25th Annual EU Pharmaceutical Law Forum 2016

Europe's leading pharmaceutical law conference

Day 1: Competition Law and Patent Litigation - Tuesday 24 May 2016

8:00 - 8:50

Conference Registration

Competition Law

8:50 - 9:00

Introduction from the Morning Chairperson

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

9:00 - 9:40

KEYNOTE PRESENTATION: Feedback from the EU Commission on competition law

Paul Csiszár,
Director "Basic Industries, Manufacturing and Agriculture", Responsible for Pharmaceutical Antitrust and Merger Cases, DG Competition, ,
European Commission

- Overview of recent developments in competition law and the pharmaceutical industry
- Reverse payment settlement agreements: Reviewing developments/decisions on the Lundbeck and Servier investigations
- Examining recent pharmaceutical mergers and product market definition
- Late lifecycle management strategies to delay generic entry

9:40 - 11:00

INTERACTIVE DISCUSSION FORUM: Reverse payment patent settlements

Galit Gonen,
SVP, General Counsel & IP,
Teva Europe

George Peretz QC,
Barrister,
Monckton Chambers

There will be no background/basic information presented in this session, in-depth and high level case law only. Representatives from in-house counsel and Monckton Chambers will share their experiences and expert legal advice on the following case law with a series of short presentations. This will be followed by interaction with the audience.

- Examining decisions and developments including but not limited to the following case law: Lundbeck, Servier, J&J, Teva and GSK

Session presenters/panellists
Please contact linda.cole@informa.com, +44(0)20 7017 6631 if you are interested in participating as a moderator or presenter in this session.

11:00 - 11:30

Morning Coffee

11:30 - 12:10

DUAL DIALOGUE: Discounts, rebates and excessive pricing in the pharmaceutical industry

Brian Sher,
Partner,
Nabarro LLP

Discounts and rebates:

- Recent Court of Justice judgment in Post Danmark II
- Different incentive structures: where does the law now stand?
- Points to be aware of in the pharma context
- Managing risks in light of enforcement policy

Excessive pricing:

- Overview of relevant case law
- Role of national pricing and reimbursement regimes
- How do you determine if a price is excessive?
- High launch prices vs. prices increases after launch

David Hull,
Partner,
Van Bael & Bellis

12:10 - 12:30

DUAL DIALOGUE: Key issues and pitfalls in the merger control review of pharmaceuticals transactions

This session will focus on recurring issues in the merger control review for approval of pharmaceutical transactions, including in relation to the scope of the information to be provided, the definition of relevant markets, and the discussion of acceptable remedy commitments.

Ingrid Vandenborre,
Partner,
Skadden, Arps

Laetitia Szaller ,
Associate General Counsel, Business Development & Technical Operations ,
UCB

12:30 - 1:50

Lunch

IP: Patent Litigation

1:50 - 2:30

DUAL DIALOGUE: Understanding the latest developments in SPCs

- Recent, pending and possible future referrals to the CJEU and EFTA Court
- Conditions for grant under Article 3
- Scope of protection under Article 4
- Obtaining SPCs for small molecule, combination and antibody products
- Meaning of "active ingredient"

Brian Cordery,
Partner,
Bristows LLP

Jennifer Antcliff,
Former IP Litigation Counsel ,
Actavis/Allergan

2:30 - 3:40

INTERACTIVE DISCUSSION FORUM: Enforcing second medical use patents

- How and by who are they infringed, or not?
- Impact of regulatory, pricing and reimbursement systems
- Patent enforcement through litigation; regulatory considerations and measures
- Latest case law

Paul Inman,
Partner,
Gowling WLG

Sergio Napolitano,
Legal Affairs And Trade Director,
Medicines for Europe

Jürgen Dressel,
Head Global Patent Litigation Strategy,
Novartis Pharma

3:40 - 4:10

Afternoon Coffee

Interaction between Competition Law, Patents and Regulatory Frameworks

4:10 - 5:20

INTERACTIVE DISCUSSION FORUM: Lifecycle management with respect to competition law, patents and regulatory frameworks

- Roche/Novartis case
- Pfizer case in Italy: The notion of abuse of rights
- Will this be applied by with national authorities and/or the EU

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

COM?
• How can you use IP legitimately and not fall foul
• This session will not cover the AstraZeneca case or patent settlements

James Horgan,
Assistant Managing Counsel, European Patents,
Merck Sharp & Dohme Corp.

Penny Gilbert ,
Partner ,
Powell Gilbert LLP

Pietro Merlino ,
Counsel,
Cleary Gottlieb Steen & Hamilton LLP

Peter Meyer,
Partner,
Simmons and Simmons

5:20 - 5:30

Closing Remarks from the Chairperson and End of Day One

5:30 - 7:30

25th Anniversary Party!

Join us in celebrating our 25th brithday this year. After a day filled with intriguing discussions unwind at our champagne reception, dine on delectable canapés and groove the night away with some all time classic floor fillers. You won't want to miss it!

Day 2: Regulatory Frameworks - Wednesday 25 May 2016

8:00 - 8:50

Conference Registration

Regulatory Frameworks

8:50 - 9:00

Introduction from the Chairperson

9:00 - 9:40

KEYNOTE PRESENTATION: Current state of the art and work in progress at the European Medicines Agency

• Evaluating data exclusivity/Regulatory Data Protection in the pharma industry
• Detailing the regulatory frameworks for biosimilars

Georgia Gavriilidou,
Legal Advisor,
European Medicines Agency

9:40 - 10:20

KEYNOTE PRESENTATION: Form follows function? Implementation of EU regulatory frameworks in pharmaceutical law at the EU Commission

• Recent progress in implementation
• Current priorities and challenges
• Early access, affordability and risk management

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

10:20 - 10:50

Morning Coffee

10:50 - 11:30

DUAL DIALOGUE: Marketing, advertising, social media, mobile aps and e-health

• How to effectively communicate with patients

• How to effectively communicate with patients
• The use of patient focus groups
• Optimising pharmaceutical marketing, co-marketing and social media
• Examining the use of mobile apps, e-Health and big data

Marc Christian Bauer,
Director & Senior Legal Counsel, International Legal Group,
Amgen

Catherine Longeval,
Partner,
Van Bael & Bellis

11:30 - 12:40

INTERACTIVE DISCUSSION FORUM: Orphan Regulation: 15 years later - ready for the future?

• Regulatory framework on orphan medicinal products
• Key concepts: Significant benefit, similar medicinal product and clinical superiority
• Orphan designation for complex drugs: Biologicals and ATMP's
• Strength and weaknesses of the system including recent case law: Teva, CTRS, Shire, Novartis
• Latest development: Draft Notice from the Commission to replace 2003 Communication on orphan medi

Marie Manley,
Partner and Head of the Regulatory Practice,
Bristows LLP

Grant Castle,
Partner,
Covington & Burling LLP

12:40 - 1:50

Lunch

1:50 - 2:30

DUAL DIALOGUE: Transparency of clinical trial data, other regulatory data and prices

• The transparency mantra
• EMA's disclosure of clinical trial and regulatory data
• EMA and Pari Pharma case law: T-235/15
• Implications of Regulatory Data Protection (RDP) and other competitive impact
• Principles of TRIPS agreements
• Transparency of prices and reimbursement status

Ian Dodds Smith,
Partner,
Arnold & Porter LLP

Sophie Pelé ,
Associate,
Dechert LLP

2:30 - 3:00

Biosimilars and the regulatory frameworks

• Recent regulatory approvals
• Recent policy issues
• Lifecycle management of a product
• Global perspective

Alexandre Mencik,
Associate General Counsel,
Amgen

3:00 - 3:30

Afternoon Coffee

3:30 - 4:00

Speaking, panellist, moderator and webinar opportunities

Join one of the sessions outlined on the agenda, present on one of the subjects listed below or suggest a topic of your choice (subject to approval by Informa).

• Pricing and reimbursement and market access
• How are HTA's working in practice
• Taking a closer look at falsified medicines directive and counterfeit products
• Paediatric products: Regulatory framework, challenges and opportunities
• Practical experience of the new pharmacovigilance legislation
• Examining the legal implications of recent advances with ATMPs

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4:00 - 5:00

INTERACTIVE DISCUSSION FORUM: Adaptive licensing and early access to medicines

- What initiatives have been put in place so far?
- How will these impact industry?
- Developments with the IMI project - Smart adapt
- IP aspects and challenges

Victoria Kitcatt,
VP & Assistant General Counsel, EU and International Regulatory Law,
Pfizer

Adela Williams,
Partner,
Arnold and Porter LLP

Christopher J. Foreman,
Senior Regional Director – Legal Affairs & Compliance – Nordics, Baltics and Belgium,
Merck Sharp & Dohme (Europe)

5:00 - 5:40

Quiz Time! Competition Law, Patents, Regulatory Frameworks and Pot Luck

Marjan Noor,
Partner,
Simmons & Simmons LLP

5:40 - 5:50

Closing Remarks from the Chairperson and End of Day Two

5:50 - 6:45

Networking Drinks Reception

Day 2: Evening Seminar, Discussion and Dinner - Wednesday 25 May 2016

6:15 - 6:30

Registration

6:30 - 8:30

Revisions to the medical devices regulation and the IVD regulation

- Outline of the changes to both regulations
- When will these come into force?
- Impact on industry
- Impact on personalised medicine and biomarkers
- Guidance on companion diagnostics

Peter Bogaert,
Partner,
Covington & Burling LLP

Shuna Mason,
Partner,
CMS Cameron McKenna LLP

David Van Passel,
Assistant General Counsel,
Johnson & Johnson

8:30 - 10:30

Networking Dinner

Day 3: Compliance: Data Privacy and Anti-Bribery - Thursday 26 May 2016

Stream 1

Attendees will be free to move between streams 1 and 2

8:00 - 8:50

Conference Registration

Compliance: Data Privacy and Anti-Bribery

8:50 - 9:00

Introduction from the Chairperson

9:00 - 9:40

Impact of the new data privacy regulation

- Outcome of the vote
- When will the regulation come into force?
- Implications for the pharmaceutical industry
- What are the fines that will be enforced?
- How to effectively transition from the directive to regulation
- Interaction between data protection regulation, clinical trials regulation and the medical device regulation

Kristof Van Quathem,
Special Counsel,
Covington & Burling LLP

9:40 - 10:20

Examining the new safe harbour ruling/agreement

- Practical experiences with the new safe harbour agreement: is it working, what rules have been put in place by companies?
- How to deal with sensitive information
- How to manage cross boarder transfer of the data within the pharmaceutical industry
- What are the broader ramifications of the Schrems ruling on safe harbour?

Beverley Flynn,
Partner,
Stevens & Bolton LLP

10:20 - 10:50

Morning Coffee

10:50 - 11:30

Data privacy and clinical trial data

- What rights do the patients have?
- If the patient pulls out how can you use their personal data?
- Patient consent for secondary use

Joyce ter Heerdt,
Head EMEA Regulatory Legal,
Johnson & Johnson

11:30 - 12:10

DUAL DIALOGUE: Transparency with regards to payments to healthcare professionals

- EFPIA code of conduct and other trade codes
- How do the codes work and what are the problems? e.g. obtaining privacy consents of HCP
- How to interpret, report and enforce
- Comparison of the U.S. Sunshine Act and the EU

Thibaut D'hulst,
Senior Associate,
Van Bael & Bellis

Ray Cresswell,
VP, RD&GC Legal Operations, Pharma R&D and Global Commercial Legal Operations,
GSK

12:10 - 1:30

Lunch

1:30 - 2:10

Essential guidance on the use of mobile apps and e-health with respect to privacy

- Industry and telecommunication companies: Data controllers or data processors?
- Processing of what data and for what purpose?
- Data processing: How should patients/consumers be informed?
- Drafting appropriate documents: Contracts and privacy policies

Olivier Mignolet,
Partner,
Simmons & Simmons LLP

2:10 - 2:30

Accountability and record keeping in a pharma context - an imperative requirement of the GDPR

- Types of records which need to be kept
- Details of those records
- For what purposes?
- What to do about Information Regulator interventions

Ashley Roughton,
Consultant Barrister,
Nabarro LLP

2:30 - 2:50

Speaking, panellist, moderator and webinar opportunities

Join one of the sessions outlined on the agenda, present on one of the subjects listed below or suggest a topic of your choice (subject to approval by Informa).

• Compliance and procurement rules
• Compliance and trade embargos

Please contact linda.cole@informa.com, +44(0)20 7017 6631 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar.

2:50 - 3:30

Anti-bribery and enforcement trends across the EU and Deferred Prosecution Agreements (DPAs): Private practice perspective

Omar Qureshi,
Partner,
CMS Cameron McKenna LLP

• Overview of EU bribery acts
• Methodologies used and what offence arose?
• Comparison of Member States
• Recent updates and the impact on industry
• DAPs: First examples
• Outline of best practice
• EU vs. US

3:30 - 4:00

Afternoon Coffee

4:00 - 4:40

Anti-bribery from a practical in-house counsel perspective

Thomas Gnielinski,
Senior Director, International Counsel, Law Department,
Alexion Pharma GmbH

4:40 - 5:20

Ensuring efficient internal investigations

Paul Ranson,
Consultant - Contractor,
Morgan, Lewis & Bockius UK LLP

• How to conduct a successful investigation
• Does it raise criminal issues and if so how should you deal with these?
• Assessing staff contracts
• Data privacy issues in internal investigations

5:20 - 5:40

INTERACTIVE PANEL DISCUSSION: How to mitigate risk

During this interactive panel discussion speakers and delegates will analyse compliance as a whole and share best practice:
• How to prevent compliance issues arising
• How to identify issues early when they do arise
• How to effectively deal with compliance issues

If you are interested in being a panellist or presenting on this topic please contact linda.cole@informa.com

5:40 - 5:50

Closing Remarks from the Chairperson and End of Day Three

Day 3: Licensing and Collaboration Agreements - Thursday 26 May 2016

Stream 2
Attendees will be free to move between streams 1 and 2

8:00 - 8:20

Conference Registration

Licensing and Collaboration Agreements

8:20 - 8:30

Introduction from the Chairperson

8:30 - 9:00

BREAKFAST BRIEFING: Examining commercial intellectual property issues in collaboration and licensing agreements

- Understanding the ownership of IP
- Joint ownership issues
- IP protection and enforcement
- IP rights of each party
- Implications of SPCs for pharma industry agreements

Sally Shorthose,
Partner,
Bird & Bird

Paul Thompson,
VP Legal Affairs for New Meds.& Business Development,
UCB

9:00 - 9:40

DUAL DIALOGUE: The importance of due diligence

- Managing risks: Due diligence vs. warranties
- Due diligence as part of a deal-making process: What, when, who, how and how much?
- Impact on the structure and terms of the proposed transaction
- Due diligence as the start of a relationship between the parties: how to build trust in you as a partner
- Ensuring confidentiality, avoiding contamination and maintaining privilege

Frank Landolt,
V.P. Intellectual Property and Legal,
Ablynx

Andrea Borrell Vila,
Senior Counsel,
Baxter

9:40 - 10:10

Obligations to exploit

- "Diligence" in the context of the obligations on a licensee to develop and commercialise a product
- Identity of licensor and impact for diligence provisions
- Failure to exploit the licensed technologies
- Examples of litigation regarding the implementation of diligence obligations

Patrick Duxbury,
Partner,
Gowling WLG

10:10 - 10:50

Morning Coffee

10:50 - 11:30

DUAL DIALOGUE: Assessing the financial aspects of licensing and collaboration agreements

- Detailing the economic considerations
- Choosing between licensing or acquisition of the product
- Detailing upfront payments
- Developmental milestones and commercial milestones: At what stage are these paid?
- Tips and pitfalls when structuring and calculating royalties
- Availability of reach through royalties

Matthieu Guérineau,
Contract Department Director,
Les Laboratoires Servier

Emmanuelle Trombe,
Partner,
McDermott Will & Emery

11:30 - 12:10

DUAL DIALOGUE: Legal and BD&L perspective: The importance of alliance management in licensing deals

- Governance structures, committees in license/collaboration

agreements
• Best practices for dispute resolution
• Insight into the operation post-license

Knut Sturmhoefel,
Head BD&L, Retina and Respiratory,
Novartis

Barbara Levi Mager,
Global Head Legal, Global Product Strategy & Commercialization,
Novartis

12:10 - 1:30

Lunch

1:30 - 2:10

DUAL DIALOGUE: Planning, negotiating and drafting termination provisions

• Termination clauses: Termination for convenience and termination for cause
• Consequences of termination: Licensor and licensee perspectives
• Transitional provisions

Daniel Pavin,
Partner,
Covington & Burling LLP

Rebecca Weston,
Country Legal Head, UK & Ireland,
Novartis Pharmaceuticals

2:10 - 2:50

DUAL DIALOGUE: Co-marketing/co-promotion agreements in the pharma industry

• Co-marketing or co-promotion?
• Competition law aspects of co-marketing/co-promotion agreements in the pharma industry
• The impact of the EU Commission Sandoz/J&J case

Stephen Reese,
Partner,
Olswang LLP

Jacob Westin,
Former Assistant General Counsel & Head of EU Competition Law,
GSK

2:50 - 3:30

Speaking, panellist, moderator and webinar opportunities

Join one of the sessions outlined on the agenda, present on one of the subjects listed below or suggest a topic of your choice (subject to approval by Informa).

• The Unified Patent Court from a commercial perspective
• Consortiums and Horizon 20/20
• The use of asset centric corporate structures as alternatives to traditional collaboration and licensing deals
• Dealing contractually with 3rd party IP rights
• The impact of regulatory frameworks on licensing and collaboration agreements

Please contact linda.cole@informa.com, +44(0)20 7017 6631 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar.

3:30 - 4:00

Afternoon Coffee

4:00 - 4:40

Outlining a recent asset deal in the pharmaceutical industry

• Negotiating the contracts
• Implementation of the transaction
• Challenges encountered and how these were overcome
• Interaction with business functions

Daniel Schulze,
Vice President & General Counsel,
Astellas Pharma EMEA

4:40 - 5:40

EXTENDED INTERACTIVE SESSION: Industry case study

During this interactive session delegates will be given either a real-life or hypothetical case study of a licensing and collaboration agreement and the opportunity to discuss issues arising in these types of transactions.

Lucinda Osborne,
Partner,
Covington & Burling LLP

Olivier Lemaire,
Assistant General Counsel, Legal Affairs, Vaccines,
GSK

Ling Zeng,
VP & General Counsel, EMEA,
Valeant Pharmaceuticals International

5:40 - 5:50

Closing Remarks from the Chairperson and End of Day Three