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Informa Life Sciences' 23rd Annual

EU PHARMACEUTICAL LAW FORUM

Wednesday 14 - Thursday 15 May 2014, The Hotel. Brussels, Brussels, Belgium

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Europe's leading pharmaceutical law conference on competition law, patent litigation and regulatory frameworks

Keynote Speakers

Stefano Marino
Head of Legal Department
European Medicines Agency

Olga Solomon
Deputy Head of Unit D5 - Medicinal Products - Authorisations, European Medicines Agency, DG Health and Consumers
European Commission

A Representative from
DG Competition
European Commission

François Arbault
Head of Unit
European Commission

Despina Spanou
Director for Consumer Affairs
European Commission

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DAY 1

Competition Law, Patent Litigation and the Interface with Regulatory Frameworks
Evening Seminar:
SPCs

DAY 2

Transparency of Clinical Trial Data, Clinical Trials Regulation, Data Exclusivity, Interaction with Healthcare Professionals, Pricing and Reimbursement, Pharmacovigilance Legislation, Personalised Medicines and IVDs, Combination and Borderline Products, Biosimilars
Evening Seminar:
Advertising, Social Media and Health Apps

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EU Pharmaceutical Law Forum Key Logos:
This year's programme will address the need for keynote presentations, new formats, interactive debate and take home messages.

EMA European Medicines Agency | COM European Commission | Interactive Discussion Forum | Dual Dialogue

Day One: Wednesday 14 May 2014

08:00 Conference Registration

09:00 Introduction from the Morning Chairperson
Ian S. Forrester QC, *Partner*, **White & Case LLP**

COMPETITION LAW

09:10 **KEYNOTE PRESENTATION:**
Feedback from the EU Commission on competition law
- Overview of recent developments in competition law and the pharmaceutical industry
- Reverse payment settlement agreements: Reviewing developments/decisions on the Lundbeck, Servier, J&J and Teva investigations
- Late lifecycle management strategies to delay generic entry
- Examining parallel trade

A Representative from DG Competition, **European Commission** (subject to confirmation)

09:50 **INTERACTIVE DISCUSSION FORUM:**
Reverse payment patent settlements
Representatives from different firms/companies 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 in the following cases: Lundbeck, Servier, J&J, Teva and GSK

Fiona Carlin, *Partner*, **Baker & McKenzie**
Paula Riedel, *Partner*, **Linklaters LLP**

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

11:00 Morning Coffee

11:30 **DUAL DIALOGUE:**
Examining parallel trade: Imports and exports
- The Spanish dual pricing system and related case law
- How the Eurozone financial crisis has impacted patient access through parallel trade
- The national responses to parallel trade driven shortages

Ilja Pohland, *Associate VP Legal Operations, Region Europe*, **Sanofi**
- Restricting exports outside of the EU: Turkey's response/ intervention towards import restriction
- Jurisdiction of competition authorities: Intersection between the effects theory and direct/indirect export bans

Gönenç Gürkaynak, *Managing Partner*, **ELIG, Attorneys-at-Law**

12:10 **Relationship between pharmaceutical companies and wholesales/distributors: Assessing the competition law aspects**
- The ideal distribution model from a control (and competition law) perspective
- Distribution models representing an acceptable level of risk for the pharma company concerned
- Factors influencing choice: How and why Shire's human genetic therapies supply chains are distinct from those used by its more conventional drugs
- Useful provisions to have in your distribution agreement
- What the business wants these days
- Potential pitfalls along the way
- Potential pitfalls ahead – including treatment of grey product

Jamie Pearson, *Senior Legal Counsel*, **Shire**

12:40 Lunch

14:00 **INTERACTIVE DISCUSSION FORUM:**
Review of high profile national cases/decisions in competition law
Each speaker will present a short talk on the topics outlined below with regards to their specific country. This will be followed by an interactive panel discussion with the audience.
- What is the infringement?
- Agreement infringement or abusive dominance?
- Differences across countries and strategies to harmonise

France: Plavix Case, Sanofi
Matthieu Guérineau, *Contract Department Director*, **Les Laboratoires Servier**
Francois Garnier, *Chief Counsel International Platform*, **Pfizer**
Turkey: Sector inquiry report released by the Turkish Competition Authority in 2013
Gönenç Gürkaynak, *Managing Partner*, **ELIG**, **Attorneys-at-Law**

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IP: PATENT LITIGATION

14:50 **KEYNOTE PRESENTATION:**
Unified Patent Court: Feedback from the European Commission
- What is the structure of this new system?
- Which Member States have opted in?
- Overcoming language issues
- Impact on industry

François Arbault, *Head of Unit*, **European Commission**

15:30 Afternoon Tea

16:00 **Detailing second medical use claims**
- What are second medical use patents and why are they important?
- How to enforce the patents – construction and infringement issues; cross-label use; relief
- Are second medical use patents fit for purpose?
- What alternative models exist to ensure that new uses for existing drugs are researched?

Brian Cordery, *Partner*, **Bristows LLP**

INTERFACE BETWEEN COMPETITION LAW, IP AND THE REGULATORY FRAMEWORKS

16:30 **INTERACTIVE DISCUSSION FORUM: Interface between competition law, IP and the regulatory frameworks**
Panellist in this session will outline major points for discussion with the audience and outline key take home messages from day 1 and how these relate to the topics discussed in day 2.
Patrick Duxbury, *Partner*, **Wragge & Co**
Bill Batchelor, *Partner*, **Baker & McKenzie**
Michael Burdon, *Head of Patent Litigation*, **Olswang LLP**

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

17:10 Closing Remarks from the Chairperson

17:20 End of Day One Followed by Networking Drinks and Evening Seminar

Evening Seminar Discussion and Dinner: Day One, Wednesday 14 May 2014
18:15 Registration • 18:30 Start • 20:30 Networking Dinner

Understanding European patent and SPC litigation: Changes ahead

2013 saw a flurry of decisions from the European Court of Justice that were relevant to obtaining Supplementary Protection Certificates (SPCs), which provide an extension of patent monopoly to protect medicinal products. From calculating the term of patent extension to identification of the first marketing authorisation in the EU that can form the basis of an SPC application, from reviewing the means of determining whether a particular patent will form the basis for an SPC to whether SPC applications might be available for combinations or new uses of known products - the CJEU decisions often created more confusion than clarity. This evening seminar aims to review the current law on obtaining and enforcing SPCs.

How SPCs fit into the new European patent system will also be reviewed. The creation of a unitary patent and a unified patent court system mean that options for obtaining patent protection, litigating infringement and challenging third part blocking patents will change. How will the new system work in relation to patents and SPCs? What are the options and what practical steps do you need to begin considering in advance?

Topics to be covered include:
- Latest developments in SPCs: Recent and pending CJEU referrals
  - Articles 3 and 4 SPC Regulation
  - Decisions on negative and zero term SPCs
  - What do these mean for the next case?
- Latest developments in litigating patents and SPCs
  - How will the current system change?
  - What are the key features of the UPC?
  - What are the strategic implications for existing patents and SPCs?

Why you should attend:
- Patents provide a period of monopoly for sales of new drugs – review how and when SPCs will be available
- Consider the opportunities and pitfalls in the new European patent system
- Find out how the new system will be different and when it will come into effect
- Review potential strategies for protecting (or challenging) patents and SPCs

Seminar Leaders:
Penny Gilbert, *Partner*, **Powell Gilbert LLP**
Simon Cohen, *Partner*, **Taylor Wessing**

Day Two: Thursday 15 May 2014

08:20 Introduction from the Chairperson

08:30 **KEYNOTE PRESENTATION:**
Implementation of the EU regulatory framework for medicinal products for human use
Olga Solomon, *Deputy Head of Unit D5 - Medicinal Products - Authorisations, European Medicines Agency, DG Health and Consumers,* **European Commission**

REGULATORY FRAMEWORKS IN PHARMACEUTICAL LAW

09:10 **INTERACTIVE DISCUSSION FORUM: Transparency of pre-clinical and clinical trial data and other regulatory data**
Representatives from private practice, in-house counsel and the EMA will share their experiences and expert legal opinion on the topics outlined below. This will be followed by interaction with the audience.

Exclusive feedback from the EMA

- The transparency mantra, set against the protection of commercially confidential information
- EMA's disclosure of pre-clinical and clinical trial data submitted to obtain MAs in response to FOI requests
- Implications for Regulatory Data Protection (RDP) and other potential competitive damage for industry
- International law issues and TRIPS
- Update on AbbVie and InterMune cases
- EMA proposed policy on pro-active release of clinical trial data
- Transparency and the revision to the Clinical Trial Regulation
- Regional initiatives in the context of global execution of clinical trials and the implementation of the EFPIA and PhARMA principles
- Transparency and sharing of clinical trial data by controlled access; possibilities in relation to requests to EMA, FDA and similar bodies in other jurisdictions

Stefano Marino, *Head of Legal Department,* **European Medicines Agency**
Ian Dodds-Smith, *Partner,* **Arnold & Porter LLP**
Alexandre Mencik, *Associate General Counsel,* **Amgen**
Caroline Stockwell, *Assistant General Counsel,* **Pfizer**

10:10 **Review of the clinical trials regulation**
- Update on the proposals by the Commission
- When will the new regulation come into force?
- What are the challenges for industry and how to overcome these
- Ensuring a smooth transition from directive to regulation

Exclusive feedback from the EMA

Shuna Mason, *Partner, Head of Regulatory,* **CMS Cameron McKenna LLP**

10:50 Morning Coffee

11:20 **INTERACTIVE DISCUSSION FORUM: Evaluating data exclusivity/Regulatory Data Protection (RDP) in the pharmaceutical industry**
Representatives from private practice, in-house counsel and the EMA will share their experiences and expert legal opinion on the topics outlined below. This will be followed by interaction with the audience.
- What is the purpose and value of RDP?
- What is a new active substance?
- The global marketing authorisation
- Latest developments and EU litigation
- The clopidogrel decision in Germany and conflicts with EU law

Stefano Marino, *Head of Legal Department,* **European Medicines Agency**
Victoria Kitcatt, *Assistant General Counsel, European Regulatory Law,* **Pfizer**
Peter Bogaert, *Partner,* **Covington & Burling LLP**

12:20 **DUAL DIALOGUE:**
Interaction with healthcare professionals - challenges and changes
- EFPIA and IFPMA codes of conduct and other national industry codes
- How does it work and what are the problems in daily practice?
- Limits of industry codices, national penal codes and law enforcement
- Progress of the new German anti-corruption law
- The Sunshine Act and the equivalent in France

Christoph Dengler, *Vice President Legal,* **STADA Group**
Catherine Longeval, *Partner,* **Van Bael & Bellis**

13:00 Lunch

14:00 **New trends in pricing and reimbursement and revisions to the EU Transparency Directive: Main focus on France, Germany, Spain, Italy and the UK**
- Impact of government budget cuts
- EU and national litigation; How to achieve harmonisation across the EU
- Revision of the EU Transparency Directive
- Impact of the revisions on industry
- Managed entry agreements

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

14:40 **Practical experience of the new pharmacovigilance legislation**
- New legal framework for pharmacovigilance activities
- Outlining the amendments to the regulation
- Practical experience of the implementation: Common hurdles and how to overcome these

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

15:10 Afternoon Tea

15:30 **Speaking and Panellist Opportunities**
We are looking for speakers and/or panellists on the following topics:
- How are HTAs working in practice?
- Understanding data protection with regards to personal data/ privacy
- Paediatric products: Regulatory framework, challenges and opportunities

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

16:00 **KEYNOTE PRESENTATION:**
Feedback from the EU Commission on the EU regulatory framework for medical devices
- Review of the regulatory framework for the medical device industry
- State of play of the Commission's proposals for a revised EU legislation on medical devices
- Consequences of The CJEU judgement on borderline products
- Assessing combination products and the interaction with the pharma industry

Despina Spanou, *Director for Consumer Affairs,* **European Commission** (subject to final confirmation)

16:30 **INTERACTIVE DISCUSSION FORUM:**
Examining the use of medical devices
The 2 topics outlined below will be covered by short presentations. Talks will be followed by interaction with the audience.

Overcoming challenges surrounding personalised medicines and IVDs
- Laboratory developed tests vs. IVDs
- Regulatory pathways for the companion diagnostics and the medicinal product
- Which business model is best for companion diagnostics?

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

Reviewing combination and borderline products
- Impact of the recent judgment by The Court of Justice of the European Union case C-109/12
- Does the fact that a product is considered to be a medical device in one Member State preclude the same product from being considered to be a medicinal product in a different Member State?
- Should the Member State that considers the product to be a medicinal product apply only to the procedures set out in the Medicinal Products Directive or should they follow the safeguard procedures in the Devices Directive?

Paul Ranson, *Partner,* **Pinsent Masons LLP**

17:10 **20 MINTUE SNAPSHOT: Biosimilars and the regulatory frameworks**
- Overview of the new EMA guidelines and drafts
- Recent regulatory approvals
- Traceability
- Unique identifiers
- Interchangeability

Anna Krusinka, *Regulatory Manager,* **AbbVie**

17:30 Closing Remarks from the Chairperson

17:40 End of Day Two Followed by Networking Drinks and Evening Seminar

Evening Seminar Discussion and Dinner: Day Two, Thursday 15 May 2014
18:15 Registration18:30 Start • 20:30 Networking Dinner

Examining pharmaceutical advertising, social media and health apps

This session will be composed of a combination of short presentations and interactive discussion with the audience.

Pharmaceutical marketing, advertising and social media
- Overview of the available technologies
- Legal considerations and code of conduct
- Approaching the healthcare professionals
- Video detailing with physicians
- The use of social media

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

The legal framework applicable to "health apps"
- How health apps are regulated – when must they be CE marked as medical devices?
- Questions to consider when assessing the qualification of an app
- Addressing EU guidance – examples to illustrate the 'grey' areas
- Practical tips to consider when marketing apps

Benefits of attending this session:
- Gain an understanding of how healthcare apps are regulated in the EU
- Learn the key principles for the qualification of healthcare apps as medical devices / IVDs
- Develop an understanding of the 'borderline' issues and case law on healthcare apps as medical devices
- Discover practical tips for the development of healthcare apps to ensure regulatory compliance
- Stay informed of the anticipated reforms of the existing Medical Devices Directives and the IVD Directive 98/79/EC, and the impact of the draft Regulations on the regulation of software

Marie Manley, *Partner and Head of the Regulatory Practice*, **Bristows LLP**
Thomas Lynch, *Senior Legal Counsel*, **Novartis Pharma AG**

NEW for 2014: EU Pharmaceutical Law Webinars

Webinars will be offered in addition to the main conference and will be available to book for all delegates, plus separately bookable to anyone who is unable to attend the event. They will be listened to pre-event for enhanced learning and will contribute towards your CPD points.

We are offering a choice of 3 conference webinars. The first is FREE of charge and a charge of £150 +20%VAT per webinar will be applied thereafter.

Wednesday 2nd April 2014:
Webinar 1: Taking a closer look at falsified medicines directive and counterfeit products
- Overview of regulatory framework
- When is the directive due into force in each MS?
- Experience of the directive by industry and regulators
- Analysis of safety features 2D and 3D

Wednesday 16th April 2014:
Webinar 2: Examining unlicensed use and off-label use
- Regulatory considerations
- Relationship with cost considerations
- Scope of the unlicensed supply exemption
- Trends in the EU
- Novartis product ECJ ruling

Wednesday 30th April 2014:
Webinar 3: Orphan drug designation: Regulatory and lifecycle considerations
- Criteria for orphan drug designation
- Procedure for orphan drug designation
- Orphan market exclusivity and SPCs
- Current 'hot topics'
- Pros and cons of orphan drug designation

Hilary Jones, *Senior Corporate Counsel - EU Regulatory Law*, **Pfizer**

Speakers for Webinars 1 and 2 to be confirmed.

Please contact **gemma.burns@informa.com** if you are interested in hosting a webinar.

Please visit www.informa-ls.com/pharmalaw for further information

NEW Flexible Format for 2014: 1 Day Passes Now Available

We know that your time out of the office is very limited so for 2014 we are offering a new flexible format whereby you can choose to attend just 1 day. We recognise that some of you are specialised lawyers and therefore only have an interest in one of the conference days. The 1 day pass will include the main conference day plus the evening seminar and is available for either day 1 or day 2. We also know that many of our regular speakers and attendees see this event as a one-stop-shop for a complete round-up of the most important legal decisions made over the past year within competition law, patent litigation and the regulatory frameworks. Therefore our 2 day conference pass remains available and at the same price since 2011. We hope you will be able to join us in Brussels for Europe's leading pharmaceutical law conference.

Hear what last year's delegates had to say

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Speaking and Commercial Opportunities

Speaking opportunities still available!

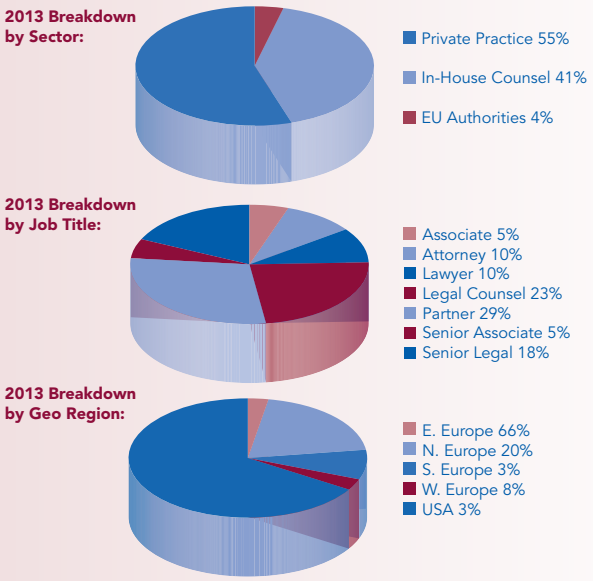
Raise your company profile and align yourself with the top ranked lawyers and law firms by speaking on the main agenda. Speaking, panellist and webinar opportunities are available via commercial opportunities. Join one of the sessions outlined on the agenda, present on one of the topics outlined below or suggest your own topic (subject to approval by Informa).

- **How are HTAs working in practice?**
- **Understanding data protection with regards to personal data/privacy**
- **Paediatric products: Regulatory framework, challenges and opportunities**

Attendee Breakdown 2013:

EU Pharmaceutical Law Attendees

71 companies
100+ attendees
Big name pharma and biotech including Pfizer, J&J, Sanofi, GSK, Novartis and many more



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