EU Pharmaceutical Law Forum

21-23 May 2019
The Hotel, Brussels
Brussels

CRITICAL GUIDANCE ON COMPETITION LAW, PATENT LITIGATION, REGULATORY FRAMEWORKS, COMPLIANCE AND LICENSING AGREEMENTS

21st MAY 2019

- Competition Law & Patent Litigation
- Evening Seminar 1: Legal Strategies for Biosimilars

22nd MAY 2019

- Regulatory Frameworks
- Evening Seminar 2: Demystifying the MDR and IVDR

23rd MAY 2019

- Stream 1: Data Privacy and Healthcare Compliance
- Stream 2: Licencing & Collaboration Agreements

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Competition Law and Patent Litigation

08.00 *Conference Registration*

08:50 **Introduction from Chairperson**

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

09:00 **KEYNOTE PRESENTATION: Update from EU Commission on Competition Law Enforcement**

- Recent updates in the EU pharmaceutical Law sector on competition law enforcement
- Insight into abusive dominance through excessive pricing
- Latest developments on reverse payment settlements

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

09.40 **INTERACTIVE DISCUSSION FORUM: Excessive Pricing in the Pharmaceutical Industry**

- Update on abusive dominance through excessive pricing case law
- Practical advice following decisions and developments in recent cases
- What constitutes excessive: identifying appropriate value indicators for originator products and understanding value to whom and compared to what

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

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

Molly Herron, Senior Legal Counsel, Antitrust EMEA, **Novartis AG,** *Belgium*

10.40 *Networking Break*

11.10 **INTERACTIVE DISCUSSION FORUM: Reverse Payment Patent Settlements**

- Insight into the Lundbeck and Servier case: practical implications for patent settlements and market definition
- Acquisitions of technology: can this be considered an abuse of a dominant position?
- How do you define the relevant market from a competition law perspective to define dominance?

Geoff Steadman, Project Director, **Competition & Markets Authority (CMA),** *UK*

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

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

12.10 **Update on Parallel Trade in a Post Brexit Era**

- Recent competition law rulings and case law for parallel trade: update on dual pricing
- Drivers of parallel trade across Europe, key risks and implications
- Exploring the impact of Brexit on the EU market and parallel trade practices
- Models and approaches for pharmaceutical companies: what opportunities and risks will Brexit offer?

Jacob Westin, Legal Counsel, **Shire Pharmaceuticals,** *Sweden*

12.50 *Networking Lunch Break*

14.40 **DUAL DIALOGUE: Examining Product Hopping: Abusive Dominance or Product Innovation?**

- Examining cases, rulings and review for product hopping as a lifecycle management strategy
- Update on the expansion of antitrust scrutiny on product lifecycle strategies
- Strategies to minimise competition law risks and protect your product

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

Angela Staunton, Vice President, Law, Patents & Compliance – Pharmaceuticals, **Bayer AG,** *Germany*

15.20 **DUAL DIALOGUE: Assessing the Current Status of SPCs**

- Update on the law of "protected by a basic patent force": how is Gilead being applied by National Courts and Patent Offices? Royalty Pharma and Janssen references
- The latest on SPCs based on 3rd party Mas: what is the direction of travel?
- SPCs for novel and inventive formulations: the Abraxis decision
- SPCs for medical devices and combined medical devices/medicinal products – the CJEU decision in Boston Scientific
- Reform of SPC law - the Max Planck report and other initiatives: evaluating the proposed manufacturing exemption

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

Nicolas Ruiz, Intellectual Property Head, European Patent Attorney, **Esteve,** *Spain*

16.00 *Networking Break*

16.30 **DUAL DIALOGUE: Patent Relief: Injunctions, Arrow Declarations, Cross Border Declarations and Injunctions**

- 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?
- What role could compulsory licences pay?
- Cross-border relief
- Update on Arrow declarations

Benoît Strowel, Managing Partner, **Hoyng Rokh Monegier LLP,** *Belgium*

Paul Inman, Partner, **Gowling WLG LLP,** *UK*

17.10 **DUAL DIALOGUE: Second Medical Use Patents**

- Examining the UKSC decision in the pregabalin case and the implications for plausibility, amendment of patents and cross-label use
- Practical steps to be taken when enforcing a second medical use patent
- How much data needs to be included in a patent? How to find the sweet-spot in which to file an application

Jennifer Sunderland, Senior Patent Litigation Counsel, Global Litigation, **Mylan,** *UK*

Hiroshi Sheraton, Partner, **Baker & McKenzie LLP, UK**

17.50 **Chairperson's Closing Remarks**

17.55 *Close of Competition Law and Patent Litigation Day*

DAY TWO: WEDNESDAY 22 MAY 2019

Regulatory Frameworks

08.00 *Conference Registration*

08:50 **Introduction from Chairperson**

09.00 **KEYNOTE PRESENTATION: EU Commission Update on the Regulatory Landscape for Pharmaceuticals**

- Update on the review into pharmaceutical incentives and rewards: views and timetable
- Key areas for analysis and the potential implications for availability and accessibility
- Areas of focus for potential legislative revision

Florian Schmidt, Legal Advisor, European Commission, **DG SANTE,** *Belgium*

09.40 **INTERACTIVE DISCUSSION FORUM: The Evolving European Regulatory Landscape Post Brexit**

- Unveiling MHRA's plans and post Brexit guidelines
  - Similarities and divergence from EU regulations
  - Practical insight into gaining marketing authorisation in the UK
- Plans and priorities for 2019 and beyond
  - Practical implications of Brexit on EU pharmaceutical regulations: how has the approach evolved?
  - Update on plans, priorities and progress: practical focus on inspections, evaluations and certification
- Impact on the pharmaceutical industry: what can we expect in the coming year?

Grant Castle, Partner, **Covington & Burling LLP, UK**

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

Florian Schmidt, Legal Advisor, European Commission, **DG SANTE,** *Belgium*

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

10.40 *Networking Break*

11.10 **Orphan Market Exclusivity: Regulatory Framework, Challenges and Opportunities**

- Update on regulations, trends and case law
- Insight into the EU Orphan Medicines Regulation review: consultation, analysis and industry view
- Market access challenges for Orphans drugs

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

11.45 **Challenges and Opportunities for Regulatory Data Exclusivity**

- Scope and practical application of regulatory exclusivity
- Practical implications of the Astellas case: impact on industry market strategies
- Challenging the notion of global marketing authorisation: pitfalls and opportunities for different routes to approval
- Examining the complexities of asserting rights to data exclusivity

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

Helen Middleton, Principal Legal Advisor, **Mundipharma International,** *UK*

12.20 **FLASH PRESENTATION: Obligations of the Nagoya Protocol for R&D on Genetic Resources**

- Understanding international and EU rules implementing the Nagoya Protocol to the Convention on Biological Diversity
- Ensuring compliance: arrangements to ensure legal utilisation of genetic resources in global R&D activities

Bart Van Vooren, Senior Associate, **Covington & Burling LLP,** *Belgium*

12.40 *Networking Lunch*

14.10 **DUAL DIALOGUE: Regulations for eHealth, Mobile Apps and Artificial Intelligence**

- Overview of the regulations and classification for digital offerings: AI, mobile apps, software, websites
- What does the rise of AI mean for legal assessments and considerations?
- Demystifying responsibility: practical scenarios which thing go wrong and who is responsible
- Common pitfalls and challenges for compliance

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

14.50 **DUAL DIALOGUE: Pharmaceutical Marketing, Advertising and Promotional Activity**

- Latest developments, and case law on pharmaceutical promotional activity
- Understanding liability when lines are crossed
- The rise and challenges of social media, mobile apps and e-health tools

Marc Christian Bauer, Vice President – Legal, Compliance and Corporate Affairs, International, **Tesaro Bio GmbH,** *Switzerland*

Livia Zamfiropol, Partner, **DLA Piper LLP,** *Romania*

15.30 *Networking Break*

16.00 **DUAL DIALOGUE: Legal Challenges for Off Label Use of Medicinal Products**

- Latest developments: update on case law and market developments
- Wider implications for the industry of recent rulings on off-label use of Avastin
- Payers perspective: what are the opportunities for off-label use and when is it appropriate to use?

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

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

16.40 **INTERACTIVE DISCUSSION FORUM: Market Access: The Convergence of Regulation, Pricing and Reimbursement**

- Latest developments: examining levers utilised by healthcare authorities in price negotiations
- The rise of compounding pharmaceuticals: challenges to authorised products and exclusivity in the Netherlands?
- Challenges for reimbursement for ATMPs and orphan medical products
- How and to what extent are countries working together to create structures and forms of co-operation to prepare for market access negotiations?

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

Hanneke Later-Nijland, Partner, **Axon Lawyers LLP,** *The Netherlands*

17.40 *Chairperson's Closing Remarks*

17.45 *Close of Regulatory Frameworks Day*

Stream 1: Data Privacy and Healthcare Compliance

08.00 *Conference Registration*

08:50 **Introduction from Chairperson**

09.00 **Uncovering the Tensions Surrounding GDPR and Clinical Trials**

- Understanding and evaluating the different legal grounds for processing personal data: experience in practice
- Examining questions around the qualification of data controller and data processor
- Exceptions and challenges for secondary use and scientific research
- Managing data subject rights in clinical trials

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

09.30 **INTERACTIVE DISCUSSION FORUM: New Data Protection Regulations and GDPR for Clinical Research**

EMA perspective: new regulation on Data Protection applicable to EU institutions and bodies

- Practical challenges for the pharmaceutical industry: varying approach to the legal basis for processing data
- Data protection authorities approach and focus: identifying the challenges and opportunities
- Health Authorities view on the application of GDPR for clinical trials

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

Stefano Marino, Head of Department, **European Medicines Agency** *(Subject to Final Confirmation)*

Alejandro Gené, Chief Privacy Counsel, Legal Advisor, **Celgene,** *Switzerland*

10.20 *Networking Break*

10.50 **Data Privacy and Risk Management as a Business Enabler in the Pharmaceutical Industry**

- Understand GDPR risk approach
- Using GDPR as an opportunity to transform life science operations
- Practical insight into how privacy can enable the strategy of a pharmaceutical business
- Comparing the privacy risk-based approach of a global multinational to a small to medium size pharmaceutical organisation

Maria Chiara Atzori, Head of Data Privacy Corporate Legal, **Novartis AG,** *Switzerland*

11.30 **DUAL DIALOGUE: Effective Compliance: Benchmarking Whistleblowing and Anti-Bribery Programmes**

- Overview of current whistleblowing protection in the EU and the proposal for EU Whistle-blower Protection Directive
- Reviewing anti-bribery regulations across Europe: lessons learnt from recent cases
- Best practice and benchmarking advice for implementing a successful compliance program
- Examining competition law considerations around whistleblowing

Nicolai Behr, Partner, **Baker & McKenzie LLP,** *Germany*

12.00 *Networking Lunch*

13.30 **Harmony Project Case Study: Anonymisation, Cross Border Compliance and Big Data**

- Maintaining compliance with national data protection laws and GDPR
- Insight into legal frameworks: how to share highly sensitive patient data amongst multiple partners
- Practical approach to safeguarding big data and anonymisation for big data analysis

Fabian Dorra, Legal Counsel, **Bayer AG,** *Germany*

14.10 **Effective Compliance: Benchmarking Whistleblowing and Anti-Bribery Programmes**

- Overview of current whistleblowing protection in the EU and the proposal for EU Whistle-blower Protection Directive
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- Best practice and benchmarking advice for implementing a successful compliance program
- Examining competition law considerations around whistleblowing

Nicolai Behr, Partner, **Baker & McKenzie LLP,** *Germany*

14.50 *Networking Break*

15.20 **DUAL DIALOGUE: Collaboration and Compliance with HCPs**

- Review of regulations and codes of conduct for transparency and collaborating with HCPs
- Self-regulation vs. regulations: analysing the compliance gaps
- Strategies for creating and maintaining successful HCP collaborations
- Compensating healthcare professionals: establishing a fair market value

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

16.00 **DUAL DIALOGUE: Mitigating Risk whilst Optimising Patient Interactions**

- Latest developments, regulations, codes related to patient interactions
- Walking the fine line: optimising interactions in a highly regulated environment
- Best practice for patient support programmes

Fausto Massimino, Director - Legal, Compliance and Governance, **Roche SpA,** *Italy*

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

16.40 **Chair's Closing Remarks**

16.45 *Close of Data Privacy and Compliance Day*

Stream 2: Licencing and Collaboration

08.00 *Conference Registration*

08:50 **Introduction from Chairperson**

09.00 **Brexit and New Market Trends in the Pharmaceutical Industry: Impact on Licencing and M&A**

- Outlook: examining the most significant changes occurring across the industry
- Brexit: impact on existing and new licencing agreements
- Are deals getting more complex? New models for M&A and partnering activity

Alex Denoon, Partner, **Bristows LLP,** *UK*

09.40 **Roundup of Commercial Litigation from the Pharmaceutical Sector: Lessons Learnt**

- Examining litigation across global commercial transactions: examining key areas of contention
- Lessons learnt: rundown of the top pitfalls to avoid during commercial transitions

Patrick Duxbury, Partner, Head of Life Sciences (UK), **Gowling WLG LLP,** *UK*

10.10 *Networking Break*

10.50 **DUAL DIALOGUE: Examining Agreements for Multi-Partner Collaboration**

- Aligning interests: how do you structure a deal to ensure all interests align?
- Multiparty collaborations: format, structure, financial and sub-licence implications
- Practical guidance and pitfalls to avoid when trying to align multi-party interests

Veronika Bednar, Senior Director, Head of Corporate & Commercial, EMEA Legal, **Astellas Pharma Europe,** *UK*

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

11.30 **DUAL DIALOGUE: The Rise of Digital and Pharmaceutical Collaborative Models**

- Examining the growth and opportunities of digital health
- Exploring partnering models and deals structures
- Practical guidance: managing partnerships, aligning diverse partner interests and culture and solving IP right challenges

Claire Solk, Senior Legal Counsel, **Astrazeneca,** *UK*

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

12.10 *Networking Lunch*

13.40 **INTERACTIVE DISCUSSION FORUM: Key Factors in Making your Collaboration a Success**

- Evaluating different strategies and models for collaboration
- What are partners looking for? Key driver's strategic partners and investors
- Where's the value? Assessing your value across your assets, know-how and IP
- What are the key aspects of an effective due diligence process
- Getting due diligence right: starting the process early and taking a multi-functional approach

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

Laetitia Szaller, Associate General Counsel, **UCB SA,** *Belgium*

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

14.40 **DUAL DIALOGUE: Competition Law Considerations in Structuring Business Development Collaborations**

- Antitrust implications of licencing and collaboration deals
- 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. Innovation competition and acquisition of start-ups and biotech

Kyriakos Fountoukakos, Partner, **Herbert Smith Freehills LLP,** *Belgium*

Chris Verleye, Assistant General Counsel, **Johnson & Johnson,** *Belgium*

15.30 *Networking Break*

16.00 **EXPERT TAX ADVICE: Tax Regimes for Innovation and Considerations when Structuring Deals**

- Tax planning for collaboration and licencing agreements
- Examining financial components of licencing agreements and their tax implications
- Transfer pricing: intragroup and arm's length arrangements
- Comparison of tax regimes for innovation across Europe

Please contact linda.cole@knect365.com, Tel +44 (0) 20 7017 6631 if you are interested in participating as a speaker, panellist, moderator or hosting webinar.

16.30 **DUAL DIALOGUE: Implementing Effective Termination Provisions in Agreements**

- The importance of early focus on termination and consequences of early termination
- Best practice advice on handling conflict in licencing negotiations: termination clauses, identifying what you can claim and when damages need to be paid
- Settling disputes: common pitfalls to avoid and best practice advice

Frank Landolt, Chief Counsel Legal & IP, **Confo Therapeutics,** *Belgium*

Paola Sangiovanni, Partner, **Gitti and Partners Studio Legale Associato,** *Italy*

17.10 **Chairperson's Closing Remarks**

17.15 *Close of Conference*

EVENING SEMINAR • DAY ONE: TUESDAY 21 MAY 2019

Legal Strategies for Biosimilars

Competition Law for Biosimilars

- Focus on competition authorities approach and enforcement for biologics and biosimilars
- To what extent do the competition law principles developed for generic drugs apply to the biological space?
- Status of abusive dominance: pricing practices and lifecycle market strategies

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

Nicolas Pourbaix, Senior Counsel, Legal Director, **Amgen,** *Belgium*
Amandine Métier, Partner, **Hoyng Rokh Monegier LLP,** *France*
Liesbeth Weynants, Partner, **Hoyng Rokh Monegier LLP,** *France*

18:15 *Registration*

18:30 *Start*

20:15 *Networking Dinner*

EVENING SEMINAR • DAY TWO: WEDNESDAY 22 MAY 2019

Demystifying the MDR and IVDR

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*

18:15 *Registration*

18:30 *Start*

20:15 *Networking Dinner*

For speaking opportunities contact Leena Shaw:
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