

5th annual

Pharmaceutical Law Summer School 2008

Monday 7th - Tuesday 8th July - Waterloo Campus, King's College London

Gain a firm foundation in pharmaceutical law and practice from the leading experts

During the two days we will focus on the most crucial issues such as **patent protection, trade marks, clinical trials, competition law, marketing, advertising, product liability, licensing contracts and other key regulatory issues.**

Attend to:

- » **Develop** a thorough understanding of the legal issues relevant to the Pharma industry – including trade marks, regulation, clinical trials, competition law, licensing, advertising, marketing, product distribution, product liability, patents and contracts in R&D, arbitration and mediation
- » **Equip** yourself with the knowledge and tools needed to master the key legal challenges in Europe
- » **Assess** key features of the European regulatory framework
- » **Embrace** expert answers to your toughest questions
- » **Take** advantage of networking opportunities to exchange ideas and make valuable business contacts with peers and like-minded experts

Distinguished line-up of speakers include:

Bert Oosting

Partner

Lovells LLP, The Netherlands

Lucinda Osborne

Of Counsel

Covington & Burling LLP, UK

James Killick

Partner

White & Case LLP, UK

Jan Bjerrum Bach

Advokat (L)/Attorney-at-Law

**Jusmedico Advokatanpartsselskab
(Jusmedico Law Firm), Denmark**

Peter Bogaert

Partner

Covington & Burling LLP, Belgium

Rob Clay

Regulatory Therapeutic Area Head,
Worldwide Regulatory Strategy

Pfizer, UK

Tim Frazer

Partner

Arnold & Porter, Belgium & UK

Tom Fox

Associate

Arnold & Porter LLP, UK

Shuna Mason

Solicitor

CMS Cameron McKenna LLP, UK

Carly Mansell

Trade Mark Counsel & Manager,
Corporate Intellectual Property

GlaxoSmithKline, UK

Sophie Lamb

Partner

Bird & Bird, UK

Media Partners



Report Buyer



“Excellent introduction to pharma law challenges, international focus, good interaction” (Jusmedico - Previous Delegate)

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Pharmaceutical Law Summer School 2008

Monday 7th - Tuesday 8th July – King’s College London

Gain a firm foundation in pharmaceutical law and practice from the leading experts

IBC’s Pharma Law Summer School will provide you with a **thorough review of the key legal issues relevant to pharmaceutical industry law**, with practical sessions presented by exclusive speakers from leading law firms and pharmaceutical companies.

During the two days we will focus on the most crucial commercial and regulatory issues to prepare you for the challenges ahead in the pharma industry.

Attend to:

- » Take advantage of this excellent introduction to pharma law and bring practical knowledge and tips back to your office
- » Discuss the state of the industry to prepare yourself for key practical challenges
- » Analyse the most crucial features of the European regulatory framework
- » Assess critical competition rules to drive your business
- » Build up your annual Law Society and Bar Council accreditation
- » Determine the essential ingredients for marketing and product distribution to gain momentum in the industry
- » Get right up-to-date with key developments affecting pharma
- » Meet and network with our leading speaker panel, as well as delegates from a variety of backgrounds and countries
- » Take the comprehensive conference literature back to the office - an invaluable guide long after the conference is over

“The topics addressed are of extreme importance and the lectures were a very positive step towards the global comprehension of law on the pharmaceutical sector”

(Simmons & Simmons - Previous Delegate)

Key areas of focus will be:

- » Patent protection of R&D products
- » Pharmaceutical trade marks
- » Pan-European advice on regulatory matters
- » Clinical trials
- » Contracts in early stage and R&D
- » Arbitration and mediation
- » Advertising and promotion
- » Product liability

Who should attend this summer school?

- ✓ Private practice lawyers
- ✓ Heads of IP
- ✓ Senior managers
- ✓ Licensing directors
- ✓ Business development directors
- ✓ Legal affairs directors
- ✓ R&D directors
- ✓ Technical directors
- ✓ Purchasing officers
- ✓ Legal & general counsel
- ✓ Legal directors/officers/managers
- ✓ Patent & trademark attorneys
- ✓ Corporate counsel
- ✓ Commercial & corporate lawyers
- ✓ Regulatory directors
- ✓ Heads of compliance & legal affairs

Group rates available, for details please email john.mahjoubi@informa.com or call +44 (0)20 7017 5623.

PROMOTIONAL OPPORTUNITIES

For details of the wide range of opportunities available, including insertion of promotional literature in the delegate pack, an onsite exhibition stand, or sponsoring a social function, please contact Kelvin McManus on +44(0)20 7017 4702, Email: kelvin.mcmanus@informa.com

Book on-line: www.ibclegal.com/pharmalawschool

For any queries email john.mahjoubi@informa.com or call +44 (0)20 7017 5623

08.30 Registration and Coffee

09.00 Chairperson's Opening Remarks



Peter Bogaert
Partner
Covington & Burling LLP, Belgium

THE BASICS

09.15 Patent Protection of R&D Products

- » The criteria for patentability and the anatomy of a patent
- » The significance of patents in the industry
- » Pharmaceutical patent life cycles
 - basic product protection
 - protection for new formulations, combinations etc.
 - second medical use claims
 - biotech patents
 - claims for devices
 - delivery systems and kits
 - research tools and reach through claims
- » The extension of patent protection - SPCs, post expiry injunctions etc.
- » Off-patent strategy
- » Enforcement of patents in Europe: forum shopping, dove-tailing evidence, expert witnesses, where does the EPO fit in? An outline of the procedures and costs



Bert Oosting
Partner
Lovells LLP, The Netherlands

TRADE MARKS

10.30 Pharmaceutical Trade Marks

- » The importance of trade marks in the industry
- » Difficulties in clearing global trade marks for pharmaceutical products
- » Types of trade marks applicable to pharma products - names, colours, shapes, packaging
- » Can trade marks be used to prevent parallel imports?



Carly Mansell
Trade Mark Counsel & Manager,
Corporate Intellectual Property
GlaxoSmithKline, UK

11.30 Morning Coffee and Networking Break

REGULATIONS

11.50 Regulatory Matters – A pan-European perspective

- » Key features of the new European regulatory framework
- » Scope
- » Marketing authorisation procedures
- » Data exclusivity
- » Biosimilars
- » Orphan medicines
- » Paediatrics incentives
- » Enforcement and inspection
- » Transparency



Peter Bogaert
Partner
Covington & Burling LLP, Belgium

13.20 Lunch

CLINICAL TRIALS

JOINT PRESENTATION

14.20 Mastering Clinical Trials

- » Legal framework
- » Choosing the right provider for your studies
- » Key challenges
- » How to handle the data conducted during a clinical trial

- » Access to evidence
- » Penalty regulations
- » PR aspects: management & public expectations (regarding data, etc)



Rob Clay
Regulatory Therapeutic Area Head,
Worldwide Regulatory Strategy
Pfizer, UK



Shuna Mason
Solicitor
CMS Cameron McKenna LLP, UK

15.20 Afternoon Tea and Networking Break

COMPETITION LAW

15.40 Competition Law in the Pharmaceutical Sector

- » Introduction to the competition rules
- » Outline of the rules on restrictive practices, abuse of market dominance
- » Identifying relevant markets in the pharmaceutical sector
- » R&D, technology transfer and vertical agreements block exemptions
- » Specific issues: parallel imports – stock allocation systems, tying, IP abuse/regulatory procedure, procedure, sector inquiry



James Killick
Partner
White & Case LLP, UK

EARLY LICENSING

16.40 Contracts and Pharma Law: Early licensing and R&D

- » Key concerns and potential conflicts
- » Financial terms - milestones, royalties and sub licensee revenues
- » The scope of the licence - subject matter, exclusivity, territory, field of use and reservation of rights by the licensee
- » Development plan and milestones - level of commitment, go/no go decision points
- » Patent prosecution, maintenance and infringement actions
- » Rights to sub-license and protections for the sub-licensee
- » Improvements and grant backs
- » Termination and the reversion of rights



Lucinda Osborne
Of Counsel
Covington & Burling LLP, UK

17.35 Chair's Closing Remarks

17.40 Close of the Day

Tuesday, 8th July 2008

08.30 Registration and Coffee

09.00 Chairperson's Opening Remarks



Peter Bogaert
Partner
Covington & Burling LLP, Belgium

ARBITRATION & MEDIATION

9.10 Arbitration and Mediation of Pharmaceutical Disputes

- » Early dispute resolution through negotiation and mediation
- » An introduction to international arbitration and the role of the leading institutions
- » Arbitration of cross-border Pharma disputes: trends and statistics, key features and benefits, case studies
- » Drafting effective dispute resolution clauses for international contracts



Sophie Lamb
Partner
Bird & Bird, UK

10.10 Morning Coffee and Networking Break

ADVERTISING & PROMOTION

10.30 Pharmaceutical Advertising

- » Legislative basis for the advertising of medicinal products in the EEA
- » What is "advertising"
- » Prohibition on "direct to consumer" advertising
- » Advertising to health professionals prior to & after grant of marketing authorisation
- » Gifts and financial incentives, including hospitality and related payments
- » Internet advertising



Jan Bjerrum Bach
Advokat (L)/Attorney-at-Law
Jusmedico Advokatanpartsselskab (Jusmedico Law Firm), Denmark

12.00 Lunch

MARKETING & PRODUCT DISTRIBUTION

13.00 Establishing an Effective Compliance Programme Enhancing Client Awareness of Key Marketing and Competition Pitfalls

- » Marketing authorisations and obligations
- » Scope and length
- » New EU members: keeping to treaties



Tim Frazer
Partner
Arnold & Porter, Belgium & UK

14.30 Afternoon Tea and Networking Break

PRODUCT LIABILITY

14.50 Product Liability

- » Pharmaceutical product liability - now and in the future
- » Impact of the Product Liability Directive and the Consumer Protection Act on healthcare product development
- » The dichotomy between strict liability and regulatory assessment of risk/benefit of pharmaceutical products



Tom Fox
Associate
Arnold & Porter LLP

THE FUTURE OF PHARMA LAW

➔ INTERACTIVE PANEL DISCUSSION

15.30 The Future of Pharmaceutical Law and Regulations

- » What do you have to watch out for?
 - » How will the legal landscape change over the next few years?
- Featuring key speakers of the conference**

15.55 Chair's Closing Remarks

16.00 Close of the Summer School

CONFERENCE DOCUMENTATION IS AVAILABLE

If you can't make it yourself, why not pass the brochure on to a colleague. Don't forget you need not miss out, the full conference notes are available after the event for £225 (£240 overseas). To order copies or for further information, contact: John Mahjoubi on Tel: +44(0)20 7017 5623 or Email: john.mahjoubi@informa.com

Pharmaceutical Law Summer School 2008

7th & 8th July

Waterloo Campus, King's College
Franklin-Wilkins Building
Stamford Street, London SE1 9NH
Telephone: +44 (0)20 7836 5454
www.kcl.ac.uk

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