VIRTUAL EVENT

# EU Pharmaceutical Law Forum

**16-20 November 2020**
Now Delivered as a
100% Virtual Conference
Central European Time Zone (CET)

## PRE-CONFERENCE DAY: MONDAY 16TH NOVEMBER

- **Seminar: Legal Strategies for Biosimilars**
- **Seminar: Market Access for Innovative Therapies**
- **Seminar: Demystifying the MDR and IVDR**

## CONFERENCE DAYS

- **Day 1 Tuesday 17th November: Competition Law and Patent Litigation**
- **Day 2 Wednesday 18th November: Regulatory Frameworks**
- **Day 3 Thursday 19th November: Healthcare Data Privacy & Compliance**
- **Day 4 Friday 20th November: Collaborations and Commercial Transactions**

Please note all sessions* will be accessible on-demand for 30 days following the event, so delegates can benefit from accessing the content at a later date/time, if desired.

**Subject to speaker permissions.*

**informaconnect.com/pharmalaw/**

@PharmaRegsIC
#EUPHARMALAW

# Legal Strategies for Biosimilars

09.30 Start – 11.30 End

### Competition Issues for Biosimilars: Rebates and Lifecycle Management Strategies

- Examining cases, rulings and review for rebates and lifecycle management strategies
- Should competition law treat biosimilars differently than generics?
- Where is the dividing line between abusive and innovative improvements?
- Update on antitrust scrutiny and innovative approaches to minimise competition law risks

### Intellectual Property Considerations for Biosimilars: Challenges and Opportunities

- Practical guidance for Biosimilars and patent infringement
- Strategies with respect to biosimilar launch and patent expiry

### Regulatory Frameworks for Biosimilars

- How are biosimilars defined and interpreted in Europe
- What is the regulatory legal framework applicable to biosimilars?
- Insight into the interchangeability of biosimilars and national substitution policies
- Reviewing pricing and reimbursement considerations for biosimilars: country specific case studies

**Ilan Akker,** Senior Enforcement Official**, ACM,** *The Netherlands*
**Nicolas Pourbaix,** Senior Counsel, Legal Director**, Amgen,** *Belgium*
**Amandine Métier,** Partner, **Hoyng Rokh Monegier LLP,** *France*
**Liesbeth Weynants,** Partner, **Hoyng Rokh Monegier LLP,** *Belgium*

# Market Access for Innovative Therapies

12.00 Start – 14.00 End

### Application of existing EU Frameworks

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

### Value and Pricing Discussion for Innovative Therapies

- 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

### Early Access Programmes

- Legal considerations for early access programmes
- Free of charge supply pending reimbursement

**Adela Williams,** Partner, **Arnold & Porter LLP,** *UK*
**Alexander Roussanov,** Partner, **Arnold & Porter LLP,** *Belgium*
**Marieke Jansen,** Head Legal Cell and Gene Europe, **Novartis,** *Switzerland*

# MDR and IVDR for the Pharmaceutical Industry

14.30 Start – 16.30 End

### New Regulations and Changes Relevant to Pharmaceutical Companies

- MDR and IVDR readiness - when what why how?
- Legal ramifications and practical implications of changes in scope of medical devices / IVD regulation and relation to Directive 2001/83
- Overview of the key areas likely to need upgrading to comply with the MDR/IVDR, such as companion diagnostics and combination products
- Practical guidance on gaining CE Marking under the MDR/IVDR

### Specifics for Combination Products, Borderline Products and Companion Diagnostics

- MDR consequences for drug - device and device - drug combination products
- IVDR consequences for companion diagnostics
- Common pitfalls and challenges for software and digital tools

**Erik Vollebregt,** Partner, **Axon Lawyers,** *The Netherlands*

# Competition Law and Patent Litigation

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

08.55 **Welcome from the EU Pharmaceutical Law Forum Team**

09.00 **Keynote Update on the Last Year**

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

09.20 **KEYNOTE PRESENTATION: Update from EU Commission on Competition Law Enforcement**

- Recent updates on competition law enforcement in the EU pharmaceutical sector
- Insight into abuse of dominance through excessive pricing
- Latest developments on reverse payment settlements and parallel trade

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

09.50 **PANEL DISCUSSION: Excessive Pricing in the Pharmaceutical Industry**

- New developments and updates on case law on abuse of dominance through excessive pricing
- What constitutes excessive: examining relevance of cost, value indicators and comparators
- Comparison of approaches and interpretations across different jurisdictions
- Practical advice on pricing decisions and negotiations in current enforcement landscape

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

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

**Julia Sabine Wahl,** Senior Economist, **Copenhagen Economics,** *Belgium*

**Wolf Sauter,** Expert, **The Netherlands Authority for Consumers and Markets (ACM),** *The Netherlands*

**Rainer Becker,** Head of Unit, DG Competition, **European Commission,** *Belgium*

11.00 *Break*

11.20 **PANEL DISCUSSION: Merger Control & "Killer Acquisitions"**

- Reviewing latest developments, cases and key issues
- Jurisdictional questions and regime changes: experiences with value-based merger control thresholds
- Product market definition: what impact will theories of "the molecule as the market" in antitrust cases have for merger control? Is market definition contextual?
- Novel theories of harm: non-product specific innovation and "killer acquisitions": what are the implications for the pharma industry?
- Is there room for consideration of synergies?

**Molly Herron,** Lead Group Antitrust Counsel, ex-Americas, **Novartis International AG,** *Switzerland*

**Julien Caminati,** Case Handler, Merger Control, DG Competition, **European Commission**

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

**Vivek Mani,** Principal, **Cornerstone Research,** *UK*

12.20 **DUAL DIALOGUE: Reverse Payment Patent Settlements**

- New developments, updates and implications: Lundbeck, Servier & GSK cases
- Acquisitions of technology: can this be considered an abuse of a dominant position?

**David Hull,** Partner, **Van Bael & Bellis LLP, Belgium**

**Rainer Becker,** Head of Unit, DG Competition, **European Commission,** *Belgium*

13.00 *Break*

14.00 **PANEL DISCUSSION: Latest Trends in Preliminary Injunctions**

- A multi-jurisdictional approach to latest developments and key trends
- Review of recent cases and enforcement decisions: the CJEU decision in Bayer v Gedeon Richter and Exeltis (25.9.19)
- Principles and trends; practical tips for (i) patent amendments (ii) cross-undertakings and (iii) balancing risks

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

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

**Kai Rüting,** Partner, **Vossius & Partner,** *Germany*

15.00 **DUAL DIALOGUE: Patent Relief and Arrow Declarations**

- Examining recent trends in the granting of relief by the major European Patents Courts
- Are final injunctions no longer to be the norm following a finding that a patent is valid and infringed?
- Latest developments and key trends for originator vs. originator disputes
- How are generics utilising Arrow declarations and how are originators protecting themselves?
- Investigating damages following injunctions
- Will we ever see FRAND licences in the life sciences arena?

**Gareth Morgan,** Partner, **CMS**

**Jean-Baptiste Thienot,** Partner, **CMS**

**Thomas Hirse,** Partner, **CMS**

16.00 **PANEL DISCUSSION: Assessing the Current Status of SPCs**

- Latest developments, case laws and future outlook for SPCs
- Update on the law of "protected by a basic patent in force"
- The latest on SPCs based on 3rd party marketing authorisations: what is the direction of travel?
- SPCs for novel and inventive formulations: the Abraxis decision: what are the wider implications of this decision?
- Post Brexit: can we expect more diverging practice?
- Manufacturing Waiver: implementation, function and impact

**Laura Reynolds**, Associate General Counsel, European IP and Regulatory Litigation, **Teva Pharmaceuticals**

**Oliver Werner,** Head of SPC Working Group, **German Patent & Trademark Office**

**Marie Manley,** Partner, Head of the UK Life Sciences Practice, **Sidley Austin LLP**

17.00 *Close of Day 1*

# REGULATORY FRAMEWORKS

*Chair:* **Jordi Faus,** Founding Partner, **Faus & Moliner,** *Spain*

08.55 **Welcome from the EU Pharmaceutical Law Forum Team**

09.00 **Chair's Opening Remarks**

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

09.10 **KEYNOTE PRESENTATION EU Commission Update on the Regulatory Landscape**

- The new European Commission 2019-2024: areas of focus for potential legislative revision
- Update on the review into pharmaceutical incentives and rewards: views and timetable
- Environmental aspects of medicines: to what extent will the industry be subjected to new environmental requirements?

**Florian Schmidt,** Deputy Head of Unit, DG SANTE**, European Commission,** *Belgium*

09.40 **KEYNOTE PRESENTATION EMA Approach to Transparency of Pharmaceutical Data**

- Legal obligations and regulators' policies on transparency of data on medicinal products
- The CJEU rulings on EMA's access-to-documents cases
- Transparency in health emergency: the COVID-19 outbreak
- Update on the Clinical Trial Regulation implementation

**Stefano Marino,** Head of Legal Department, **European Medicines Agency**

10.10 **New Developments in Orphan and Paediatric Medicines**

- Review of the EU Paediatric and Orphan Medicines Regulations
- Is the existing legislation fit for purpose and how can we stimulate the development of more treatments for rare childhood diseases?

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

10.40 *Break*

11.00 **New Developments on Availability and Shortage of Medicine Across Europe**

- Availability challenges and shortage of medicines
- New developments, legislation and policies to address shortage of medicines
- How will developments affect industry practice and how should industry respond?

**Kristine Peers,** General Counsel, **EPFIA**

11.30 **PANEL DISCUSSION Affordability of Medicines, Price Transparency and Market Access**

- The WHO Draft resolution "Improving the transparency of markets for medicines, vaccines and other health products"
- Review of national procurement approaches to the challenge of affordability of medicines
- National levers being employed to drive competition and encourage transparency
- Examining the legal issues and challenges for pricing transparency and discounts
- Will increased price transparency advance the affordability and sustainability of healthcare?

**Arianna Greco,** Vice President, Head of International Legal, **Alnylam Pharmaceuticals**

**Sophie Pele,** Partner, **Dechert LLP, France**

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

12.30 *Break*

13.30 **DUAL DIALOGUE Regulatory Frameworks for Advanced Therapeutics: Focus on Gene Therapy**

- Examining the criteria and potential pitfalls in regulatory frameworks
- Legal levers and solutions to assist in the licencing authorisation of advanced therapeutics
- Borderline and combination product issues for approval

**Marco de Morpurgo,** Partner, Global Co-Chair, Life Sciences Sector, **DLA Piper**

**Amy Altshul,** Vice President, Associate General Counsel, Head of Legal and Compliance, **GlaxoSmithKline**

14.20 **DUAL DIALOGUE Legal Considerations Regarding the Use of Unapproved Products**

- Unapproved products in the context of COVID-19'
- Rise in the use of the "compassionate use" mechanism
- Examining compounding and the Hospital Exemption
- Recent developments regarding off-label and unapproved products
- Legal challenges and the wider implications for industry

**Hilary Jones,** Senior Director, Legal, **Gilead Sciences,** *UK*

**Catherine Longeval,** Partner, **Van Bael & Bellis LLP,** *Belgium*

15.00 *Break*

15.30 **DUAL DIALOGUE EU MDR Regulations for eHealth, Mobile Apps and Artificial Intelligence**

- New regulations and classification for digital offerings: AI, mobile apps and software
- Demystifying responsibility: practical scenarios when thing go wrong and who is responsible
- EU MDR timelines, challenges and update on notified body designation

**Giorgio Rizzello,** Legal Director EMEA, **Johnson & Johnson,** *Belgium*

**Marc Martens,** Partner, **Bird & Bird LLP,** *Belgium*

16.10 **DUAL DIALOGUE Pharmaceutical Marketing, Advertising and Promotional Activity**

- Latest developments, EFPIA guidelines and case law on pharmaceutical promotional activity
- Are European codes fit for purpose in a global digital space?
- Promotional issues for pharmaceuticals when combined with devices

**Ilja Moree,** Head Legal Oncology Region Europe**, Novartis AG,** *Italy*

16.40 *End of Day Two*

# HEALTHCARE DATA, PRIVACY & COMPLIANCE

09.00 **Welcome from the EU Pharmaceutical Law Forum Team**

09.05 **Chair's Opening Remarks**

09.10 **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,** *UK*

09.40 **PANEL DISCUSSION Legal Challenges for Managing Clinical Research Data**

- Interplay between GDPR and clinical trial regulations
- Status on roles of parties and legal grounds for processing data
- Evolving challenges between GDPR and secondary scientific research
- Investigating joint controllership in clinical research and plans for harmonisation

**Veronique Ciminà,** Legal Officer, **European Data Protection Supervisor**

**Orsolya Eotvos,** Assistant Data Protection Officer, **European Medicines Agency**

**Brendan Barnes,** Director, Data Protection and IP, **EFPIA**

**Uwe Fiedler,** Chief Privacy Officer, **Parexel International**

**William RM Long,** Partner, **Sidley Austin LLP, UK**

10.40 *Break*

11.00 **PANEL DISCUSSION Healthcare Data Challenges in a Digital Age of E-Privacy**

- GDPR and E-Privacy directives: exploring tensions between consent and legitimate interests
- Legal frameworks for sharing digital patient data amongst multiple partners
- What are the legal risks when something goes wrong?

**Martijn ten Bloemendal,** Global Legal Privacy Counsel**, AbbVie,** *The Netherlands*

**Madalina Florea,** Global Investigations Director, **AstraZeneca,** *UK*

12.00 **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

**Kevin Braine,** Managing Director and Head of EMEA, Compliance Risk and Diligence, **Kroll,** *UK*

12.30 *Break*

13.30 **DUAL DIALOGUE Managing Legal Challenges for the use of Real-World Evidence**

- Examining the sources of RWE for the pharmaceutical industry
- Legal standards for the use of RWE: marketing, regulatory data submissions and reimbursement
- Examples and case studies of disputes and liability involving RWE
- Challenges and legal pitfalls for the use and re-use of outcomes data

**Simon Costello,** Associate General Counsel, **UCB,** *UK*

**Peter Bogaert,** Partner, **Covington & Burling LLP,** *Brussels*

14.10 **DUAL DIALOGUE Data Compliance for Patient Support Programmes**

- Reviewing key regulations, guidance, policy and codes governing data sharing
- How to ensure privacy by design for Patient Support programmes: key considerations in light of new and emerging privacy laws
- Balancing interests and ensuring both the patients right to health and right to privacy
- What are the legal risks when something goes wrong?

**Maria Chiara Atzori,** Head Group Data Privacy Policies, **Novartis International AG,** *Switzerland*

**An Vijverman,** Partner, **Dewallens & Partners,** *Belgium*

14.50 **Navigating the 'Grey Zone' when Interacting with HCPs and HCOs**

- Overview of pharma regulations and codes of conduct for collaborating with HCPs and HCOs
- Compensating healthcare professionals: establishing a fair market value
- Grants & donations: local regulations vs EU industry codes
- Strategies for creating and maintaining successful HCP and HCOs collaborations

**Annabelle Bruyndonckx,** Counsel, **Simmons & Simmons,** *Belgium*

15.20 *End of Day Three*

# COLLABORATIONS AND COMMERCIAL TRANSACTIONS

09.00 **Welcome from the EU Pharmaceutical Law Forum Team**

09.05 **Chair's Opening Remarks**

9.10 **KEYNOTE INTERACTIVE DISCUSSION FORUM Success Factors for Commercial Collaborations**

- What are partners looking for? Key drivers for strategic partners and investors
- Roundup of commercial case law: lessons learnt and top pitfalls to avoid when negotiating commercial transitions
- Is termination an appropriate remedy if it deprives licensee of its fundamental asset?
- When things go wrong: identifying what you can claim and when damages need to be paid

**Marie Fillon,** National Partner**, Dechert LLP,** *France*

**Alex Nesbitt,** Senior Director and General Counsel, Corporate & Transactions, **Teva Pharmaceuticals Europe BV,** *The Netherlands*

**Mayalen Lacabarats,** Head of Unit - Legal Department, **Servier,** *France*

**Uwe Froehlich,** Associate General Counsel, Head of Legal & Compliance EMENAR, **Swedish Orphan Biovitrum AB**

10.10 **DUAL DIALOGUE: Competition Law: Mergers, Collaboration & Distribution**

- Update on Competition Authority and EU Commission cases in the pharmaceutical sector
- What is and isn't permissible?
- Understanding the thresholds and conditions for triggering block exemptions
- Practical guidance on how to define a "relevant" market and the redefinition of potential collaborators and competitors
- Beyond just collaboration: M&A and full-function joint ventures; Distribution and Co-marketing; Innovation competition and acquisition of start-ups and biotech

**Miranda Cole,** Partner, **Covington & Burlin**g LLP, *Brussels, Belgium*

**Chris Verleye,** Assistant General Counsel, **Johnson & Johnson Law Department Europe,** *Belgium*

10.50 *Break*

11.10 **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?

**Frances Stocks Allen,** Associate, **Latham & Watkins LLP,** *UK*

**Gail Crawford,** Partner and Chair of the Data Privacy Committee, **Latham & Watkins LLP**

11.40 **DUAL DIALOGUE: Legal Tools to Monetize Data in Digital Collaborations when Data is the Principle Asset**

- 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 unsuitable
- Can regulatory frameworks and data regulations be utilised for digital transactions?
- Best practice in structuring your contracts to ensure success

**Adam McArthur,** Assistant General Counsel, Corporate, **AstraZeneca,** *UK*

**Sally Shorthose,** Partner, **Bird & Bird LLP, UK**

12.40 *Break*

13.40 **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,** *USA*

14.10 **Pharmaceutical Licencing: Are we Stuck in Our Ways?**

- Key components of licencing deals and examining where they are best deployed and their limitations
- Examining corporate Special Purpose Vehicle (SPV): purpose and benefits as an alternative to a customary licence deal. Attracting asset centric investment and tax benefits.

**Janita Good,** Partner, **Osborne Clarke LLP,** *UK*

14.40 **PANEL DISCUSSION Innovative Multiple Stakeholder Transactions using SVP: from Clinical Trial to Commercialisation**

- Aligning interests for different stakeholders from pharma, biotech and medical devices: which legal and contractual tools fit best?
- Case study insight on the use and benefits of corporate SPV to catapult you from pre-clinical into the clinic through to commercialisation
- Strategic advice to design corporate structures to facilitate harmonious working structures making the most of the skills of a management team

**Janita Good,** Partner, **Osborne Clarke LLP,** *UK*

**Steven Gill,** Founde**r, Innervate Therapeutics,** *UK*

15.40 *End of Day Four & Conference*

# Connect with key buyers at the EU Pharmaceutical Law conference 2020 in Brussels

Whether you're increasing your company profile, launching a new product or focusing on new business development opportunities, collaborate with us to identify custom solutions to help you reach your goals.

Contact Linda Cole: Linda.Cole@informa.com | +44 207 017 6631

## 2020 ASSOCIATE SPONSORS

Bird & Bird

Copenhagen Economics CE

Dechert LLP

WHITE & CASE

## 2020 CONFERENCE SPONSORS

CMS Law.Tax

CORNERSTONE RESEARCH

DLA PIPER

Faus & Moliner

Kroll | A Division of DUFF & PHELPS

LATHAM LATHAM&WATKINS

Skadden Skadden, Arps, Slate, Meagher & Flom LLP & Affiliates

VAN BAEL & BELLIS

## 2020 EXHIBITOR

OneTrust DataGuidance™ REGULATORY RESEARCH SOFTWARE

## Be part of the EU Pharmaceutical Law Forum 2020

Sponsorship and speaking opportunities are still available, please contact:
Linda Cole: Linda.Cole@informa.com | +44 207 017 6631

## 2020 MEDIA PARTNERS

BRUSSELS LEGAL

EuroLegalJobs

EuroPharmaJobs

glg global legal group

The global IP Matrix

PHARMAnetwork

Pharma VOICE

Pink Sheet Informa Pharma Intelligence

Women's IP World