

2nd Annual Congress:

Legal Strategies for Developing Generic Medicines

Hear how the patent, litigation and regulatory landscape will affect your business

Monday 9th July – Wednesday 11th July 2007. Crowne Plaza Hotel, Amsterdam City Centre, The Netherlands

Key speakers include:

- **Howard Rosenberg**, *Patents Director, Merck Generics*
- **Hugh Bigwood**, *Executive Director, Legal, Barr-PLIVA*
- **Bill Haddad**, *CEO/Chairman, Biogenerics Inc*
- **Dr Thomas Bräuner**, *Head of Regulatory Affairs, Ratiopharm GmbH*
- **Alan Shephard**, *Executive Vice-President, Europe Generics, Dr. Reddy's Laboratories (UK) Limited*
- **Dr Stephen Cherkez**, *VP Product Development and IP, Perrigo Israel*
- **Marjan Noor**, *Partner, Taylor Wessing*
- **Neil Jenkins**, *Partner, Bird & Bird*
- **Sally Shorthose**, *Partner, Bird & Bird*
- **Simon Cohen**, *Partner, Taylor Wessing*
- **Kristoff Roox**, *Partner, Crowell & Mooring*
- **Klaas Bisschop**, *Partner, Lovells*
- **Bert Oostings**, *Partner, Lovells*
- **Chris Thornham**, *Lawyer, Patent & Pharmaceuticals Group, SJ Berwin LLP*

At this event you will:

- Discuss the implications of the most recent updates in European Pharmaceutical Legislation and regulatory procedures, including an overview of some of the new EU Member States
- Learn from case-study presentations of recent law court proceedings in pharmaceutical patent litigation
- Receive advice from experts in the generics industry on strategies to overcome evergreening and thoughts on authorised generics and reverse payments in Europe and the US
- Meet delegates in patent and IP departments from generics companies from all across Europe and the CEE

Pre-conference Workshop: Monday 9th July
**Selecting a Reference Member State
for your Generics Application**

Evening Briefing: Tuesday 10th July 2007
Introduction to EU Pharmaceutical Law

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2nd Annual Congress: Legal Strategies

Monday 9th July 2007: Pre-Conference Workshop CQ2145W

Selecting a Reference Member State for your Generics Application

Registration commences at 09:30 for a 10:00 start; this workshop will end at 17:00. Includes refreshments, lunch and documentation.

Are you new to the European Generics market and want a brief introduction to the current legislative procedures that apply to your generics company when trading in this market?

How can you streamline your registration process to successfully compete with your competitors and how different are regulatory procedures in Europe? Learn the best routes to authorisation in a selection of Member States from the UK and Germany to Slovenia and Romania. Share your experiences of the different legal and regulatory frameworks and gain strategic information about making applications with the different regulatory agencies.

Introduction to generic applications in EU Member states

- Purposes of regulatory agencies
- EU institutions and legislation
- The different regulatory procedures that are now available to generic applications:
 - Centralised procedure
 - Decentralised procedure
 - Mutual recognition procedure

What factors will affect your choice?

- Advantages and disadvantages of applying
- Ease of use of procedures
- Timing
- Pitfalls

- Whether the law has been implemented in a Member State
- European Reference Product
- Law systems and policy stability

Hear a focus on UK, Germany, Denmark and more.

Perspective from Accession States:

How do new Member States compare to the rest of Europe? Focussing on Romania and Bulgaria

- Romanian pharmaceutical market evolution
- Products registered: original vs. generics, Rx vs. OTC, hospital products vs. retail
- Numbers of MA holders - players in the market
- Regulations regarding the dossiers registration
- Generic market opportunities.
- How does Bulgaria compare?

The Regulator's Perspective: Slovenia

Afternoon discussion session: How can you streamline your registration processes?

Workshop leaders include:

Simona Basturesco, CEO, Grannus Generics, Romania
Dr Vesna Koblar, Counsellor to the Government, Agency for Medicinal Products and Medical Devices, Slovenia

Tuesday 10th July: Evening Briefing CQ2145X

Introduction to European Pharmaceutical Law

Innovation, obviousness, prior art and inequitable conduct as illustrated by recent generic litigations

This informal dinner briefing will commence at 18:00 and finish at 21:00. Includes dinner and documentation

Briefing led by: **Malcolm Ross, Managing Director, Generapharm (Training and Consultancy)**

This informal one-stop-shop will give a comprehensive overview of the current legal climate surrounding the European Pharmaceutical industry from a generics perspective. Delegates in recent and candidate EU Member States looking for an introduction to European Pharmaceutical law will have the opportunity to hear about different patent laws, infringement issues, methods of litigation, impact of the WTO TRIPS agreement, and the relevance of the Enforcement Directive 2004/48/EC, Directive 2004/27/EC, Directive 2001/20/EC and Regulation (EC) 726/2004.

About your briefing leader: Malcolm Ross holds a B.Pharm and Ph.D from London University, was a lecturer in Pharmacology at the Welsh School of Pharmacy and a Senior Lecturer in the Dept. of Chemistry at Bar Ilan University. Before establishing Generapharm he was working in the CEE and has been involved with the introduction of Project Management systems and cultural issues related to change management and strategy. Malcolm is a frequent speaker at international conferences.

Who will you meet at this conference?

From Generics and Biogenics:

- IP Specialist
- Patent Lawyer/Counsel
- Patent Attorney
- In-house Counsel
- Product Development Director
- Head of Regulatory Affairs
- Head of Product Intelligence
- Head of R&D

From Private Practice:

- Patent Lawyer
- Patent Attorney
- IP Lawyer

"A very good overview of some of the hottest topics..."

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Conference Day 1 – Tuesday 10th July 2007

08:30 Coffee and Registration

09:00 Opening remarks from the Chairperson

Regulatory Issues in Europe

09:10 Keynote: Developments in European Pharmaceutical Legislation
The new European Pharmaceutical Legislation has been designed to speed up access to medicines across Europe. This talk will discuss the impact the revised legislation will have on the submission of your generics application.

- 1-year update and overview on the current state of implementation
- Fundamental aspects of EU Directive 2004/27 focusing on the generic industry
- The Roche-Bolar provision and its relevance to your generics' development strategy

Dr Thomas Bräuner, Head of Regulatory Affairs, Ratiopharm GmbH

09:50 Implementing the Roche-Bolar Provision across the EU
EU directives 2001/82/EC Articles 13(1) to 13(7) and 2001/83/EC Articles 10(1) to 10(5) aim to harmonise European patent infringement law in respect of clinical trials, via the introduction of a Bolar-like exemption. Differences in the implementation of the Bolar exemption by Member States and Accession States and differences in national law defences to patent infringement mean disparities in the 'safe harbour' for prior work to patent expiry. This talk will cover the following:

- Update of the legal aspects of this provision
- How has this been applied across EU countries and where is it yet to be applied?
- How can new EU countries apply this provision to come in line with European procedure?
- What impact does this have on the industry in terms of speeding up the development of generic drugs?

Neil Jenkins, Partner, Bird & Bird

10:30 Morning Coffee

11:00 New European paediatric provisions/legislations: European Regulation (EC) No 1901/2006
Since 26th January 2007, the new European paediatric legislation allows patent extension for the development of an existing drug for use in children.

- How long can originator patents be extended for?
- How are the originators protected?
- What does this mean for data exclusivity?
- What strategies can you implement to ensure profitability in this new environment?

Sally Shorthose, Partner, Bird & Bird

The United States Perspective

11:40 US pharmaceutical regulatory and legal procedures: an overview
The US regulatory and legal framework is very different to that of Europe. When preparing to enter the US market what steps will you have to take to ensure the approval of your generic product?

- What are the differences between EU/US regulatory laws?
- The notion of discovery and civil litigation in the US
- 180-day exclusivity and implications of the Hatch-Waxman Act
- P4 patent litigation in the US

Kevin Murphey, Partner, Frommer Lawrence & Huag LLP

Success with Biosimilars

12:20 The regulatory framework for biosimilars
Biosimilars are an expensive option for generics companies, however, as shown by Omnitrope, they are a possibility. How can you get around the regulatory hurdles to ensure success

- What are the patent issues in Europe and how do they apply to biosimilar development?
- What are the regime essentials and new guidelines for quality, nonclinical and clinical issues and specific products?
- Where are we in terms of regulatory framework?
- What is happening in the USA with a proposed regulatory mechanism?
- What will the biosimilar marketplace look like?

Peter Wittner, Director, Interpharm Consultancy

13:00 Lunch

14:00 Case-study of biosimilar products in Europe
From concept-to-approval of a new biosimilar product, what are the cost-effective and time-saving strategies you can implement to succeed?

- Benefits and pitfalls of branching into the biosimilar market
- Lessons learnt from the past
- The Omnitrope story and how this can be translated to other products
- Legal strategies employed to achieve success
- The future prospects of biosimilars for generics companies

Bill Haddad, CEO/Chairman, Biogenics Inc

Patent Issues

14:40 Supplementary Protection Certificates
Protecting originator intellectual property rights for 5–15 years after initial patent expiry can certainly affect your plans for launch. What is the current legislative climate for accession countries? The following topics will be covered:

- Requirements for protection
- SPCs for line extensions: A review of recent cases
- Predicting how courts will tackle infringement issues
- Accession countries and SPCs
- Effect of new paediatric regulations

Marjan Noor, Partner, Taylor Wessing

15:20 Afternoon Refreshments

15:50 Strategies for Generic Patent Filings
As your generic company increases in size and accumulates a greater market share, the need to patent your own formulations and processes becomes vital to protect your own intellectual property. This speaker will cover the following:

- Trends in generic patent filings
- Freedom-to-operate vs. competitor blocking
- Patents as a marketing tool
- Ethical life-cycle extension strategies
- API filing strategies
- Pharma filing strategies

Dr Stephen Cherkez, VP Product Development and IP, Perrigo Israel

16:30 Panel Discussion: Dealing with originator strategies to extend their product life-cycles

Both SPCs and Evergreening legislation allow originators to protect their intellectual property rights thus hampering the launch of your generic product. Should you choose between waiting for all the patents to expire or apply for marketing authorisation and run the risk of litigation and the associated costs and delays? This panel discussion will provide expert insight into such issues with ideas for directing your legal strategy to deal with such legislation.

The following points will be covered:

- Reformulation innovations – finding the ones that fall short of being improved
- The risks and pitfalls of next-generation product development
- Oral and injectable innovative delivery
- New combinations to treat two concomitant conditions with one therapy
- What does the stockpiling of patent protections mean for the generic market in Central & Eastern Europe?

Today's speakers will be joined by:

Howard Rosenberg, Patents Director, Merck Generics
Alan Shephard, Executive Vice-President, Europe Generics,
Dr. Reddy's Laboratories (UK) Ltd

17:00 Closing remarks from the Chairperson

17:10 End of conference day one

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Conference Day 2 – Wednesday 11th July 2007

08:30 Coffee and Registration

09:00 Opening remarks from the Chairperson
Howard Rosenberg, Patents Director, Merck Generics

The Current Litigation Landscape

09:10 **Pharmaceutical patent litigation: an overview**

A number of developments have come to light over the past few months, including ongoing litigation battles between originator and generic companies. In identifying the implications of the current legal situation, the following topics and cases will be covered:

- Implications of Directive 2004/48/EC for the enforcement of intellectual property rights
- Alendronate-litigation: MSD vs several generic companies
- Pfizer vs Ranbaxy (Lipitor)
- Safe launch strategies to avoid patent litigation

Kristoff Roox, Partner, Crowell & Mooring

09:50 **Launch strategies and European development**

This talk will focus on the patent considerations before a generic drug launch.

- Regulatory and patent considerations
- Patent (non)infringement and (in)validity analyses
- Interim injunctions and "clearing the way"
- Launch strategies and authorised generics

Chris Thornham, Lawyer, Patent & Pharmaceuticals Group, SJ Berwin LLP

10:30 Morning Coffee

11:00 **A practical guide to legal proceedings**

This talk will focus on both identifying the opportunity of an out-of-court settlement and avoiding an appeals case in the European courts.

- Developments with European Patent Litigation and at the European Patent Office
- Evaluating your patent position and ensuring a trouble-free launch
- Putting together a petition to challenge the patent and defending an infringement action
- Handling the appeals procedure

A joint presentation by:

Simon Cohen, Partner, Taylor Wessing
Nigel Stoate, Partner, Taylor Wessing

Authorised Generics: Is There a Future?

11:40 **Panel Discussion: Authorised Generics & 'reverse payments' in the US and Europe**

In the opportunistic yet highly competitive generics market, there are opportunities to partner with originator companies to produce authorised generics. Some originator companies have also begun selling generic versions of their own products to both maintain and expand their market share. However, this is an area of contention and some generics companies refuse to enter into such partnerships. Hear expert opinions on the following:

- How do you identify these opportunities?
- Cutting deals and making a profit
- Interim injunctions and cross-undertakings
- Clearing the way before a generic launch

Today's speakers will be joined by

Bill Haddad, CEO/Chairman, Biogenetics Inc

Bert Oostings, Partner, Lovells

Hugh Bigwood, Executive Director, Legal, Barr-PLIVA

Kevin Murphey, Partner, Frommer Lawrence & Huag LLP

12:10 Lunch

14:00 **Spotlight session**

For details on presenting to this audience, please contact Linda Cole: linda.cole@informa.com; Tel: +44 (0)20 7017 6631



Combating Global Competition

14:30 **Indian patent issues and TRIPS compliance**

Indian generics companies have grown from strength-to-strength and are now a major global competitor for both generic and originator companies. How are Indian patent laws different and what impact does this have on your current market share and possible expansion strategies?

- Differences between EU and Indian patent laws
- GSK vs Ranbaxy
- Novartis vs Indian Government (Gleevac) and future implications for the cost of drugs in less-economically developed countries
- Product infringement issues and how to avoid it
- Legal strategies to maintain a market share in this increasingly competitive environment

Speaker to be announced.

For more details please visit www.informa-ls.com/legalgenerics

15:10 Afternoon Refreshments

EU Competition Law Update

15:30 **Competition laws affecting pharmaceutical companies**

Focussing on the current competition law issues affecting pharmaceutical companies across Europe, this talk will examine the following:

- Overview of key legal provisions
- GSK and dual-pricing in Spain
- Authorised generics and litigation/settlement agreements
- Stock allocation schemes and the on-going Glaxo litigation
- AstraZeneca and abuse of patent and regulatory procedures

Cameron Firth, Lawyer, SJ Berwin LLP

16:10 **Update on parallel importing and repacking**

The ever-present issue of parallel importing is stealing a significant percentage of generic companies' market share, however there is little that can be done to curb the importers' enthusiasm. In identifying the legal strategies to combat the parallel importers and successfully compete in the European market, this talk will focus on:

- Legal updates and implications of Article 7(2) of Trade Marks Directive for generics companies
- How does the TRIPS Agreement affect this issue?
- Stopping the parallel importers and imposing pricing quotas
- Overview of Boehringer Ingelheim & others vs Swingward & others

Klaas Bisschop, Advocate, Lovells

16:50 Closing remarks from the Chairperson

Howard Rosenberg, Patents Director, Merck Generics

17:00 End of conference

The Venue: Amsterdam

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Informa Life Sciences 2nd Annual Congress on the Legal Strategies for Developing Generic Medicines offers you the unrivalled opportunity to hear how the latest updates in the European Pharmaceutical Legislation and issues in patent litigation will affect your generics business.

On average, legal proceedings cost a generics company 70% of their annual budget. With the constantly growing European market, and approximately US \$12 billion of branded medications due to come off patent in 2008, now is the most important time to hear how you can get your new generic to the market quicker, avoid infringement issues, lower your legal costs and still increase your market share.

By attending, not only will you have the opportunity to hear focussed presentations with case-study examples given by legal experts from across Europe and the US, you will also hear first-hand accounts from speakers within the generics industry as they discuss their strategies and give expert advice. Generics companies include **Merck Generics, Barr-Pliva, Ratiopharm GmbH and Dr. Reddy's Laboratories.**

What legal strategies should you implement in developing your generic product for the European and US markets? how do you overcome originator product life-cycle extension strategies? How do you protect your own intellectual property? These questions and more will be answered in this comprehensive 2-day congress.

What if you don't have a legal background or are new to the European generics market? Then attend our pre-conference symposium where you will hear how to launch your generic product in a range of EU Member States. Our unmissable informal evening briefing will give you a valuable introduction to European pharmaceutical law.

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Plus, don't miss out on our pre-conference symposium and evening briefing where you will gain a valuable insight into the legal procedures when registering your generics product, and an overview of European Pharmaceutical Law

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