VIRTUAL EVENT

EU Pharmaceutical Law Forum

CELEBRATING 30 YEARS

17TH - 20TH MAY 2021 | 100% VIRTUAL

THE GO TO EU PHARMACEUTICAL LAW CONFERENCE FOR IN-HOUSE AND EXTERNAL LAWYERS ALIKE

Get to the Heart of Collaborations, Competition Law, Data Privacy, Patent Litigation, and Regulatory Frameworks.

AGENDA

WORKSHOP DAY
MONDAY 17TH MAY 2021
Think Tank: Sameness / Similarity for Orphan ATMP Products
Market Access for Innovative Therapies

MAIN CONFERENCE TRACKS		
TUESDAY 18TH MAY 2021	WEDNESDAY 19TH MAY 2021	THURSDAY 20TH MAY 2021
Competition Law & Patent Litigation	Regulatory Frameworks	Healthcare data, privacy and compliance
		Collaborations and Commercial Transactions

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The Virtual EU Pharmaceutical Law Forum Experience: What to Expect...

EU Pharmaceutical Law Forum's virtual experience has been tailored to you and your ease. Get up-to-speed with cutting edge topics and key trends delivered through multi-speaker formats, offering you differing views and in-depth analysis on the hottest topics affecting the industry from the comfort of your desk.

For speaking opportunities **contact leena.shaw@informa.com**
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YOUR DIGITAL EXPERIENCE

Expert insight delivered directly to your screen:
Get direct access to the information and experts who will help answer your burning questions. Enjoy the same high-level legal insights from the EU Commission, Competent Authorities, General Counsel and Private Practice law firms

Reshaping the networking experience:
Our virtual platform offers a sophisticated and fully interactive conference experience. Submit questions in advance or live to speakers during Q&As, live roundtables and panel discussions. Arrange one-to-one and group video meetings with speakers, sponsors and other delegates from around the world, and form connections with leading experts through our dedicated networking sessions

FLEXIBLE DIGITAL FORMAT - EASILY INTEGRATED WITH YOUR WORKING DAY

High level live-streamed content:
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More content-on-demand for learning at your convenience:
benefit from a packed roster of on-demand sessions pairing senior counsel with private practice, ensure a high-quality learning with practical industry perspective. And, with all presentations made available on-demand for 30-days post-event*, you will be able to attend more presentations than ever before!

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COMPETITION AND PATENT LITIGATION

	Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
9.30 – 10.10	**KEYNOTE INTERVIEW Update from EU Commission on Competition Law Enforcement** • Recent updates on competition law enforcement in the EU pharmaceutical sector and future focus for 2021 and beyond • Examining EU Commission response to COVID-19: comfort letters, exceptional framework guidance and the scope for more structural measures going forward **Paul Csiszár,** Director, DG Competition, **European Commission** **Kyriakos Fountoukakos,** Managing Partner and EMEA Regional Head of Practice for Competition, Regulation and Trade, **Herbert Smith Freehills LLP**	**DUAL DIALOGUE Antitrust Market Definition** • Practical guidance on how to define a "relevant" market and the redefinition of potential collaborators and competitors • Determining what is and isn't permissible • Understanding the thresholds and conditions for triggering block exemptions **Angela Staunton,** VP Antitrust, **Bayer Pharmaceuticals** **Jemima Stratford QC,** Barrister, **Brick Court Chambers**
10.30 – 11.30	**INTERACTIVE DISCUSSION Excessive Pricing in the Pharmaceutical Industry** • Key updates and new developments on abuse of dominance through excessive pricing • Comparison of approaches and interpretations across different jurisdictions • Practical advice on pricing decisions and negotiations in current enforcement landscape **Alessandro Noce,** Head of the Agri-food, Pharmaceutical and Transportation Department, **Italian Competition Authority (ICA)** **Rainer Becker,** Head of Unit, DG Competition, **European Commission** **Jacob Westin,** Head of Legal, Nordics & EUCAN Competition Law Specialist, **Takeda Pharmaceuticals** **Lourenço Ventura,** Legal Director, **Competition and Markets Authority (CMA)** **Ingrid Vandenborre,** Partner, Antitrust/Competition, **Skadden, Arps, Slate, Meagher & Flom LLP** Moderator: **Marion Provost,** National Partner, **Dechert LLP**	**DUAL DIALOGUE Antitrust and IP Considerations for Mergers, Collaboration & Distribution** • Beyond just collaboration: M&A and full-function joint ventures; Distribution and Co-marketing; Innovation competition and acquisition of start-ups and biotech • Practical advice on structuring contracts to minimise risk **Chris Verleye,** Assistant General Counsel, **Johnson & Johnson Law Department Europe** **Michael Clancy,** Partner, **Van Bael & Bellis LLP**

11.50-12.50

INTERACTIVE DISCUSSION Anticompetitive Unilateral Conduct and Emerging Agreements

- Recent developments, updates and implications for the industry
- Antitrust authority approach to market definition in the context of unilateral conduct
- Examining the scope of activities, practices for delay and minimum value transfer to trigger antitrust action

Henri Piffaut, Vice President, **French Competition Authority,** (subject to final confirmation)

Nicolas Pourbaix, Legal Director, **Amgen**

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

Margaret K. Kyle, Chair, Intellectual Property and Markets for Technology, MINES ParisTech and Expert, **Cornerstone Research**

Moderator: **Mélanie Thill-Tayara,** Antitrust/Competition Partner, **Dechert LLP**

Examining Parallel Trade and Drugs Shortages

- New national developments and legislative initiatives to limit shortages and impact on parallel trade
- How can drugs companies mitigate the risk of shortages? And their exposure to?
- What is the impact of the Falsified Medicines Directive?
- Jurisdiction of competition authorities

Nicolas Pourbaix, Senior Counsel and Legal Director, **Amgen**

12.50 – 15.10

ROUNDTABLE SESSIONS and ON-DEMAND VIEWING TIME

Attendees are invited to take part in the following discussion sessions:

13:00 - 13:30 **ROUNDTABLE IP / Litigation strategies and antitrust considerations – a deep dive into the recent Teva Copaxone case on divisional patent and litigation strategies**

Kyriakos Fountoukakos, Managing Partner and EMEA Regional Head of Practice for Competition, Regulation and Trade, **Herbert Smith Freehills**

Laura Orlando, Managing Partner, Italy and EMEA Co-Lead Partner – Life Sciences, **Herbert Smith Freehills**

Stephen Wisking, Managing Partner of Competition, Regulation and Trade, **Herbert Smith Freehills**

13:45 - 14:15 **ROUNDTABLE The In-House Counsel Guide to Discounts, Denigration and Divisionals**

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

14:30 - 15:00 **ROUNDTABLE Antitrust Roundtable led by Cornerstone Research**

15.10 - 15.40

KEYNOTE UPDATE European Commission Intellectual Property Action Plan

- Initiatives to ensure better enforcement and promote fair play globally for IP
- Implications for the pharmaceutical industry

Denis Dambois, Administrator, DG Research, **European Commission**

Moderator: **Liesbeth Weynants,** Managing Partner, **Hoyng Rokh Monegier LLP**

INTERACTIVE DISCUSSION Latest Trends in Preliminary Injunctions

- A multi-jurisdictional approach to latest developments and key trends
- Review of recent cases and enforcement decisions across UK, The Netherlands, France, Italy, and Switzerland
- Principles and trends; practical tips for (i) persuasive evidence (ii) cross-undertakings and (iii) balancing risks

Morag Macdonald, Partner, **Bird & Bird**

16.00 - 17.00

INTERACTIVE DISCUSSION Latest Developments and Key Trends for Innovator vs. Innovator Collaborations and Disputes

- Appropriateness of injunctive relief in innovator vs. innovator disputes; compulsory licensing and potential crown use
- Principles of general application: what to patent, at what stage; what can you claim, what do you have support for?
- Validity and implication of patents that are too broad
- Review of recent cases and enforcement decisions

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

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

Brian Cordery, Joint Head of Patent Litigation, **Bristows LLP**

Assessing the Current Status of SPCs

- New initiatives, latest developments and case law for SPCs: update on proposal for single SPC application and granting body
- Manufacturing waiver in practice and practical implementation
- Enforcement of SPCs: national court strategies
- SPC interaction with paediatric and orphan extensions

James Horgan, Assistant Managing Counsel, **Merck Sharp & Dohme Ltd**

REGULATORY FRAMEWORKS

	Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
10.00 – 10.40	**KEYNOTE PRESENTATION EU Commission Update on the Regulatory Landscape** • Updates on the EU Commission's pharmaceutical strategy • Areas of focus for legislative revision • Update on the review into pharmaceutical incentives and rewards **Florian Schmidt,** Deputy Head of Unit, DG SANTE, European Commission Moderator: **Kristine Peers,** General Counsel, The European Federation of Pharmaceutical Industries and Associations (EFPIA)	**IP Regulatory Rights: New Developments in Orphan and Paediatric Medicines** • Review of the EU Paediatric and Orphan Medicines Regulations • Is the existing legislation fit for purpose and is there a need to change scope of qualifying conditions to increase protection for orphan medicines? **Georgia Gavriilidou,** Associate General Counsel, Amgen **Julia Sabine Wahl,** Senior Economist, Copenhagen Economics
11.00 – 12.00	**INTERACTIVE DISCUSSION Regulatory Flexibility: New Approaches and Future Scope** • Lessons learned from COVID-19 and how to convert these to "fit for innovation" regulation • New initiatives including rolling reviews and adapted approaches to regulatory assessments: could these initiatives be used more broadly? • Is current regulatory legislation sufficiently flexible to be responsive for future emergency situations? **Sandra Vanlievendael,** Head of Pharmaceutical Law, Legal Department, European Medicines Agency (subject to final confirmation) **Virginia Acha,** Associate Vice President, Global Regulatory Policy, MSD **Eveline Van Keymeulen,** Partner, Latham & Watkins Moderator: **Jordi Faus,** Founding Partner, Faus & Moliner	**DUAL DIALOGUE Real World Evidence in Practice** • The rules governing the conduct of real world evidence projects: - The EU legislation - EMA draft guideline on registry-based studies - The FDA approach • Making real world evidence projects work in practice: - Planning, designing and implementing a successful project • Examples of real world evidence use in the context of regulatory approvals **Hilary Jones,** Senior Director, Legal, Gilead Sciences **Sophie Pele,** Partner, Dechert LLP
12.00 – 14.30	**ROUNDTABLE SESSIONS and ON-DEMAND VIEWING TIME** Attendees are invited to take part in the following discussion sessions: 12.15 – 12.45: **ROUNDTABLE Pandemics and Public Procurement of medicinal products and medical devices** **Marc Martens,** Partner, Bird & Bird 13.00 – 13.30: **ROUNDTABLE Expanding Possibilities for Off-Label Use of Medicines Before and After Marketing Authorisation?** **Peter L'Ecluse,** Partner, Van Bael & Bellis **Catherine Longeval,** Partner, Van Bael & Bellis 13.45 – 14.15: **ROUNDTABLE Regulatory Frameworks Roundtable led by Copenhagen Economics**	
14.30 - 15.30	**INTERACTIVE DISCUSSION Pharmaceutical Market Access** • Increased synergy between HTA and regulatory agencies, and national and joint procurement levers being employed • Impact of international reference pricing from the US on European pricing and reimbursement landscape • Update on joint procurement alliances across Europe: legal challenges and points to consider for joint HTAs and joint negotiations **Francis Arickx,** Country Co-ordinator for Belgium, Beneluxa Initiative and Head, Directorate Reimbursement of Medicines and Pharmaceutical Policy, National Institute for Health and Disability Insurance (NIHDI RIZIV/INAMI) **Georgia Gavriilidou,** Associate General Counsel, Amgen **Marie Manley,** Partner & Head of the UK Life Sciences Practice, Sidley Austin LLP	**DUAL DIALOGUE Pricing, IP and Regulatory Challenges for Companion Diagnostics and Combination Products** • IVDR regime for companion diagnostics • MDR consequences for drug - device combination products • Commercial and IP considerations for pharmaceuticals when **Noemie Barberis,** Director, Senior Counsel R&D Legal – Science, Technology & Innovation Team, GlaxoSmithkline Biologicals **Peter Bogaert,** Partner, Covington & Burling LLP

15.50 - 16.50

INTERACTIVE DISCUSSION Evolution of UK Medicines and Medical Devices Regulations

- Overview of new regulatory frameworks in the UK and support for life sciences innovation
- UK regulation in the national, European and Global contexts
- Practical challenges for industry in operating under the new regulatory systems across the UK

Victoria Kitcatt, Vice President and Assistant General Counsel, **Pfizer**

Steve Hoare, Quality, Regulatory Science & Safety Policy Director, **The Association of the British Pharmaceutical Industry (ABPI)**

Jonathan Mogford, Director of Policy, **MHRA**

Moderator: **Anneli Howard QC,** Barrister, **Monckton Chambers**

INTERACTIVE DISCUSSION Legal and Ethical Considerations for Digital Innovation

- Evolving role of the pharmaceutical industry in digital innovation and patient support programmes (PSPs)
- Legal and ethical frameworks for digital innovation, PSPs, telehealth and telemedicine
- Case study examples of challenges for AI, PSPs, and telemedicine
- Navigating regulatory and data challenges: examining regulations, frameworks and guidance

Rhianon Ebsworth, Senior Compliance Counsel, Business Ethics Compliance Office, **Novo Nordisk A/S**

Alejandro Bes, Global Senior Legal Counsel, Digital, **Novartis**

Cristiana Spontoni, Partner, **Jones Day**

DUAL DIALOGUE Guidance for Digital Interactions: HPOs, HCPs, Patient Organisations and Patients

- Examining legal risks for digital interactions including e-communication, virtual events, e-commerce, e-advertising
- Guidance on marketing unauthorised products at HCP conferences
- Do regulators view digital interactions differently to face-to-face interactions?

Caroline Stockwell, VP, Head of Legal International, **Intercept Pharmaceuticals**

Peter L'Ecluse, Partner, **Van Bael & Bellis LLP**

HEALTHCARE DATA, PRIVACY & COMPLIANCE

	Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
10.00 – 11.00	**INTERACTIVE DISCUSSION New Legal Challenges for Managing Clinical Research Data** • Clinical research data, GDPR and COVID-19: challenges of bringing data in line with protocols and remote monitoring • Updates from European Data Protection Board (EDPB): new guidelines in context of pandemic • Processing of personal data in non- interventional studies and early access programmes • National adoption from individual country Data Protection boards • Challenges for multi-jurisdictional trials: focus on outliers including The Netherlands, UK and Germany • EMA's proposed Q&A regarding secondary use of clinical trial data **Veronique Ciminà,** Legal Officer, **European Data Protection Supervisor** **Maria Chiara Atzori,** Head, Group Data Privacy Policies, **Novartis International AG** Moderator: **William RM Long,** Partner, **Sidley Austin LLP**	**On-going Tensions Surrounding GDPR and Data Sharing for the Pharmaceutical Industry** • Update on the key issues and tensions for healthcare data • Reviewing key regulations, guidance, policy and codes governing data sharing • Understanding and evaluating the different legal grounds and examining key questions **William RM Long,** Partner, **Sidley Austin LLP**
11.20 – 12.20	**INTERACTIVE DISCUSSION New Challenges for International Data Transfer** • EU Commission guidance for international data transfer following invalidation of Privacy Shield • Updates from USA, China, Russia and India on data localisation provisions and the impact on multi-jurisdictional trials • "Supplemental measures": where are we nearly a year after Schrems II? • Practical legal challenges and approaches **Chris Foreman,** Deputy Chief Privacy Officer, **Merck & Co., Inc.** **Martijn ten Bloemendal,** Global Legal Privacy Counsel, **AbbVie** **Ralf Sauer,** Deputy Head of Unit, DG Justice and Consumer International Data Protection Unit, **EU Commission** Moderator: **Andrew Dyson,** Managing Partner and Global Co-Chair, Data Privacy & Security Group, **DLA Piper**	**Trends in Whistleblowing, Anti-Bribery and Anti-Corruption Law and Enforcement** • EU antibribery, anticorruption and whistleblowing protection update • US FPCA code changes: update on the global impact of your operations • Best practice and benchmarking advice for implementing a successful compliance program

12.20 – 14.00 **ROUNDTABLE SESSIONS and ON-DEMAND VIEWING TIME**

COMMERCIAL TRANSACTIONS & COLLABORATIONS

Live Programme	Accessible On-Demand Throughout to Watch At Your Leisure
14.00 – 15.00 **INTERACTIVE DISCUSSIONS: May the Force Majeure be with You and Contract Enforcement: Arbitration, Litigation or a 3rd Approach?** • COVID-19: a classic force majeure event? Lessons learnt from COVID-19 pandemic and contract enforcement challenges for the future • Examining benefits and challenges for different approaches for contract enforcement within the pharmaceutical sector: arbitration, litigation or a third way? **Niall O'Sullivan,** Legal Director, Licensing and Acquisitions, Established Pharmaceuticals, Abbott **Oliver Gandy,** Senior Legal Counsel, Boehringer Ingelheim **Adam McArthur,** Assistant General Counsel, Digital, IT and Operations, AstraZeneca **Erica Stein,** Partner, Dechert LLP Moderator: **Marie Fillon,** National Partner, Dechert LLP	**DUAL DIALOGUE Top 5 Clauses to Future Proof Contracts** • Lessons learnt from COVID-19 pandemic and contract enforcement challenges • Identifying the key clauses to ensure you are covered • Key points to consider in deal negotiations • From perfect contracts to contract implementation - How to avoid pitfalls **Florence Bakri-Lerer,** Senior Legal Counsel, Merck **Sally Shorthose,** Partner, Bird & Bird
	DUAL DIALOGUE Data Sharing in Collaborations and Commercial Transactions • Examining GDPR risks and strategies to share data in collaborations • How do you balance enhanced data subject rights with commercial incentives to share as much data as possible? • What is the minimum data needed to transfer products in sales transitions? • Can data be monetised as if it was IP? **Laetitia Szaller,** General Counsel and VP Business Development, AM Pharma **Frances Stocks Allen,** Associate, Latham & Watkins
	New Market Trends in the Pharmaceutical Industry: Impact on Licencing and M&A Roundup of commercial case law: lessons learnt and top pitfalls to avoid when negotiating commercial transitions Outlook: examining the most significant changes occurring across the industry **Andres Liivak,** Partner, White & Case LLP

End of conference

MARKET ACCESS FOR INNOVATIVE THERAPIES

10.00 - 12.00 **Application of Existing EU Frameworks**

- General principles
- EU co-operation on HTA/ legislative proposal/ EUnet HTA
- Joint procurements

Value and Pricing Discussion

- Comparison of different European national approaches to reimbursing and financing of innovative medicinal products (orphan, ATMP, novel therapies)
- Legal tools available to support value and pricing discussion

Innovative Payment Models and Structuring Contracts

- Agreements on net price with governmental authorities and other stakeholders
- Pay for Performance/payment for results/ risk sharing agreement
- Data collection/ real world evidence
- Transparency
- Discussion on the risk to pharmaceutical companies entering these agreements

Marieke Jansen, Head Legal Cell, and Gene Europe, **Novartis**

Adela Williams, Partner, **Arnold & Porter LLP**

Alexander Roussanov, Partner, **Arnold & Porter LLP**

Jordi Faus, Founding Partner, **Faus & Moliner**

Christian Jervelund, Managing Partner, **Copenhagen Economics**

THINK TANK: SAMENESS/SIMILARITY FOR ORPHAN ATMP PRODUCTS

14.00 - 16.00 **Regulatory Landscape for Assessment of Similarity for ATMPs**

- 2016 Commission consultation, 2018 amendment of Commission Regulation 847/2000 and high level ATMP Q&A
- General principles, precedents and global alignment
- How are the rules applied to the science in practice
- Challenges for health authorities in interpreting the guidelines

Data Requirements for Applications

- Difference between the New Active Substance (NAS)/Similarity assessment
- Importance of orphan exclusivity for ATMPs
- Data needed to prove (non)similarity for the purpose of assessing the scope of the orphan exclusivity
- Data needed to prove superiority for the purpose of derogating orphan exclusivity
- US FDA approach vs. EU approach and the relevance for global drug development

Practical guidance for Industry

- How have the regulations been applied to date?
- Where are the risks in the context of similarity for sponsors developing ATMPs for orphan indications?
- Industry concerns and additional guidance needed for the industry

Spyridon Drosos, Head of Litigation Office, Legal Department, **European Medicines Agency (EMA)**

Shaun Stapleton, VP Regulatory Affairs and Pharmacovigilance, **ReNeuron**

Constance Vercambre-Lallia, Head of Litigation Exclusivity, **Novartis**

Carla Schoonderbeek, Partner, **Hoyng Rokh Monegier**

Rocio Salvador Roldan, Policy Officer, DG SANTE, **European Commission**

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