



Pharmaceutical Law Europe 2005

26th - 27th January 2005, London, UK

Including presentations on key issues like:

- Antitrust compliance in a global context
- The Community patent and Europe wide patent issues
- Avoiding pitfalls in pharmaceutical contracts
- Implementation of legislation in new Member States

Post-conference workshop - 28th January 2005

A Guide to Regulatory Data Protection

Led by:

Stephen Bennett, Senior Associate, **LOVELLS**

Supporting Association:



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Speakers Include:

- Nathalie Joannes, Group General Counsel,
SERONO
- Dr. Arno Hartmann, Corporate Head of Patents
Pharmaceuticals,
MERCK
- Thomas Bols, Director Government Affairs, Europe,
AMGEN
- Emma Stopford, Vice President &
Trade Mark Counsel,
GLAXOSMITHKLINE
- Urs Jaisli, Deputy Director, Corporate Law
Department,
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- Patricia Barclay, General Counsel,
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- Romano F. Subiotta, Partner,
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- Jerry Temko, General Counsel – Europe,
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- Nuria Amarilla, Chief Executive Officer,
**EUROPEAN PHARMACEUTICAL
LAW GROUP**
- Dr. Christoph Rehfuess, Director Intellectual
Property,
MEDIGENE
- Francis Marsland, Legal Director,
BIOGEN IDEC
- Philipp Saame, Senior Counsel,
BAXTER
- Fiona M. Carlin, Partner,
BAKER & MCKENZIE
- Johan Ysewyn, Partner,
LINKLATERS
- Alison Blakey, Patent Counsel and Director of IP,
PROSIDION
- David Hull, Partner,
COVINGTON & BURLING
- Stephen Bennett, Senior Associate,
LOVELLS
- Dr. Dirk Ehle, Counsel,
BAYER HEALTHCARE
- Assoc. Prof. Ludevit Martinec PhD., Director,
**STATE INSTITUTE FOR DRUG CONTROL
(SLOVAK REPUBLIC)**



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Pharmaceutical Law Europe 2005

26th - 27th January 2005, London, UK

Day One: 26th January 2005

08:30 Registration and coffee

09:00 Opening remarks from the Chair:
Jerry Temko, *General Counsel-Europe*,
YAMAOUCHI PHARMACEUTICALS

INTRODUCTORY ADDRESS

09:10 **The European Future Medicines Legislation: One Year On**

- Key features of the legislation
 - An update on the progress of implementation in different national states: where are we up to?
 - Controversial issues
 - Next steps by the European Commission
- Thomas Bols**, *Director Government Affairs, Europe*,
AMGEN

COMPETITION LAW

09:45 **Examining the Antitrust Compliance Program of a Globally Engaged Group**

- Roche's "Behaviour in Business" program
 - How to identify and assess compliance risks
 - Roche guideline on behaviour in competition
 - Roche E-learning program "ROCLID"
 - Document management Policy, including e-mails
 - Performance of antitrust audits
 - What to consider in case of a dawn raid
 - Training of employees
 - Support of top management
- Urs Jaisli**, *Deputy Director, Corporate Law Department*,
F. HOFFMANN-LA ROCHE

10:20 Morning tea and coffee

10:45 **Defining the Pharmaceutical Market and how this Definition Underpins EC Competition Law**

- Why and when is it necessary to define the market?
 - new competition regime and dominance/abuse
 - burden of proof
 - How is it possible to define the market?
 - product, geographic definitions
 - commission notice
 - examples (e.g. the Sanofi / Aventis merger)
 - Utilising therapeutic value to define the market
 - using the ATC3 level
 - examples of drugs with multiple indications
 - Using supply-side and distribution models
 - Substitutability
 - How does a narrower market benefit some companies and not others?
 - Does regulation stifle or encourage competition?
- Francis Marsland**, *Legal Director*, **BIOGEN IDEC**

11:20 **Market Dominance and Market Abuse: Understanding How, When and Why the EC Gets Involved**

- Market dominance and abuse: understanding how, when and why the EC and national authorities get involved
 - The significance of market definition in establishing dominance
 - Common "abuses" in the pharma sector (pricing practices, restricting supply to frustrate parallel trade, refusal to license)
 - The European Commission's review of Article 82 - what are the prospects for "modernisation"?
- Fiona M. Carlin**, *Partner*, **BAKER & MCKENZIE**

11:55 **Knowing about the Increased Powers of the EC: What They Can and Can't Do**

- Revisions in competition law under the new Regulation 1/2003- what the business needs to know

- The increased role of national competition authorities under the new rules
- What EC investigators can search and when
 - the pressure is on
- The ultimate sanction: an increase in fines and penalties - how much could companies effectively be required to pay?

Johan Ysewyn, *Partner*, **LINKLATERS**

12:30 Lunch for delegates and speakers

14:00 **IMS Health v NDC Health: Licensing and Market Abuse Implications**

- Overview of the case and relevant precedent
 - When must a dominant company license its IP rights?
 - What is the relevance to the Microsoft case?
 - Practical implications of the court's judgment
- David Hull**, *Partner*, **COVINGTON & BURLING**

14:35 **Technology Transfer Block Exemption: The Impact of the New Guidelines and How They Relate to Competition Law and Agreements**

- What agreements does it cover?
 - What are the new revisions to the TTBE?
 - Understanding how to define competitors and non-competitors
 - Defining markets and market share: do you have to start from the beginning every time?
 - Ongoing monitoring in a changing world
- Patricia Barclay**, *General Counsel*, **FERRING HOLDING**

CONTRACT LAW

15:10 **Avoiding Common Legal, Licensing and Tax Pitfalls in Pharmaceutical Contracts**

- Formation of contracts and letters of intent - what constitutes an agreement?
 - "Planning for the unplannable" in licensing arrangements - confronting 'doomsday' scenarios
 - Warranties, product liability and indemnification - establishing reasonable and workable boundaries for liability between the parties
 - New developments in EU taxation
- Jerry Temko**, *General Counsel - Europe*,
YAMAOUCHI PHARMACEUTICALS

15:45 Afternoon tea and coffee

16:10 **Recent EU Directives and Their Impact on Contracts of the Pharmaceutical Industry - 2001/20/EC, 2001/83/EC, 2002/98/EC**

- Relevant changes in directives regarding Good Clinical Practice, pharmacovigilance, blood products and their adoptions in Member States
 - Conclusions for the organization within pharmaceutical companies
 - Supply and distribution agreements
 - Clinical trial and development contracts
 - Selected clauses
 - Outlook
- Philipp Saame**, *Senior Counsel*, **BAXTER**

16:45 **Bayer v European Commission (Adalat) and the Definition of an "Agreement"**

- Summary of the factual background of the case
 - Evolution of the definition of an "agreement" - analysis of previous case law
 - Redefining the concept of an "agreement"?
 - Practical implications
- Dr. Dirk Ehle**, *Counsel*, **BAYER HEALTHCARE**

17:20 Closing Remarks from the Chair

17:25 End of Day One

17:30 **Drinks Reception**

Delegates are invited to join the speakers, sponsors & exhibitors at an informal drinks reception.

Day Two: 27th January 2005

08:30 Registration and coffee

09:00 Opening remarks from the Chair:
Thomas Bols, *Director Government Affairs, Europe,*
AMGEN

PATENT AND TRADEMARK PROTECTION

09:10 **The Community Patent: is it a Dying Dream or Can it be Resuscitated?**

- Drawbacks of the European patent system: the Community patent versus national patents
- The cost aspect
- Legal uncertainty due to the lack of a central jurisdiction
- The Community Patent: history and current state of the legislation process
- The Competitiveness Council of Ministers
- Other ways to efficiently obtain patent protection in Europe
- Where do we go from here?

Dr. Christoph Rehfuess, *Director Intellectual Property,*
MEDIGENE

09:45 **How to Enhance the Overall Use of Your IP Portfolio**

- Hidden assets in your IP portfolio
- Life cycle management under difficult economic conditions
- Enhanced exploitation of your IP portfolio
- New opportunities for your company from an IP perspective

Dr. Arno Hartmann, *Corporate Head of Patents*
Pharmaceuticals, **MERCK**

10:20 Morning tea and coffee

10:45 **Data Exclusivity and Regulatory Data Protection: Has it Improved or Not? Comprehending the New Regime of Data Exclusivity and What it Ultimately Means**

- When can data exclusivity affect the bottom line?
- What is the current position for additional data on further indications, revised formulations, further formulation types and variants to API?
- Effect of the decisions in the generics and Cyclosporin cases and AG's opinions in Prozac and Seroxat
- Current regime: Is there any room left for additional periods of exclusivity?
- The new regime: "generic medicinal product" and "global marketing authorisation". How is the generic/innovative balance affected?

Stephen Bennett, *Senior Associate,* **LOVELLS**

11:20 **Supplementary Protection Certificates: Knowing When, How and Why they can be Used**

- Understanding the definition and scope of SPCs
- SPCs as IP rights - utilising them to best effect
- Calculating the period of protection available
- Knowing what patents can provide the basis for SPCs

Alison Blakey, *Patent Counsel and Director of IP,*
PROSIDION

11:55 **The Increase in Counterfeit Medicines - What can be Done to Counteract These and Why is it Vital for the Pharmaceutical Industry?**

- Defining counterfeit medicines and trademark law
- Why are counterfeit medicines harmful and how?
- How can companies monitor their existence?
- How can companies utilise IP law to stop their existence?

Emma Stopford, *Vice President & Trade Mark Counsel,*
GLAXOSMITHKLINE

12:30 Lunch for delegates and speakers

GENERAL LEGAL ISSUES: SARBANES-OXLEY, PARALLEL TRADE, ADVERTISING LAW, EU ENLARGEMENT

14:00 **Sarbanes-Oxley ex-US: the New Challenge in Corporate Governance**

- The Disclosure Committee: its charter
 - How Legal is impacted by SOX 404
 - The cascading certification process
 - The reporting obligation for attorneys under SOX 307
- Nathalie Joannes**, *Group General Counsel,* **SERONO**

14:35 **Educating and Informing your Consumers Without Infringing Appropriate Advertising Laws**

- Knowing what is and what isn't acceptable to advertise
 - What information can be given about the product?
 - Differences between "information" and "advertisement"
 - Knowing what safety claims you can make and why
 - The issue of "comparative advertising"- is it possible?
- Nuria Amarilla**, *Chief Executive Officer,*
EUROPEAN PHARMACEUTICAL LAW GROUP

15:10 Afternoon tea and coffee

15:35 **Overview of the Implementation of EU Recent Day Legislation in New Member States**

- Implementation and practical arrangement of the EU legislation after EU accession
- Transitional arrangements
- The European Clinical Trials Directive - implementation experiences
- Ongoing implementation of the EU new legislation in the new member states

Assoc. Prof. Ludevít Martinec PhD., *Director,*
STATE INSTITUTE FOR DRUG CONTROL
(SLOVAK REPUBLIC)

16:10 **Parallel Trading and Re-Packaging: an Overview of the Issues and how Pharma Companies are Directly and Indirectly Influenced**

- Current state of the ECJ's case law
- Analysis of the application by courts other than the ECJ of the principles established by the ECJ
- Discussion of open issues, including issues currently before the ECJ

Romano F. Subiotto, *Partner,*
CLEARY, GOTTLIEB, STEEN & HAMILTON

16:45 Closing Remarks from the Chair

16:55 Champagne prize draw

17:00 End of conference

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Post-Conference Workshop - Friday 28th January 2005

A Guide to Regulatory Data Protection

Led by: **Stephen Bennett, Senior Associate, LOVELLS**

About the Workshop:

This highly interactive workshop is designed to introduce delegates to the concept of data exclusivity and examine the new regime. This workshop will examine the differences between Europe and the rest of the world, as well as look at what new tests the new regime will introduce. Find out how to best utilise the new data exclusivity regime for best effect in your legal operations.

SESSION ONE:

- Definition of data exclusivity
- How does protection in EU compare with US/Japan?
- When does it give market exclusivity?

SESSION TWO:

- Current legislative framework: an overview
- How does a competitor get to rely on your data?
- "Essentially similar" - how the ECJ has made it broader (Generics, Cyclosporin, Prozac and Seroxat cases)

SESSION THREE:

- New directive = new test: "Generic Medicinal Product"
- Does new regime favour generic or innovator?
- When could extra data get extra data exclusivity?

The workshop will start at 0900 and close at 1300, when lunch will be served for all participants.

About your Workshop Leader

Stephen Bennett is a senior associate in the Life Sciences Practice in Lovells' London office. He specialises in patents, trademarks and confidential information. Stephen has worked extensively on recent innovator/generic patent issues including the UK ZOCOR and FOSAMAX litigation. The focus of his work in the pharmaceutical regulatory area is the interface between intellectual property and the regulatory regime and issues of data exclusivity. Stephen is involved in all aspects of intellectual property from registration, licensing, exploitation and enforcement to IP aspects of business disposals and flotations.

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- **General and Senior Counsels**
- **Heads of legal affairs**
- **Trademark and patent attorneys**
- **Company solicitors**
- **Legal personnel in pharmaceutical and biotech companies**



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Date & Venue

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