

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

Media Partners



The 18th Annual

EU Pharmaceutical Law Forum

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

www.informa-ls.com/pharmalaw

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

Competition Litigation

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

Sponsors

HOGAN & HARTSON

BIRD & BIRD

Simmons & Simmons



The course is CPD accredited, gaining you formal recognition for your attendance

To Register Please Tel: +44 (0) 20 7017 7481 Fax: +44 (0) 20 7017 7823

Book online: www.informa-ls.com/pharmalaw

Email registrations@informa-ls.com Please Quote CQ5083

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

Sponsored By: **BIRD & BIRD**

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**

Yueng Yueng Yap Ph.D., Legal Counsel, **Johnson & Johnson Law Department Europe**

10.30 Morning Coffee

To Register Please Tel: +44 (0) 20 7017 7481 Fax: +44 (0) 20 7017 7823

Book online www.informa-ls.com/pharmalaw Email registrations@informa-ls.com

Unrivalled networking opportunities

Join over 130 colleagues from across the globe at the meeting place for pharmaceutical legal professionals

"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-EMA 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
- EMA 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 cosmeceuticals

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

Commercial Opportunities: Call for Sponsors and Exhibitors

Now in its 18th year Informa LifeSciences' EU Pharmaceutical Law Forum is the annual meeting place for general counsel in pharmaceutical companies in addition to lawyers in private practice advising the pharmaceutical sector.

1. **Position your company before a global audience.** Last year's event was attended by over 130 senior level professionals from 19 countries (Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, The Netherlands, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, UK and USA)
2. **Access senior level professionals.** Those who attended include: Advocate, Associate, Attorney, Chief Legal Counsel, Chief Legal Officer, Corporate Counsel, Corporate Regulatory Affairs Manager, Director & Senior Counsel, Director of Legal Affairs, European Patent Attorney, General Counsel, Head of Legal Affairs, Head IP, Lawyer, Legal Counsel, Managing Partner, Partner, Regulatory Counsel, Solicitor, & VP from General Counsel in pharmaceutical companies in addition to lawyers in private practice advising the pharmaceutical sector.
3. **Association with Europe's leading Pharmaceutical Law conference.**

Feedback from previous sponsors:

"As sponsors of EU Pharma Law 2008, we were really pleased with the event. It was very well organised, we made some good contacts and are definitely interested in supporting again. Thank you for organising an excellent conference"

Partner in IP/Life Sciences, Bird & Bird

For more information on how your organisation could benefit from this event and to discuss the full range of lead generating, networking and branding opportunities that exist please contact:

Linda Cole on Tel: +44(0) 20 7017 6631
Email: Linda.cole@informa.com

2009 Sponsors

BIRD & BIRD Simmons & Simmons

HOGAN &
HARTSON

To Register Please Tel: +44 (0) 20 7017 7481 Fax: +44 (0) 20 7017 7823

Book online www.informa-ls.com/pharmalaw Email registrations@informa-ls.com

LS/RT/WW/LC/CC/TR

EXCLUSIVE CRA INTERNATIONAL DISCOUNT

CLAIM YOUR 25% DISCOUNT
quoting your VIP CODE

CQ5083CRA

5 Easy ways to Register

- +44(0) 20 7017 7481
- +44 (0) 20 7017 7823
- registrations@informa-ls.com
- www.informa-ls.com/pharmalaw
- The Bookings Department
Informa UK Ltd
P O Box 406
Byfleet
KT14 6WL

Group Bookings: To take advantage of group bookings please contact Simon Lau, Tel: +44(0) 20 7017 7165 email simon.lau@informa.com

Type of pass (2 day, 3 day etc)	Code	Book before Friday 27 Feb 2009	Book between 28 Feb – Friday 10 April 2009	Book after 11 April 2009
Main conference only	CQ5083C	<input type="checkbox"/> £1299 + VAT 21% = £1571.79	<input type="checkbox"/> £1399 + VAT 21% = £1692.79	<input type="checkbox"/> £1499 + VAT 21% = £1813.79
Main Conference and evening symposium and dinner	CQ5083CW	<input type="checkbox"/> £1799 + VAT 21% = £2176.79	<input type="checkbox"/> £1899 + VAT 21% = £2297.79	<input type="checkbox"/> £1999 + VAT 21% = £2418.79

Are we mailing you correctly? To update your contact details on our database please email integrity@informa.com

DELEGATE DETAILS – Please photocopy form for multiple bookings!

(Mr/Mrs/Ms/Miss/Dr) Family Name _____

Forename _____

E-mail _____

Tel _____ Fax _____

Job _____ Title _____

Any special requirements?

To assist us with future correspondence, please supply the following details:

Head of Department: _____

E-mail _____

Tel _____ Fax _____

Approving Manager _____

E-mail _____

Tel _____ Fax _____

Name of Company _____

Department _____

Address _____

_____ City _____

Postcode _____ Country _____

Tel _____ Fax _____

Nature of Company Business _____

No. of employees on your site: 1) 0-49 2) 50-249 3) 250-499 4) 500-999 5) 1000+

PAYMENT INFORMATION

Please invoice

Credit Card. Please debit my:

Card No: _____

CVV Number _____ (this is the 3 digit code on the back of your credit card)

Expiry Date:

Signature:

Credit card billing address:

Contact Number for Card Holder:

Please note that cards will be debited within 7 days of your registration on to the conference

Yes I agree to the terms and conditions as stated on this form.

Delegates who do not pay with their booking are requested to provide a copy of bank transfer / credit card / cheque details to help payment allocation. Staff at the event will request a credit card guarantee for delegates without proof of payment.

Venue Details:

Hotel Bloom!
rue Royale 250, B - 1210 BRUSSELS, BELGIUM
Tel: +32 (0)2 220 66 11 Fax: +32 (0)2 217 8444
info@hotelbloom.com www.hotelbloom.com

Reduced Rate Accommodation:

The cost of the accommodation is not included in the conference fee. Reduced rate accommodation can be obtained by filling in the Reservation Form which you can download from the conference website www.informa-ls.com/pharmalaw and fax it back to the venue +32 2 217 84 44. Please book early to avoid disappointment.

Terms and Conditions

FEE: This includes all technical sessions, lunch and documentation.

CANCELLATIONS: Cancellations received in writing before and on 28 April 2009 will be subject to a service charge of £99. The full conference fees remain payable after 28 April 2009. Substitutions are welcome at any time. It may be necessary for reasons beyond the control of the organiser to alter the content and timing of the programme or the identity of the speakers. In the unfortunate event that an event is cancelled Informa are not liable for any costs incurred by delegates in connection with their attendance. This contract is subject to English Law.

ARE YOU REGISTERED?: You will always receive an acknowledgement of your booking. If you do not receive anything, please call us on +44(0) 20 7017 7481 to make sure we have received your booking.

DATA PROTECTION: The personal information shown on this form, and/or provided by you, will be held on a database and may be shared with other companies in the

Informa Group in the UK and internationally. If you do not wish your details to be available to companies in the Informa Group please contact the Database Manager at the above address, Tel: +44 (0)20 7017 7077, Fax: +44 (0)20 7017 7828 or email: integrity@informa.com

Occasionally your details may be obtained from, or made available to, external companies who wish to communicate with you offers related to your business activities. If you do not wish to receive these offers, please tick the box

INCORRECT MAILING: If you are receiving multiple mailings or you would like us to change any details or remove your name from our database, please contact the Database Manager at the above address, Tel: +44 (0)20 7017 7077, Fax: +44 (0)20 7017 7828 or email: integrity@informa.com - quoting the reference number printed on the mailing label

ANY SPECIAL REQUIREMENTS:
Please inform us if you have any special requirements by calling Customer Services on +44(0) 20 7017 7481.

Conference Documentation: Cannot Attend?

For those busy executives who cannot take full advantage of this event, the papers give you a useful record of the presentations made at the event. The set of speakers papers and/or slides from the conference is available after the event for £299 plus VAT @15% = £343.85.
Contact Customer Services on tel: +44(0) 20 7017 7481, fax: +44 (0) 20 7017 7823 or e-mail: registrations@informa-ls.com