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12-13 May 2009
Hotel Bloom, Brussels, Belgium

Bringing together top level legal know-how

Ian Dodds-Smith, **Arnold & Porter LLP**
Marleen Van Kerkhove, **Arnold & Porter LLP**
Sally Shorthose, **Bird & Bird**
Maria Manley, **Bristows**
Nick Beckett, **CMS Cameron McKenna LLP**
Grant Castle, **Covington & Burling LLP**
Peter Bogaert, **Covington & Burling LLP**
Prof. dr. Geert van Calster, **K.U. Leuven and DLA Piper**
Linda Horton, **Hogan & Hartson LLP**
Elisabethann Wright, **Hogan & Hartson LLP**
Tanguy Van Overstraten, **Linklaters**
Gavin Robert, **Linklaters**
Matthijs Visser, **RBB Economics**
Tony Woodgate, **Simmons & Simmons**
Cameron Firth, **S J Berwin LLP**
Ian Forrester QC, **White and Case**
Clare Sellars, **McDermott, Will & Emery LLP**
Hiroshi Sheraton, **McDermott, Will & Emery LLP**

PLUS Pharmaceutical Feedback

Victoria Kitcatt, **Pfizer European Pharmaceutical Operations**
Ray Cresswell, **GlaxoSmithKline**
Yuung Yuung Yap, **Johnson and Johnson**

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The 18th Annual

EU Pharmaceutical Law Forum

Leading legal opinion on the years most high profile cases and regulatory reforms

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A timely agenda covering the most important subjects for legal professionals in the pharmaceutical sector. 6 Key Sessions include:

1. **The EU Pharmaceutical Sector Inquiry** – Hear key findings direct from the EU Commission and assess what it means for the industry and possible follow ups
2. **Trade and Anti-Trust** – Latest information on competition law and IP including analysis of GSK decision in light of Articles 81 and 82
3. **The New Regulatory Pharmaceutical Package –** Detailed explanation of the main components of the new legislative package plus feedback on the potential impact of the new legislation
4. **Implementation of New Regulations** – Practical advice from those with first hand experiences of working with regulations in the areas of: Paediatric Medicines, Advanced Therapies, Combination and Borderline Products and Nanomedical Products PLUS analysis of the future reform of the Clinical Trials Directive
5. **Judicial Review Actions & Health Technology Assessments** – Examination of current and future trends and challenges featuring key cases from across Europe
6. **Pharmaceutical Marketing and Advertising** – Practical advice for companies marketing and promoting pharmaceutical products in Europe

PLUS – Evening Seminar and Networking Dinner • 12 May 2009

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Ensure you have the latest information:

Day 1 - Accurate Facts on Antitrust - Sector Inquiry, Competition Law and IP

Day 2 - Up-to-date Information on Key Regulatory Developments

Conference Day One: 12 May 2009

08.15 Registration and Coffee

09.00 Chairman's Introduction

The EU Pharmaceutical Sector Inquiry

09.10 The EU Pharma Sector Inquiry
- Main findings
- Possible follow-up

A Representative, **European Commission**

09.50 Impact of the Sector Inquiry on Innovator and Generic Pharma
- What does it mean?
- How does it change things? What remains uncertain?
- What implementation is needed, and how long will this take?
- Concrete steps companies need to take - minimising risk

Tony Woodgate, Partner, Life Sciences, **Simmons & Simmons**

10.25 Morning Coffee

11.05 Life-Cycle Management & Settlement Strategies Post Sector Inquiry
- Which types of life cycle practises and circumstances are allowed, which may result in infringement?
- Settlements –how far can companies go (can you have reverse payments, side agreements), examining legal boundaries

Marleen Van Kerkhove, Partner, **Arnold & Porter**

11.40 Panel Session
Discussion on the Wider Implications of the Sector Inquiry
Gavin Robert, Partner, **Linklaters** and speakers from the session

12.00 Lunch

Trade and AntiTrust: Competition Law & IP

13.30 Market Definition and Dominance in Pharmaceutical Markets
- ATC-classification and market definition
- IP rights and dominance
- Ethical and generic products
- The Article 82 guidelines

Matthijs Visser, Partner, **RBB Economics**

14.05 Catch Up On Competition Law from the Past 12 Months
- Astra / Zeneca CFI appeal
- Reverse payment cases
- Other new developments in DG COMP
- Case law developments in Member States

Cameron Firth, Senior Associate, **SJ Berwin LLP**

14.40 Parallel Trade after GSK
- Analysis of the decision in light of Articles 81 and 82
- What impact will this decision have on supply chain management?
- Consequences of the decision for planning a distribution system

Ian Forrester QC, Partner, **White and Case**

15.15 Parallel Trade/IP – Repackaging Decisions and Implications
Nick Beckett, Partner, **CMS Cameron McKenna LLP**

15.50 Afternoon Tea

16.20 The Current European Patent System – A Patentee's Headache?
- A unified and integrated European patent system by 2012: Myth or reality?
- EPLA/Community Patent: The fundamental difficulties
- It's not all gloom: Recent developments

Sally Shorthose, Partner, **Bird & Bird**

16.55 Where do we stand on the Supplementary Protection Certificates front?
- How and when are you entitled to an SPC?
- What conundrums do you need to overcome?
- Duration of SPCs: Is there any space for a zero/negative SPC?
- Latest jurisprudence: Are we at a turning point?
- Commission investigations: How do these affect your SPC strategy?

Maria Manley, Partner, **Bristows**

17.30 End of Day One Networking Drinks

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EVENING SEMINAR AND DINNER

Competition Litigation

From the Opening of the Case in Brussels to Final Judgement in Luxembourg: How to Maximise Your Chances of Success

18.30 Registration 18.45 Start 21.00 Dinner

An interactive discussion of real-world scenarios with experts that will offer practical tips for a successful litigation strategy during the administrative phase before the Commission and on appeal before the EU courts.

- Information requests and access to the file: Can the Commission use information gathered in the sector inquiry? What information do you have to provide and when and how should you object if the Commission denies access to documents in its file?
- How can you rely on the Commission's general transparency rules during administrative investigations?
- What kinds of arguments will help position your case for a possible appeal and how do you present them most effectively?
- How can you use experts and witnesses most effectively?
- Should you request a hearing?
- Strategic litigation: How do you ensure that the court addresses the issues that matter?
- Swift judgment vs extensive review: What are the pros and cons of an expedited procedure?
- When does it make sense to apply for interim measures?

Seminar Leaders;
Georg Berrisch, Covington & Burling
David Hull, Covington & Burling
Pascal Cardonnel, Référendaire, **Court of Justice of the European Communities,** Luxembourg

Conference Day Two: 13 May 2009

08.30 Morning Coffee

08.55 Chairman's Introduction

09.00 Update on the Current Regulatory Framework
Ian Dodds-Smith, Partner, **Arnold & Porter LLP**

The New Regulatory Pharmaceutical Package

09.30 The New Regulatory Pharmaceutical Package
- Overview of the main components of the legislative package
- Counterfeiting-explanation of commission proposal, short overview, examples recently found in Europe
- Information to patients- Status of proposal, timing, if implemented in current forms- What are the pros and cons? In practice what will it allow or restrict companies from doing?
- Pharmacovigilance- Understanding the proposals, relevance, legal angle, financial penalties
- General policy trends

Grant Castle, Partner, **Covington & Burling LLP**
Yuung Yuung Yap Ph.D., Legal Counsel, **Johnson & Johnson Law Department Europe**

10.30 Morning Coffee

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"A very useful and comprehensive update of some of the key legal issues in the pharma industry" (EU Pharmaceutical Law 2008, Senior Legal Counsel, Novartis)

Implementation of New Regulations

11.10 Future Reform of the Clinical Trials Directive
- European Commission-EMEA Conference and Report
- Successes and problem areas
- Proposed reforms within the current legal framework
- Proposed reforms through a revised legal framework
- Transparency: Registration, publication of CT results

Linda Horton, Partner, **Hogan & Hartson LLP**

11.40 Complying with the EU Data Privacy Directive in the Pharmaceutical Sector
- EU data privacy: Legal framework and key concepts
- Anonymisation and pseudonymisation (encoding) of personal (health) data
- Other privacy issues relating to clinical trials
- Transfer of studies data outside the EU: Strategic considerations for international, multi-centre trials
- Data privacy notification and authorisation requirements
- Non-compliance risks

Tanguy Van Overstraeten, Partner, **Linklaters LLP**

12.10 Update on the Paediatric Medicines Regulation
- Experiences to date
- Challenges encountered
- Prospects for obtaining the SPC extensions under the Regulation

Victoria Kitcatt, Assistant General Counsel, European Regulatory Law, **Pfizer European Pharmaceutical Operations**

12.40 Lunch

14.00 The Advanced Therapies Regulation
- Which therapies does the Regulation cover?
- What does the Regulation say?
- The Committee for Advanced Therapies
- Implementation of the Regulation in Directive 2001/83
- Experience to date

Ray Cresswell, Vice President, GSK R&D Legal Operations, **GlaxoSmithKline**

14.30 Legal and Regulatory Requirements for Combination & Borderline Products
- Classification of product types/legal definitions and associated regulations
- EMEA guidelines
- Round up of ECJ decisions
- The regulation of neutraceuticals in the EU
- When in doubt, what criteria can be applied to distinguish between medicinal products and cosmoceuticals

Elisabethann Wright, Counsel, **Hogan & Hartson LLP**

15.00 Regulatory Requirements and Guidelines for Nanomedical Products
- Overall nano-regulatory approach
- Transatlantic convergence?
- Specific requirements for nano in medicinal regulation
- The forest and the trees

Prof. dr. Geert van Calster, K.U. Leuven and DLA Piper

15.30 Afternoon Tea

Judicial Review Actions & Health Technology Assessments in Europe

16.00 Judicial Review of Marketing Authorisations - Key Principles and Challenges
- What are the practices in the Member States and what principles apply before the EC courts? Which parties can challenge a medicine approval?
- What arguments can be used in courts?
- What are the administrative practices for 3rd parties?

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

16.30 Health Technology Assessments - Where Does Europe Stand?
- What is involved in health technology assessments?
- Different approaches to health technology assessments
- Recent legal issues, developments and challenges
- The future of health technology assessments

Clare Sellars, Counsel, **McDermott Will & Emery UK LLP**
Hiroshi Sheraton, Partner, **McDermott Will & Emery UK LLP**

Pharmaceutical Marketing and Advertising

17.00 Marketing and Promotion: Ensuring Compliance
- Basic rules for pharmaceutical advertising: The do's and don'ts
- Promotions to professionals
- Internet advertising: What can be included on a website intended for consumers?
- Overview of different approaches of different jurisdictions in Europe

A Representative, **Novartis Pharmaceuticals UK Limited**

17.30 End of Conference

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