

INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY

Topics to be included at this event:

- Recent EPO Pharmaceutical and Biotech Case Law
- Key decisions in the U.S. Pharmaceutical Sector
- Competition – The Role of Generic drugs and Settlement Agreements in Europe and the U.S.
- Biosimilars legislation and its impact
- SPC Law in Europe
- Litigation – Are National Courts becoming more consistent?

Chairman:

Kevin Mooney Simmons & Simmons LLP (UK)

Speakers:

Claire Baldock Boulton Wade Tennant (UK)

Richard Ebbink Brinkhof (Netherlands)

Hiroshi Sheraton McDermott Will & Emery UK LLP (UK)

Marjan Noor Simmons & Simmons LLP (UK)

Isabelle Romet Véron & Associés (France)

Mario Siragusa Cleary Gottlieb Steen & Hamilton LLP (Italy)

Dr Anthony Tridico Finnegan, Henderson, Farabow, Garrett & Dunner (Belgium)

* An industry speaker has been invited but not confirmed

Register on-line at www.management-forum.co.uk
or telephone +44 (0)1483 730071, fax 730008

11 March 2011
The Rembrandt Hotel, London

WHY SHOULD YOU ATTEND?

- Take advantage of the opportunity to listen to experts from across Europe
- Gain an update on EPO pharmaceutical and biotech case law
- Hear the latest developments and implications of competition in the industry
- Understand more about the chaos surrounding SPC Law in Europe
- Find out how recent decisions in the U.S. pharmaceutical sector could impact you
- Analyse whether litigation inconsistencies across national courts are improving or increasing

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 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

Claire Baldock is a Chartered Patent Attorney and European Patent Attorney and has been a partner at Boulton Wade Tennant since 1994. She is head of the firm's biotechnology and life science practice and is one of the leading patent attorney practitioners in the biotechnology field.

Richard Ebbink's practice concentrates on coordinating European patent litigation. He represents international companies before the Courts of The Hague and is internationally respected for his poise in coordinating parallel national proceedings and EPO oppositions. Richard is a member of the Board of Directors of EPLAW and recently won the award for Excellence in Patent Practice/Litigation in Private Practice at the WorldLeaders International IP Awards.

Hiroshi Sheraton is a partner in the law firm of McDermott Will & Emery based in the London office. He focuses his practice on all aspects of intellectual property law with a particular emphasis on the life sciences sector. He advises and represents clients in contentious patent, trade mark and other cases in the English Courts, before other tribunals such as the EPO and European Court of Justice. He has particular experience involving several jurisdictions, both in Europe, Asia-Pacific & the US.

Marjan Noor is a partner in the intellectual property group at Simmons & Simmons, London. She specialises in contentious and non-contentious intellectual property with a particular focus in patent and regulatory law in the life sciences sector. Marjan advises on a range of regulatory issues including product life cycle management, routes for obtaining marketing authorizations, paediatric regulations, data exclusivity provisions, supplementary protection certificates, medical device classification and advertising and borderline products.

Isabelle Romet is entirely dedicated to patent litigation, as are the 12 other lawyers of the firm Véron & Associés. Admitted to the Bar in 1988 and based in Paris, her practice encompasses patent validity, infringement and ownership in most technical areas, especially in complex technological fields and in an international context. She has handled landmark cases relating to cosmetics, pharmaceuticals, ophthalmology, nanotechnology, molecular diagnosis, genetically modified plants, green technologies, veterinary, and phytosanitary products.

Mario Siragusa is a Partner of Cleary Gottlieb Steen & Hamilton LLP in Rome. His practice focuses on corporate and commercial matters and he specialises in EU and Italian competition law and complex commercial litigation. Mr. Siragusa appears frequently before the European Court of Justice, the Court of First Instance of the European Communities, and the Directorate General for Competition of the European Commission.

Anthony Tridico is the Managing Partner of Finnegan's European office in Brussels, Belgium. He practices all aspects of intellectual property law, from strategic patent portfolio management to litigation. Dr. Tridico's practice involves diverse technical areas, focusing on pre-litigation analysis and strategic client counselling, due diligence investigations, licensing, patent portfolio management and analysis, prosecution of both U.S. and foreign patent applications, and appeals and oral hearings at the Board of Patent Appeals.

ACCREDITATION

This conference merits 6.5 hours under the UK Solicitors Regulation Authority self-accreditation scheme.

Ref: CJA/MAFO

This course is potentially relevant CPD for fellows of CIPA

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.

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

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PROGRAMME

09.30 ▶ **Chairman's welcome**

09.45 ▶ **EEUPC Update**

Kevin Mooney, Simmons & Simmons LLP

- How will Enhanced Cooperation work for the Unitary EU Patent?
- The ECJ Opinion-the aftermath
- Will Enhanced Cooperation be needed for the EEUPC?

10.00 ▶ **Update on EPO Pharmaceutical and Biotech Case Law**

Claire Baldock, Boulton Wade Tennant

- Relationship between inventive step and sufficiency of disclosure
- The position with medical use claims post G02/08
- Antibody claims - what can be allowed now?
- Disclaimers - recent developments

11.00 ▶ **Tea**

11.15 ▶ **Competition in the Pharmaceutical Sector: View from the EU and U.S. on the role of Generic Drugs and Settlement Agreements**

Mario Siragusa, Cleary Gottlieb Steen & Hamilton & Anthony Tridico, Finnegan, Henderson, Farabow, Garrett & Dunner

- The Commission Inquiry into Competition in the Pharmaceuticals Sector and its 1st Report on the Monitoring of Patent Settlements between originator and generic drug companies
- The AstraZeneca case
- Developments and implications for the pharmaceutical sector
- The view of U.S. Courts on ANDA settlements
- Legislation aimed at ANDA settlements
- Strategies of settlement

12.15 ▶ **Biosimilars in Europe and the U.S.**

*Anthony Tridico, Finnegan, Henderson, Farabow, Garrett & Dunner and Industry Speaker**

- Understanding the quagmire that is the Biosimilars legislation
- Preparing for the patent information exchange
- Patent strategies in view of the legislation

13.15 ▶ **Lunch**

14.15 ▶ **The Chaos around SPC Law in Europe**

Marjan Noor, Simmons & Simmons LLP

- Enantiomers, new vaccine combinations, different formulations, different delivery methods, medical devices: which are entitled to an SPC?
- Fixed dose combinations and drugs used in combination: when does a patent protect the combination; when does a marketing authorisation cover the combination; and how to avoid falling between two stools?
- Infringement during SPC term
- Aggressive SPC tactics: where marketing authorisation holder is independent of patentee

15.00 ▶ **Coffee**

15.15 ▶ **Litigation – Are National Courts becoming more consistent?**

Richard Ebbink, Brinkhof, Isabelle Romet, Véron & Associés & Hiroshi Sheraton, McDermott Will & Emery

- How the various courts differ in their approaches and procedures
- How the courts have endeavoured to co-operate and provide consistency
- Where do EPO Oppositions fit in?
- Specific case studies showing how the courts of different jurisdictions have approached the same cases
- How will a Central European Patent Court affect this?

16.45 ▶ **Recent Decisions in the U.S. Pharmaceutical Sector**

Anthony Tridico, Finnegan, Henderson, Farabow, Garrett & Dunner

- Inequitable Conduct: Where are we after Therasense?
- Obviousness and secondary patents
- Balancing Enablement and Non-obviousness

17.30 ▶ **End of Conference**

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