Economics

Ingrid Vandenborre, Partner, Antitrust/Competition, Skadden, Arps, Slate, Meagher & Flom LLP

10:45 - 11:15 - Networking Break

11:15 **DUAL DIALOGUE Competition Law Consideration for Information Exchanges**

- Revised EU Horizontal Block Exemption regulations impacting information exchanges
- CMA's consultation on rules applicable to collaborations and information exchanges between competitors and scope of inconsistencies
- Practical advice on how to engage with competitors and customers
- Global implications of the Brazilian and Turkish investigations into antitrust violations involving exchange of information between HR departments for your organisation

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

Fiona Carlin, Partner, Baker McKenzie

Agenda - Day 1
Competition Law, Patents & SPCs - Tuesday, 21 May 2024

11:55 **PANEL Foreign Subsidies Regulation: Application and Practicalities for the Pharma Sector**

- Foreign Subsidies regulation (FSR): what are the obligations?
- FSR implications for public procurement
- Visibility on how FSR is operating and practical realities

Grímur Jóhannsson, Legal Manager,EFPIA

Alexandru Biolan, Member of the Legal Service, European Commission

Jonas Koponen, Partner, Cooley LLP

Angélique de Brousse, Head of Competition Law and Policy Group EMEA, Johnson & Johnson

13:00 - 14:30 - Networking Lunch

14:30 **DUAL DIALOGUE Pricing Developments: Discriminatory Pricing, Discounts and Rebates**

- EC's consultation on the formal guidelines on the application of Article 102 TFEU to exclusionary abuses of dominance: potential implication to the pharmaceutical industry with respect to discounts and rebates
- Practical advice on pricing/rebate decisions and negotiations in current economic environment and enforcement landscape
- How can you resist clawbacks (VPAS) and other austerity measures without falling fowl of competition law compliance?

Michael Clancy, Partner, Van Bael & Bellis

Alexandru Potlog, Legal Director, UK & Ireland, AbbVie

15:10 **TRI DIALOGUE Key Developments at the Intersection of Antitrust and Intellectual Property**

- Implications of the Teva/Copaxone case and Novartis case on unilateral conduct and divisional strategies for IP and reg exclusivities
- Potential implications if the EU Commission adopt a new theory of harm
- Implications from the Servier case: where are we with patent settlements and practical guidance on managing antitrust risk

James Killick, Partner, White and Case LLP

Anna Vernet, Head of Unit, DG Competition, European Commission

Nicolas Pourbaix, Senior Counsel, Amgen

15:50 - 16:15 - Networking Break

16:15 Opening Remarks from Afternoon Chair

Agenda - Day 1
Competition Law, Patents & SPCs - Tuesday, 21 May 2024

16:20 **DUAL DIALOGUE Examining Patent Changes in the Pharmaceutical Package: Compulsory Licensing and SPCs**

- Proposed new EU-wide compulsory licensing instruments and the implications for RDP
- WTO international trade aspects of compulsory licensing and review of current national provisions
- Analysis of the SPCs revisions to patent protection in the European pharmaceutical package
- Will the proposed streamlined approach to obtaining EU-wide SPC protection have the desired positive impact for pharmaceutical companies?

Michael Swita, IP Director, EFPIA

Liesbeth Weynants, Partner, Hoyng Rokh Monegier

Amandine Métier, Partner, Hoyng Rokh Monegier

17:00 **TRI DIALOGUE Unitary Patent & Unified Patent Court: Opportunities and Challenges**

- Current experience, practicalities, challenges related to the Unitary Patent package
- Practical considerations and management of future filings
- Trends and predictions on how to innovators, generics and biosimilar companies can utilise the Unitary Patent & UPC

Mathilde Rauline, Head of Greater Europe Patent Litigation, Sanofi

Stefan Luginbuehl, Head of Department European Legal Affairs, European Patent Office

Judith Krens, Partner, Pinsent Masons

17:40 - 18:40

Close of Competition Law, Patents & SPCs Day Followed by Networking Drinks Reception

Agenda - Day 2
Regulatory Frameworks - Wednesday, 22 May 2024

08:50 Opening Remarks from Morning Chair

Eveline Van Keymeulen, Partner, Latham & Watkins

09:00 **KEYNOTE EU Commission Update on the Regulatory Landscape**

Future direction of travel for the EU Commission

Florian Schmidt, Principal Administrator, DG Health and Food Safety, European Commission

09:30 **KEYNOTE PANEL Exploring Progress on Proposals in the EU Pharmaceutical Legislation Revision**

- Recent developments in the legislative process - EU Parliament
- Evaluating the impact of legislative revisions on Europe's competitiveness and investment landscape
- Update of the incentive schemes and a holistic assessment of regulatory challenges from the EU Pharmaceutical Package (paediatrics, investigation plans, AMR)
- Implications of the requirements for a shortage prevention plan for medicines and APIs
- Examining developments and benefits for a regulatory sandbox
- Repurposing existing products and requirements for registration of new indications by MA holder

Pernille Weiss, MEP and Rapporteur, European Union's Pharmaceutical Directive

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

Kristine Peers, General Counsel, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Eveline Van Keymeulen, Partner, Latham & Watkins

10:30 - 11:00 - Networking Break

11:00 **DUAL DIALOGUE Updates on Regulatory Protection and Enforcement of Regulatory Exclusivity Rights**

- Latest developments on data and marketing protection and enforcement
- Enforcement of orphan market exclusivity - what measures can originators take to ensure their rights are respected by competitors?

Peter Bogaert, Partner, Covington & Burling LLP

Victoria Kitcatt, VP & Assistant General Counsel, Pfizer (Paed)

11:40 **DUAL DIALOGUE Risks of Compounding and Hospital Exemptions for Approved Products**

- Analysis of business risks posed by Leadiant Case
- Rise in the use of the "compassionate use" mechanism
- Examining compounding and the Hospital Exemption
- Legal challenges and the wider implications for industry

Jonas Lind Hansen, Obesity Lead and Senior Corporate Counsel, Global Legal & Patents, Novo Nordisk

Catherine Longeval, Partner, Van Bael & Bellis

Agenda - Day 2
Regulatory Frameworks - Wednesday, 22 May 2024

12:20 - 13:40 - Networking Lunch

13:40 Opening Remarks from Afternoon Chair

Christian Jervelund, Partner, Copenhagen Economics, Belgium

13:50 **PANEL Market Access Challenges and Developments for Pharmaceutical Firms**

- National developments for price transparency: recent decisions, legal issues and challenges
- Individual prices in tender decisions: to what extent do we need to make this transparent?
- Discounts and clawback schemes impacting reimbursement and turnover: German combination rebate, NHS VPAS scheme, schemes in France
- Latest trends & developments: HTA regulations - friend or foe?

Ilja Moree, Head Legal Oncology Region Europe, Novartis AG

Jordi Faus, Partner, Faus Moliner

Christian Jervelund, Partner, Copenhagen Economics, Belgium

14:50 **TRI DUAL DIALOGUE Guidance and Risks for Decentralised Clinical Trials**

- Regulatory frameworks and guidance for decentralised, direct to patient clinical trials
- Legal considerations on the use of digital health technology for the use in clinical trials
- Practical legal considerations: from consenting and privacy to the use of third-party vendors

George Pickering, Vice-President and Head of Legal for Research, Development and MDS, GSK PLC

Alison Dennis, Partner, Taylor Wessing

Beverly Rubin, General Counsel, Lightship

15:30 **DUAL DIALOGUE Progressing Advanced Therapy Medicinal Products (ATMPs) Regulatory Frameworks**

- Review of the EU Blood Directive and the EU Tissues and Cells Directive
- Insights into the latest proposed Substances of Human Origin (SoHO) Regulations
- Evaluating how coherent the proposed revisions are with existing medicinal product regulations
- Examination of emerging developments related to hospital exemptions ATMPs

Marc Martens, Partner, Co-Head of the International Life Sciences and Healthcare Group, Bird & Bird

16:00 - 16:30 - Networking Break

Agenda - Day 2
Regulatory Frameworks - Wednesday, 22 May 2024

16:30 **TRI DIALOGUE Regulatory Framework Developments for Artificial Intelligence**

- How does the EU MDR and IVDR fit with the AI Act?
- Practical considerations for pharmaceutical companies and device manufacturers
- Update on EMA reflection paper on use of AI in medicinal product lifecycle
- Overlaying European proposals with US frameworks for AI and the implications for global policies

Luis Pinheiro, Senior Epidemiology Expert, European Medicines Agency (EMA)

Hilary Jones, Senior Director, Legal Pharmaceutical Regulation, BioNTech UK Limited

Sophie Pelé, Partner, Dechert

17:10 **DUAL DIALOGUE Striking a Regulatory Balance for Companion Diagnostics: Analysing Tensions Between Pharmaceutical and IVDR Frameworks**

- Managing the conflict of IVDR with the EU Clinical Trial regulation
- Commercial and IP considerations for pharmaceuticals when combined with devices and companion diagnostics
- Practical challenges of reimbursement for companion diagnostics
- The use of hospital exemptions for companion diagnostics

Xisca Borrás, Partner, Bristows

Simone Heitz, Associate General Counsel, Merck

17:50 - 18:50
Close of Regulatory Frameworks Day Followed by Networking Drinks Reception

Agenda - Day 3
Thursday, 23 May 2024

Healthcare Data, Privacy & Compliance

08:50 Opening Remarks from Morning Chair

Caroline Stockwell, VP and Head of Legal – International, Amicus Therapeutics

09:00 **KEYNOTE PANEL Is your Data at Risk? Legal Implications of European Health Data Space**

- Overview of key legal frameworks shaping clinical research including the European Health Data Space, Digital Data Act and upcoming Data Act
- Threats and opportunities of the EHDS for the pharmaceutical industry
- What types of data are appropriate for inclusion in EHDS and where should the line be drawn for commercially sensitive data?
- Will IP give you sufficient protection for your proprietary data?
- Legal frameworks for sharing digital patient data amongst multiple partners
- How to prepare, what is the effect, status etc

Guillaume Byk, Legislative Officer, DG SANTE, EU Commission

Chris Foreman, Chief Privacy Officer, Merck Sharp & Dohme

Kristof Van Quathem, Partner, Covington & Burling LLP

10:00 **DUAL DIALOGUE Round-up on Key Data Privacy Concerns and Conflicts for the Pharmaceutical Industry**

- Update on key challenges surrounding the secondary use of clinical research data
- Advertising online and cookie transfers: all clear or still a problem?
- New developments in the collection of cookies by healthcare authorities: will US developments eventually impact EU?
- Demystifying GDPR for international data transfers – are we looking at a Schrems 3?
- Anonymised vs. Pseudonymised Data: managing inconsistencies between EU and UK
- Review of conflicts and overlaps between Swiss Federal Data Protection Act (FADP) and GDPR

Florian Zabel, Chief Privacy Officer Roche Group, F. Hoffmann-La Roche Ltd

Partner, Private Practice

Cristiana Spontoni, Partner, Jones Day

Commercial Transactions

Opening Remarks from Chair

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

09:10 - 09:50 - **Transaction Trends and Deal Landscape in the Life Sciences Sector**

- Expected deal trends for 2024/2025 in light of current market conditions
- Issues for deal makers arising from the EU Pharma Package
- Hot areas for investment in the life science sector
- Update on deal structures

Sally Shorthose, Partner, Bird & Bird

09:50 - 10:20 - **Regulatory Scrutiny on Deals: Update on Foreign Direct Investment Screening**

- Growth of protectionist policies internationally and their impact for pharmaceutical commercial transactions and collaborations
- Avoiding delays: knowledge on national requirements for the disclosure of knowledge and of supply chain management issues

Orion Berg, Partner, White & Case

Agenda - Day 3
Thursday, 23 May 2024

	Healthcare Data, Privacy & Compliance	Commercial Transactions
		10:20 - 10:50 - Networking Break
10:50	10:40 - 11:10 - Networking Break	10:50 - 11:30 - **DUAL DIALOGUE Advice on Key Antitrust Hurdles Impacting Commercial Transactions** • Foreign subsidies regulation: what are the obligations? • Review of recent pharmaceutical merger control cases and authority approach • Horizontal Block Exemption Regulations and revised Horizontal Guidelines • Given today's environment how can you prepare for regulatory scrutiny in commercial transactions? **Niels van Nuland,** International Competition Law Counsel, Senior Director Legal, Gilead **Marion Provost,** National Partner, Dechert LLP
11:10	**DUAL DIALOGUE New Developments in the Regulation, Conduct and Use of Real-World Evidence/Data** • Ensuring RWE is fit for purpose: quality standards for regulatory submissions, pricing authority approvals and marketing • Building your capabilities: practical tools you utilise and how to align functions • Recent developments regarding the use of RWE including the EMA's DARWIN EU project and H2O Health Outcomes Observatory **Arianna Greco**, Senior Vice President, Head of Global Commercial Legal, Alnylam Pharmaceuticals **Lincoln Tsang, Partner,** Ropes & Gray	11:30 - 12:10 - **DUAL DIALOGUE How to Draft a Good Licencing Agreement** • Key topics that cause tension when they draft / negotiate deals • What is the rationale for licencing compared to other deals eg M&A, distributions etc • Key considerations: what is everyone's roles, due diligence, risk and IP management, etc • Deal structures: exclusive licencing or not, milestones, royalties • Key terms: indication, scope, termination, governance, IP (including improvements), warranties, non-compete, US vs continental (best efforts, reasonable efforts) etc **Isabella Fabbri,** Senior Counsel Legal EMEA & Asia Pacific, PTC Therapeutics, Inc. **Ewan Townsend,** Partner, Arnold & Porter

Agenda - Day 3
Thursday, 23 May 2024

Healthcare Data, Privacy & Compliance

11:50 **TRI DIALOGUE Utilising and Managing the Risk of Generative Artificial Intelligence in Day-to-Day Pharma Activities**

- Applications of AI across different business functions in pharmaceutical businesses
- Legal considerations to ensure robust management of risk
- How to ensure a balanced risk/benefit in the use of AI
- Legal, IP, Data privacy considerations when inputting data into AI

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

Florence Bakri-Lerer, Senior Legal Counsel, Merck

Vincent Rezzouk-Hammachi, Partner, Bird & Bird

12:30 - 13:50 - Networking Lunch

13:50 **DUAL DIALOGUE Key Developments for Advertising and Promotional Materials**

- Is there an evolution of the notion of advertising? Examining the implications of the Euroaptieka SIA case and the broadening of parameters affected by advertising rules in Europe
- Practical legal considerations for activities such as patient support programmes, disease awareness campaigns
- Proposed developments for comparative advertising in the pharma Legislative package and the implications for promotional materials

Antje-Katrin Weigelt, General Counsel, Teva

Elisabeth-Ann Wright, Partner, Cooley LLP

Commercial Transactions

12:10 - 13:40 - Networking Lunch

13:40 - 14:20 - **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

Tinne Gilles, General Counsel, CSL Vifor

Andres Liivak, Partner, White & Case LLP

14:20 - 15:00 - **DUAL DIALOGUE Key Aspects of IP and How to Avoid Litigation in Deals**

- Advice and practical scenarios on how to structure the deal so it is win/win
- The importance due diligence and how to mitigate risk for both parties before drafting in the agreement
- Practical tips on drafting contracts to avoid litigation
- IP: how to draft an indication/field clauses to ensure success
- Examining key considerations of clawback clauses
- Restructuring and unwinding troubled or underperforming commercial relationships including if it goes bankrupt

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

Alexandra Pygall, Partner, Stephenson Harwood LLP

Agenda - Day 3 - Thursday, 23 May 2024

Healthcare Data, Privacy & Compliance

14:30 **DUAL DIALOGUE Compliance Challenges when Supporting Healthcare Systems: Disease**

- Awareness Campaigns, Patient Support Programmes and Healthcare Service Delivery
- Understanding compliance frameworks for additional support activities
- What activities are acceptable? Where are the grey areas and common trip points for the pharmaceutical activity?
- Common pitfalls with support activities associated with decentralised trials

Sabrina Ballet, Vice President, International Legal and Compliance, Blueprint Medicines

Marie Manley, Partner, Sidley Austin

15:10 - 15:40 - Networking Break

15:40 **DUAL DIALOGUE Corporate Disclosure Frameworks for Environmental, Social, and Governance (ESG)**

- Approach for ESGs to be meaningfully integrated into your business in the Life Science sector
- The role of senior leadership and legal departments in this evolving area
- Updates on reporting requirements on ESGs and the EU Corporate Sustainability Reporting Directive (CSRD)
- Key ESG metrics in pharmaceutical firms: practical application and how they work to drive institutional change and values

Philipp Kohlhaas, Senior Legal Counsel ESG, Boehringer Ingelheim

Peter Sellar, Partner, Fieldfisher

16:20 **DUAL DIALOGUE Revisions in Whistleblowing, Anti-Bribery, Anti-Corruption Law and Enforcement**

- Anti-bribery & Corruption: What's new for distributors, principles and CROs
- Oversight of distributors as part of adequate procedures for anti-bribery and corruption
- What is the impact and what do you need to do?

Cristina Alexandrescu, Assistant General Counsel, GSK Biologicals

Annabelle Bruyndonckx, Partner, Simmons & Simmons LLP

17:00 Close of Conference

Commercial Transactions

15:00 - 15:30 - Networking Break

15:30 - 16:10 - **DUAL DIALOGUE How to Manage AI in Commercial Deals**

- Hottest trends for AI in (bio)pharma licencing deals
- Key considerations for the value in input, output of the system as well as the system itself
- What and how to effectively protect developments made in improving and adapting AI and machine learning
- Constructing value for AI in IP licensing negotiations
- Key risks and considering future potential of your investment/IP

Kathryn Robinson, Senior Legal Counsel, Isomorphic Labs

Sarah Hanson, Partner, CMS

16:10 - 16:50 - **DUAL DIALOGUE Monetising Data in Digital Deals**

- What is the minimum data needed to transfer products in sales transitions?
- Best practice in structuring your contracts to ensure success
- New developments and updates on data infringement
- The role of IP and licencing structures: are they fit for purpose in data-based transactions?
- Examining alternative legal structures and mechanisms when IP and licencing is unsuitable
- Can regulatory frameworks and data regulations be utilised for digital transactions?
- Application of block exemptions for digital deals

Alessandra Cincotti, Senior Corporate Counsel - Licensing, Business Development & Partnering - Digital Health, Sanofi

16:50 - 16:55 - Close of Conference

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