



INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY

Topics to be covered at this event:

- Update on European Case Law
- Key US Decisions
- Implications of the European Sector Inquiry
- Effective European Patent Litigation
- Intersection of IP and Regulatory Law
- Developments in Supplementary Protection Certificates
- The Safe Harbor Provision in the U.S

Chairman:

Kevin Mooney Simmons and Simmons (UK)

Speakers:

Michael Best Lederer Keller (Germany)

Joachim Feldges Howreys (Germany)

Cameron Firth SJ Berwin LLP (UK)

Kirk Gallagher D Young and Co (UK)

Paul Inman Howreys (UK)

Lori-Ann Johnson Finnegan, Henderson, Farabow, Garrett & Dunner (Belgium)

David Rosenberg GlaxoSmithKline (UK)*

Tony Rollins Merck Sharp & Dohme Ltd (UK)

Chris Thornham SJ Berwin LLP (UK)

Anthony Tridico Finnegan, Henderson, Farabow, Garrett & Dunner (USA)

Mark van Gardingen Brinkhof (Netherlands)

Tony Woodgate Simmons and Simmons (UK)

*Speaker to be confirmed

Register on-line at www.management-forum.co.uk
or telephone +44 (0) 1483 730071

WHY SHOULD YOU ATTEND?

Obtain key information from top class speakers from private practice and industry –

- Hear case law updates from Europe and the US
- Learn about the implications of the EU sector inquiry for your company
- Improve your European Patent Litigation strategy
- Gain an industry perspective on litigation
- Compare experiences with delegates from across Europe

WHO SHOULD ATTEND?

- Patent Attorneys (both in private practice and in industry)
- Patent Lawyers
- IP Managers
- Lawyers
- Others wishing to improve their knowledge of this area

CHAIRMAN

Kevin Mooney specialises in contentious and non-contentious intellectual property matters, focusing specifically on patent litigation, especially in the pharmaceutical industry.

Kevin is recommended by "Chambers Guide to the Legal Profession" as being cited by peers as "the doyen of patent law". He is specifically recommended by Legal 500 for his "pre-eminent reputation for patent expertise". He is also specifically rated as a leader in his field by "The Legal 500", for Patent Litigation and in advising the Pharmaceutical and Biotechnology sector, and the "Global Counsel 3000".

SPEAKERS

Dr. Michael Best is a German Patent Attorney, European Patent Attorney and Partner of Lederer & Keller in Munich, Germany. He qualified as a German Patent Attorney and European Patent Attorney in 1995 and has special experience in pharmaceutical and macromolecular chemistry.

Dr. Joachim Feldges is Managing Partner of Howrey's Munich office. He has a strong international reputation for complex patent litigation with a particular focus in the fields of pharmaceuticals and biotechnology. In addition to legal representation in German courts and in international arbitration, his experience includes the development and implementation of international patent litigation strategies.

Cameron Firth is a solicitor in SJ Berwin's EU and Competition Department, based in London. He has a particular interest in the pharmaceutical industry and advises clients on both regulatory and competition law issues.

Kirk Gallagher joined D Young & Co in 2001, and became Partner in 2004. Kirk is a Chartered Patent Attorney, a European Patent Attorney and a European Design Attorney. Before joining D Young & Co, Kirk gained experience in an intellectual property department of a major pharmaceutical company.

Kirk specialises in pharmaceutical patent work and advises clients in all areas of patent law.

Paul Inman is a partner in Howrey's London office. He has a background in Molecular Biology and Biochemistry and has been the lead solicitor in a large number of high profile patent infringement and revocation actions in the UK Patents Court. Most of those actions have involved coordinating with parallel patent cases in other jurisdictions worldwide. He has also advised in relation to EU pharmaceutical regulatory legislation.

A Certificate of Attendance for Professional Development will be given to each participant who completes the course.

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Lori-Ann Johnson is the managing partner of the Brussels office of Finnegan, Henderson, Farabow, Garrett & Dunner. Lori-Ann's practice involves patent drafting and procurement, opinion work, and client counselling primarily in the chemical area. She has significant experience in all phases of utility and design patent preparation and procurement, infringement, validity and patentability opinion preparation, re-examination practice, and licensing.

Tony Rollins qualified as a Chartered Patent Attorney in 1978. He joined Merck Sharp & Dohme Ltd. in September 2004 as Managing Counsel, European Patents. Tony has considerable experience of patent litigation throughout the world, as well as of patent prosecution and licensing matters, and is a UK Patent agent litigator and a member of the Litigation Accreditation Board for the UK Chartered Institute of Patent Agents.

David Rosenberg is an English solicitor. He worked for 12 years in the IP department of Clifford Chance, engaging in litigation and transactional work, primarily in the patent field. David joined GSK in February 2000 to perform a policy role in the IP department. Since then he has worked extensively on access to medicines issues (questions relating to European patent litigation reform and CBD).

David represents GSK on the IP committees of key pharmaceutical industry organisations (PhRMA, EFPIA and IFPMA) and on various UK and European cross-industry organisations.

Chris Thornham is a patent lawyer within the Intellectual Property Group of SJ Berwin. Chris acts for clients in UK patent litigation. He also works with patent attorneys and overseas patent lawyers supporting co-ordinate disputes and advice in Europe (e.g. national court cases in Germany, the Netherlands, France, Ireland, Spain and Norway) and elsewhere in the world (most notably the US).

Anthony C. Tridico is a U.S. Patent Attorney with Finnegan, Henderson, Farabow, Garrett & Dunner in Washington, DC. He is a partner in the Biotechnology/Pharmaceutical Practice Group where his practice focuses on client counseling, IP portfolio management, due diligence investigations and patent prosecution.

Mark van Gardingen (partner at Brinkhof, the Netherlands) specializes in European patent litigation, with a focus on pharmaceutical/chemical inventions. In 2007/2008, Mark's clients included Boston Scientific (Supreme Court proceedings about cardiovascular catheters), Novartis (defending the blockbuster Lescol®, and litigating a European extended wear contact lens patent of Ciba in infringement proceedings against Johnson & Johnson), Ratiopharm (attack against Merck Inc.'s patents for alendronate/Fosamax, and attack against Lundbeck's patent and SPC for es-citalopram/Cipramil), and Ranbaxy (attack against Pfizer's patents for Lipitor).

Tony Woodgate is the Managing Partner of the EC, Competition and Regulatory practice of Simmons and Simmons in London. He has extensive experience in all aspects of EU and UK competition and regulatory law, including litigation. He has been involved in major EC and UK antitrust law investigations before Member State courts. Tony advises organisations in all areas including pharmaceuticals, media, energy and commodities, together with high technology sectors.

ACCREDITATION

This Course merits 6 hours under the UK Solicitors Regulation Authority self-accreditation scheme

Ref: CJA/MAFO.

This course is potentially relevant CPD for fellows of CIPA

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all MANAGEMENT FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

PROGRAMME

09.30 ▶ **Chairman's welcome**

09.45 ▶ **European Case Law Update**

Paul Inman and Joachim Feldges

- Product per se claims
- German law of novelty
- Selection patents
- Obviousness
- Interim injunctions

10.30 ▶ **Recent US Decisions**

Lori-Ann Johnson

- When is something in Phase III Clinical trials "Ready for Patenting"?
In re Omeprazole Litigation
- Obviousness post KSR: small molecules
- Update on written description and enablement
- Latest cases on Inequitable Conduct
- Claim Preclusion and the Reverse Doctrine of Equivalents

11.15 ▶ **Coffee**

11.30 ▶ **The EU Sector Inquiry – Status and Next Steps**

Tony Woodgate and David Rosenberg

- Implications for your Company
- Patent Settlement Agreements
- Patenting practices/patent litigation
- Dealings with the Regulators
- Lifecycle Management strategies
- Likely outcomes including enforcement actions

12.30 ▶ **Lunch**

13.45 ▶ **European Patent Litigation Strategies**

Chris Thornham, Mark van Gardingen and Michael Best

- EPO oppositions and the inter-play with national proceedings
- Dealing with divisionals
- Amendment (central and local)
- Pre-launch clearance and interim injunctions
- Choice of forum (time, cost, what you get)
- Different court approaches (novelty, inventive step, sufficiency)
- Using material from one case for another
- Appeals

15.15 ▶ **Tea**

15.30 ▶ **European Patent Litigation – An Industry Perspective**

Tony Rollins

- Managing litigation across Europe
- Interim injunctions
- Second medical use patents

16.00 ▶ **Developments in Supplementary Protection Certificates**

Kirk Gallagher

- Importance of patent term extensions
- Relevant EU Regulations & national law
- Strategies for maximising patent term extension
- Recent changes in law and practice (sitagliptin, finasteride etc)

16.30 ▶ **The Intersection of IP and Regulatory Law**

Cameron Firth

- Data exclusivity
- The Community Code for marketing authorisations
- Regulatory litigation and bringing products to market
- Competition law

17.00 ▶ **The Safe Harbor Provision in the U.S: §271(e)(1) and the scope of the research exemption**

Anthony Tridico

- The Hatch-Waxman act
 - When does the safe harbor provision apply?
 - Lack of clarity regarding research tools
 - Medical devices and the safe harbor provision
- Proveris Scientific Corp. v. Innovasystems*
- Effect of 271(e)(1) "Safe Harbor" in ITC Actions

Amgen v. Int'l Trade Comm'n and Roche

17.30 ▶ **End of seminar**

Drinks reception in hotel bar





INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY

APPLICATION TO REGISTER

27th March 2009, Conf. No. H3-5009

Please PRINT your details:

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If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
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REGISTRATION INFORMATION

Date 27 March 2009

Times Start 09.30 – Finish 17.30

Registration & Coffee 09.00

Drinks Reception 17.30

Venue

The Rembrandt Hotel, 11 Thurloe Place, London SW7.

Directions

Opposite V&A Museum.

Nearest Underground station: South Kensington.

Map available on Website under Hotels and Venues.

Accommodation

A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7, at a special rate of £131.07 (Superior) £148.93 (Executive) both including English breakfast, excluding 15% VAT – subject to availability.

A special rate for Friday, Saturday and Sunday of £118.30 (Superior) including English breakfast, excluding 15% VAT – subject to availability when booked as additional nights.

Hotel Tel: +44(0)20 7589 8100.

Hotel Fax: +44(0)20 7225 3476.

Email: reservations_rembbrandt@sarova.co.uk

All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.

Conference Fee

£575 + 15% VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. H3-5009

Discounted Rates

Available on application for personnel from non-profit making organisations and registered charities.

Group discount available on request.

Cancellation Policy:

Over 14 days prior to the Seminar: Cancellation fee of £75.
7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.

NB: Cancellations must be received in writing by lesley@management-forum.co.uk.

In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.

Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact Judith Black
(email: judith.black@management-forum.co.uk)

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