

6th Annual in our legal pharmaceutical series

# EUROPEAN PHARMACEUTICAL LAW 2004

Wednesday 21st and  
Thursday 22nd January 2004

## THE MOST UP TO DATE REVIEW OF THE LEADING CASE LAW OF 2003

- The Bayer/Adalat case
- The AstraZeneca case
- Repackaging cases and ECJ decisions  
- Merck Austria, Boehringer Ingelheim,  
Aventis
- Paranova v Lake Medelsverket &  
the Ferring case
- SPCs and the Swiss-Leichtenstein case
- Essential similarity: the Novartis  
pharmaceutical case & the Eli Lilly case

## PLUS....

- ✓ EU Enlargement
- ✓ The pharma law review
- ✓ Changing data protection  
rules
- ✓ Generics, patents and  
competition law
- ✓ Free movement of goods rules
- ✓ Parallel Trade

Pre-conference workshop  
**Data Protection:  
the changing legislation**  
*Led by Lovells*

Equivalent to  
12 CPD points\*

\*based on hours  
of learning



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Altana Pharma AG

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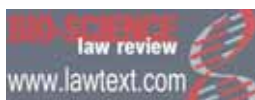
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## Regulators and key industry associations

The State Institute for  
Drug Control, Slovak  
Republic

EGA (European  
Generics Association)

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# What angles might companies pursue fo

## Day one: Wednesday 21st January 2004

09.00 Registration and coffee

09.30 Welcome from Vision in Business

09.35 Opening remarks from the Chair

David Crenshaw, *Legal Director, European Operations*  
Schering-Plough Corporation

09.45 **Forecasting the impact of EU enlargement on innovative drug manufacturers: outlining the threats and opportunities for 2004 and beyond**

- New markets for manufacturers versus the costs of dealing with parallel import
  - Bottom-line implications and the legal challenges
- Outlining what is permissible and not permissible for parallel importers repackaging an original manufacturer's products
- Labelling and packaging strategies to deter parallel traders: clarifying the legal boundaries
- Patent protection and infringement: outlining the advantages and disadvantages of the procedures for the granting of marketing authorisation
  - Mutual recognition procedures
  - Centralised procedures
  - National procedures
- What are the immediate consequences following accession for products that have not been licensed or patented in the new member countries?
  - Clarifying the **Accession Treaty** draft issues
- The suspension of the patent exhaustion rule

Simon Harper, *Legal Counsel Europe*  
Johnson & Johnson

10.30 **EU Accession: Preparing for EU enlargement – CEE regulator's perspective**

- Current status of implementation of the 'acquis communautaire'
- Recent regulatory trends and drug law amendments
- Complying with EU regulations for approval procedures: outlining the systems that are in place to ensure rigorous controls
  - Parallel imports
  - IP protection: loopholes and open issues
  - Data protection and exclusivity
- Current status of the registration procedures
  - The use of **CADREAC** simplified procedures
  - Timing for approval
  - Variations and renewals
- What are the risks and challenges for pharmaceutical companies during the transition period?
- Outlining the key legal and regulatory challenges for manufacturers post accession?
- Will accession improve the availability of medicines
- Assessing the impact of accession on the price of drugs

Dr. Ludevit Martinec, *Director*  
State Institute for Drug Control, The Slovak Republic

11.15 Morning coffee and tea

11.45 **PANEL DISCUSSION**

### EU Enlargement

- The impact of current and future regulatory legislation on accession countries
- The Commission's communication on the application of Community legislation in the context of enlargement (expected in November/December)
- EU accession and data protection: the impact on generics and innovators
- IP protection and data exclusivity: the legal and commercial implications
- Assessing the risks and challenges for pharma manufacturers during the transition period
- Competition, regulation and parallel trade in the post accession period

### Panelists:

Christoph Feddersen, *Partner*, Cleary Gottlieb Stein & Hamilton  
Beata Stepniewska, *EU Accession Manager*, EGA  
Dr. Ludevit Martinec, *Director*, State Institute for Drug Control, The Slovak Republic  
Simon Harper, *Legal Counsel Europe*, Johnson & Johnson

12.45 Lunch for speakers and delegates

14.00 **Assessing the current position regarding the free movement of medicinal products in the context of recent ECJ decisions relating to parallel trade and packaging**

- What strategies can a trade mark or brand owner use to combat parallel trade?
- What is reasonable re-packaging?
- Clarifying the correct balance to be struck between the rights of the trade mark owner and the free movement of goods principle in **Articles 28 and 30 of the EC Treaty**
- The ECJ guidelines for re-packaging, re-labelling and re-affixing of products allowing a trademark owner to oppose re-packaging
- What are the exceptions to the rules?
- Reviewing recent re-packaging cases and ECJ decisions:
  - **Merck Austria**,
  - **Boehringer Ingelheim**
  - **Aventis**
- Clarifying the extent to which manufacturers may rely on trademarks in challenging the parallel import of re-packaged or re-labelled pharma products
- Are parallel importers over-packaging trademark?
- Can innovators find ways of innovative packaging products to prevent parallel trade?
- Assessing the strategic implications for the business model

Duncan Sinclair, *Barrister, EC and Competition Group*  
Simmons & Simmons

14.45 **A pharmaceutical industry perspective: patent developments in the European Union**

- Community Patent regulation: outlining the implications for the industry
  - Why is it important to have a community patent, and why not?
  - The present situation - cross border injunctions: is this a satisfactory way of doing litigation in Europe?
  - What will Community Patent regulations mean for the patent holder?
  - Assessing the risks of invalidation action that is valid for the whole of Europe
- Clinical trials and patent infringement
  - Legal clarification: are clinical trials exempt?
  - What do we mean by clinical trials?
  - Comparison with the US
  - Research exemptions: how to use it in a global organisation

Dr. Filip De Corte, *Senior Director J&J Patent Law Department*  
Head of the Patent Department of Janssen Pharmaceutica NV

15.30 Afternoon tea and coffee

15.45 **SPCs: The Swiss-Liechtenstein issue and its implications for pharmaceutical companies in Europe**

- SPCs in the Community, EEA and Switzerland: reviewing how the system works
- What is the significance of first marketing authorisation for SPCs and why?
- Economic and legal implications of prior marketing authorisations in Switzerland
- The pending cases before the Court of Justice – status, trends and the likely outcome
- How can pharmaceutical companies 're-start' the clock?
- What to do with yesterday's, today's and tomorrow's SPCs?  
An assessment of the legal and strategic ramifications

Christoph Feddersen, *Partner*  
Cleary, Gottlieb, Steen & Hamilton

16.00 **Parallel Trade: the role of IPRs and EU competition law and policy in the regulation of parallel imports in Europe**

- Competition Law and intellectual property law: harmonisation or conflict between national IPRs and EU principles?
  - The role of the ECJ in balancing competing interests
- **Paranova v Lake Medelsverket** and the **Ferring case**: Intellectual property and the cessation/revocation of parallel import licenses
- Parallel distribution of centralised marketing authorisations
  - EMEA-policy

Bert Oosting, *Partner, Head of Pharma*  
Lovells, Netherlands

16.45 Chairman's closing remarks

17.00 End of day one

# Following the outcomes of recent case law

Dinner for speakers and delegates Invitation to Vision in Business dinner  
Make the most of your time in Brussels by joining us as a guest of Vision in Business for a delicious dinner. Over fine Belgium cuisine, network with fellow delegates and speakers, consolidate your business relationships and make new contacts in this formal environment.  
Just tick the box on the booking form and we will reserve you a place.

## Day two: Thursday 22nd January 2004

### 09.15 Chair's opening remarks

**Christina Ackermann**, *Head of Legal, Technical & Ophthalmics*  
Novartis

### 09.30 The innovative drug manufacturer's perspective

**The EU Pharma Law review on regulatory data protection: Will the changes to the pharmaceutical legislation stimulate innovation and research in the pharmaceutical industry?**

- Data exclusivity & generics. Who will benefit from the new provisions?
- Protection of data supporting new indications. Will the changes of the legislation stimulate and reward research and development into existing molecules?
- Exclusivity for data generated in support of an OTC switch. A motivation to switch an existing active ingredient from Rx to OTC?

**Heinrich Schneider**, *Head of Regulatory Affairs Worldwide*  
Roche Consumer Health

### 10.15 PANEL DISCUSSION

**The Pharma Law Review**

- How are the changing rules regarding data protection impacting licensing decisions
  - Moving towards a standardised rule on data protection for a 10 year period
  - What effect will this have on the innovative pharmaceutical industry?
- The implications for generic companies
- Reviewing the impact and interpretation of the **Bolar-type provision**
- Harmonisation of SmPcs and the use of patents
- The impact of enlarging the scope of centralised procedures versus national authorisations
- Data transfer issues: Coping with inconsistencies in EU and US laws for a global player
- What are the implications on patent protection rules?
- The wider commercial and strategic implications of the changing laws

**Panelists include:**

**Suzette Kox**, *Senior Scientific and Regulatory Affairs Director, EGA*  
**David Crenshaw**, *Legal Director, European Operations*  
Schering Plough Corporation  
**Trevor Cook**, *Partner & Joint Head of the Life Sciences Group,*  
Bird and Bird

11.00 Morning coffee and tea

### 11.30 Parallel imports, stock allocations and quota systems: the implications of Bayer / Adalat case

- Assessing why the CFI (Court of First Instance) overturned the Commission's decision
- What angles may companies be able to pursue following the outcomes of the Bayer case
- Looking ahead: the implications of the impending Court of Justice judgement
- When does an agreement exist between the manufacturer and its wholesalers?
- The strategic implications for the manufacturers in combating parallel trade without contravening EU law
- Defining when intra-group stock allocation arrangements are lawful
- How far can companies go in using volume-based and selective pricing strategies to stop parallel imports?
  - Monitoring the sale of products
  - **The Nintendo decision**
  - **"Dual Pricing"**
  - Limiting the number of distributors and volumes

**Romano Subiotto**, *Partner*  
Clear, Gottlieb, Steen & Hamilton

### 12.15 IP and Patent Law: following the latest European developments impacting the pharmaceutical and biotech industries

- Reviewing the impact of technology transfer block exemption proposals and consequences of the 'modernisation' proposals with regard to the enforcement of EU competition rules

### • How imminent is **Community Patent Regulation**?

- Outlining the implications of centralised proceedings to halt infringement
- How will pharma patent law operate in the future?
- Outlining the pros and cons
- Should clinical trials be exempt from patent infringement?
  - The current position
  - Is a 'Bolar-type' provision the future for Europe?
- **The Biotech Directive:** the implications for the industry
  - Are genes patentable?
  - Outlining the progress on implementation and recent developments

**Dr. Penny Gilbert**, *Partner BioPharma Group*  
Bristows, London

13.00 Lunch for speakers and delegates

### 14.00 Harmonisation, rationalisation & latest developments in national pricing and reimbursement systems

- Is convergence of national systems a prerequisite for an effective single market?
  - What are the options for convergence?
- Regionalisation: assessing the trend towards decentralisation and greater regional power
- How to balance the apparent divergent trends of European harmonisation and the devolution of national systems to regional authorities
  - Regionalisation versus harmonisation
- **The Finish judgement:** outlining criteria for reimbursement
  - what is objective and verifiable criteria?

**Janice Haigh**, *Consultant, IMS Health*

### 14.45 The Clinical Trials Directive: implementing the new responsibilities and procedures to ensure compliance whilst minimising time to market

- Outlining the challenges in submitting applications to ethics committees under the new directive
- What is the impact on timelines: will this mean greater delays?
- What are the increased responsibilities of the key players? Defining the legal requirements, implications, obligations and liability risks for sponsors
  - Legal
  - Regulatory
  - GMP (Good Manufacturing Practice)
- Adhering to GCP (Good Clinical Practice) and preparing for inspections
- Assessing the effect on on-going trials and should preparations be made for retrospective compliance?
- Implementation of **EUDRACT** and managing intellectual property and data protection
- Does the implementation of the **Clinical Trials Directive** across the EU meet expectations?
- European harmonisation of the control of clinical trials?

**Mohamed Baccouche**, *Senior Director, Information & Worldwide Regulatory Affairs*  
Altana Pharma AG

### 15.30 Generics, patents and competition law: identifying the pitfalls and potential abuses of behaviour in the legal system

- **The AstraZeneca case:** the alleged misuse of governmental authorisation
  - What means can patent holders use to prevent or delay generic substitution?
  - At what speed can generics access a market?
- Assessing the implications of the current trend in the interpretation of the abridged procedure for the granting of marketing authorisations
- Regulatory data protection issues: to what extent can an applicant for a marketing authorisation make use of existing data – the aftermath of the **Generics Case**

**Trevor Cook**, *Partner & Joint Head of the Life Sciences Group,*  
Bird and Bird

16.15 Closing remarks from the chair and champagne draw

16.30 End of conference

# Pre-Conference Workshop

Tuesday 20th January 2004

## Data Protection: the changing legislation

### OVERVIEW

Pharmaceutical companies are forced to work in a highly regulated environment in which legislative changes keep coming up.

This workshop is aimed at people that work with or in pharmaceutical companies and/or regulatory bodies and therefore have to be prepared for this constantly changing environment. Lovells brings solutions from their extensive industry experience on how a good preparation can result in better patent and data protection etc.

Registration for the workshop is at 09.00, and the workshop will run from 09.30-16.30, lunch and breaks included.

### INTRODUCTION

#### Session 1.

##### Regulatory context and the upcoming changes

- What are the difficulties of the current provisions and case law?
- Do we now have clarity on essential similarity issues?
- Do the proposed changes solve the difficulties?
- How to deal with difficulties?
- What are the new implications and challenges for the industry?
- How to deal with the upcoming enlargement of the EU?

#### Session 2.

##### Impact of the current review of the data protection legislation

- What are the difficulties of the current provisions?
- What are the new proposals and how do you implement these?
- How to deal with new therapeutic indications?
- What is the impact of these new proposals for your clinical trials?
- What can we learn from some case studies?

#### Session 3.

##### Harmonisation of SmPC's and second medical use patents

- What is the regulatory background of harmonisation of SmPC's?

- What are the practical complications?
- How to deal with new therapeutic indications that are subject to an extended data protection period?
- How to use your patent rights in relation to second medical use?
- What is the impact of second medical use patents on harmonisation of SmPC's?

#### Session 4.

##### Data protection and clinical trials

- What is the impact of data protection on clinical trials?
- What are the potential effects on the EU market for pharmaceuticals of the enlargement of the EU?
- How can the industry prepare for and deal with this?
- How can the industry make data processing legitimate?

### 5 Closing remarks

*All sessions are designed to focus on addressing real industry issues and bringing solutions from the experience of both Lovells and the audience. The issues will focus on the impact of changing regulations on data protection and intellectual property rights and the impacts thereof on the industry. By attending the workshops people working in the pharmaceutical industry will be better prepared for the challenges of the upcoming legal changes and challenges.*

### About your workshop leader

**Bert Oosting** heads the Intellectual Property and Information Technology group as well as the pharmaceutical group of the Amsterdam office of Lovells. His practice encompasses all areas of Patent Law, as well as Pharmaceutical law. He regularly lectures on these areas of law and has many published articles. Some of the reported cases in which Mr Oosting has acted include: Merck v Monsanto, Lilly ICOS v Pfizer, Glaxowellcome v Roche, Centocor v Serono and Sanofi-Synthelabo/BMS v Astra Zeneca.

# LESSONS FROM 2003 AND LOOKING AHEAD TO 2004

## WHY ATTEND THE PHARMA LAW FORUM?

The pharmaceutical industry is one of the most heavily regulated in the commercial sector. Moreover, the correlation between legal issues and the financial health of a company is much more direct than in most industries. If legal advice, whether in-house or external, is not up to date and accurate it can cost the company enormous amounts of money and cause considerable damage to the share price.

Attend the leading pharma law one-stop shop to ensure you are best placed to tackle the key legal challenges for 2004. As a result of in-depth research carried out by Vision in Business, a conference programme has been produced tackling all the most important business critical recent case law. Find out WHAT ANGLES COMPANIES MIGHT PURSUE FOLLOWING THE OUTCOMES OF:

- |  |   |
|--|---|
| ✓ The Bayer/Adalat case                        | ✓ Paranova v Lake Medelsverket & the Ferring case       |
| ✓ The AstraZeneca case                         | ✓ SPCs and the Swiss Leichtenstein case                 |
| ✓ Merck Austria, Boehringer Ingelheim, Aventis | ✓ The Novartis pharmaceutical case & the Eli Lilly case |

## 8 Reasons why you must attend:

- 1) Hear from leading pharma manufacturers about implications, obligations and liability risks of the changing rules
- 2) Get the equivalent of 12 hours of expert advice from the leading pharmaceutical lawyers in Europe – WHAT WOULD THIS COST YOU IN LEGAL FEES?
- 3) Discover how **J & J** are tackling the threats and opportunities presented by the EU enlargement
- 4) Hear **Roche** Consumer Health's perspective on the pharma law review
- 5) Learn how to combat tactics used by parallel importers
- 6) Gain an insight into how the latest developments in IP and Patent law are impacting the pharmaceutical industry
- 7) Identify the pitfalls and potential abuses of behaviour in the legal system: generics, patents and competition law
- 8) Where else can you get a comprehensive understanding of all the implications for your business of recent case law in just 2 days?

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The international review **Pharmaceuticals policy and law** studies and evaluates the legal status of medicinal products in the EU, and its implications in other markets. The journal intends to participate in the process of world convergence of pharmaceutical legislation helped by a network of academic centers specializing in pharmaceutical law, without omitting a scientific, economic and social approach to medicinal products.

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Yes, I would like to register for:

- The 2-day conference **Pharma Law** Ref: 12391
- Pre-conference workshop **Data Protection** Ref: 12391A
- The 2-day conference plus the pre-conference workshop **Data Protection** – including a €140 discount Ref: 12391B
- Hard copy of the documentation – at €50 (for conference delegates) Ref: 12391C
- I cannot attend the conference but would like to receive the documentation – at €490 Ref: 12391D
- YES, I would like to attend the complementary conference dinner on Wednesday 21 January 2004

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### Date & Venue

The 2-day conference will take place on 21st and 22 January 2004. The pre-conference workshop will take place on 20th January, and the post-conference workshop 23rd January. The venue for all 4 days will be in a centrally located hotel in Brussels, venue to be confirmed on registration.

### Fee

The fee for the 2-day conference is €1699 + TVA where applicable (€2055.79). The cost of the pre-conference workshop is €999 +TVA where applicable (€1208.79). The cost for attending the 2 day conference and workshop is €2558 +TVA where applicable (€3095.18) a saving of €140. Morning and afternoon refreshments, lunch, conference dinner and online documentation are included in the price.

**Fees must be paid in advance.**

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### Hotel

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