



## 1st EGA LEGAL AFFAIRS FORUM

Hotel Radisson SAS Portman  
22 Portman Square - London W1H 7BG, UK  
2<sup>nd</sup> February 2005

THE EUROPEAN GENERIC MEDICINES ASSOCIATION

(PROGRAMME UPDATED 3 JAN 05)

WEDNESDAY 2<sup>nd</sup> February 2005

Legal Affairs Forum

08:30 Registration and Welcome Coffee

09:30 Session 1 Chair | Greg Perry Director General EGA

- **The long awaited European "Bolar" provision - Art 10(6) of 2001/83 (as amended)**  
Speaker | Neil Jenkins, Bird & Bird, UK
  - Does Europe now have a "Bolar" provision?
  - What does the provision cover?
  - When is the provision due to be implemented?
  - How will implementation affect CROs and manufacturers of generics and biogenerics?
  - Does the Bolar have any implications in manufacturing and stockpiling during a patent or SPC?
- **Data exclusivity as an instrument of market protection**  
Speaker | Stephen Kon, SJ Berwin, UK
  - What is "data exclusivity" and why the confusion with "data protection"?
  - Effects of recent ECJ court cases on application of data exclusivity in the EU?
  - What will be the impact of the outcome of the Swiss/Liechtenstein case C-207/03 with regards to the data exclusivity calculation?
  - Implications of the new data exclusivity provisions in the EU Pharmaceutical Legislation
  - Could generic companies benefit from the 1 year data exclusivity for well established products and OTC Switch?

11:00 Coffee Break

11:30 Session 2 Chair | György Thaler - Chairperson EGA Legal Affairs and IP Committee

- **How second medical use patents are used to extend product lifecycle?**  
Speaker | Bert Oosting, Partner, Lovells, Netherlands
  - Types of patents granted and what claims are covered?
  - The importance of usage patents.
  - Impact of second medical use patents on regulatory procedures.
  - Implications of the revision of European Patent Convention
  - Comparisons with US patent system



Making Medicines Affordable

- **Strategies for maximising the launch of a generic medicine in Europe**

Speaker | Peter Klusmann, Hoffmann-Eitle, Germany

- Key points of the European Patent system
- Opposition procedures at the EPO
- Challenging flawed patents
- Clearing the way and informing the originator
- Avoiding unnecessary litigation

13:00 Lunch Buffet

14:00 **Session 3 Chair** | György Thaler - Chairperson EGA Legal Affairs and IP Committee

- **Issue of similarity of medicinal products in the context of free movement of goods in the EU**

Speaker | Jordi Faus Santasusana, Faus & Moliner Abogados, Spain

- How is similarity of medicinal products defined in the context of parallel import?
- What does the Communication from the Commission on parallel imports of proprietary medicinal products (30.12.2003) say about 'similarity of medicinal products'?
- What does the European Court of Justice say?
- Peculiarities of parallel trade in the generic sector

- **Supplementary Protection Certificates**

Speaker | Richard Milchior, Cabinet Milchior & Smilevitch, France

- Application of the SPC Regulation to date
- Status of SPC Regulation in enlarged EU
- Implications of the outcome of the Swiss/Liechtenstein Novartis case
- Effects of the proposed EU Regulation on paediatric medicines

15:30 Coffee Break

16:00 **Session 4 Chair** | Greg Perry - Director General EGA

- **EU competition policy and generic medicines**

Speaker | Georg de Bronett, Head of the Pharmaceuticals and Food Unit at DG Competition, European Commission

- Key points of EU competition policy and how this relates to the pharmaceutical sector
- Inter-relationship with patent rights and competition law
- Case studies in the pharmaceutical sector
- Implications for generic companies

- **Implications of the EU IP enforcement Directive for generic manufacturers**

Speaker | Veronica Lowe, Mayne Pharma, UK

- Key points of the Directive and timetable for implementation
- Implications for current rules on interim injunctions
- Importance of safeguard clauses and ensuring that Member States endorse these

17:00 Closure of the Forum

17:00 - 18.00 Cocktail Reception

For more information and to register on-line please visit

[www.gpaconferences.com](http://www.gpaconferences.com) or [www.egagenerics.com](http://www.egagenerics.com)

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Registrations close officially the 21st January 2005 & are subject to availability