

# 2<sup>nd</sup> EGA LEGAL AFFAIRS FORUM

| 1<sup>st</sup> February 2006 |

Hotel Radisson SAS Portman  
22 Portman Square - London W1H 7BG, UK

WEDNESDAY 1<sup>st</sup> February 2006

Legal Affairs Forum

08:00 Registration and Welcome Coffee

09:00 **Session 1**      *Chair* | György Thaler - Chairperson EGA Legal Affairs and IP Committee

- **Update on the interpretation of the European ‘Bolar’ provision after its implementation in national legislations**
  - Have all the Member States implemented the legislation into their national laws? How have they implemented it?
  - What is permissible under the Bolar provision? Comparison with other situations worldwide.

*Speaker* | Ewan Livesey, IVAX, Vice President Legal Affairs Europe, UK

- **Harmonization of Data Exclusivity periods in Europe and internationally**
  - Understanding the new data exclusivity regulation
  - Implications of the new data exclusivity provisions in the EU Pharmaceutical Legislation
  - Comparison with other situations worldwide

*Speaker* | Bert Oosting, Lovells, NL

- **SPCs: Latest Developments**  
*Speaker* | Cameron Firth, SJ Berwin, UK

11:00 Coffee Break

11:30 **Session 2**      *Chair* | Greg Perry Director General EGA

- **Patent Linkage to Regulatory Approval**
  - Patent linkage- New threat to generic competition in EU  
*Speaker* | Suzette Kox, Senior Director Scientific Affairs, EGA
  - Update on anticompetitive strategies directed to constitute a linkage between regulatory procedures and patent infringement.  
*Speaker* | Larry Cohen, Partner IP Group, McDermott Will & Emery, UK
  - Patent and Regulatory abuse: the Astra Zeneca case COMP/37.507  
*Speaker* | Stephen Kon, SJ Berwin, UK

13:00 Buffet Lunch



Making Medicines Affordable

**14:00**   **Session 3**   **Chair** | Lidia Mallo - Legal Affairs and Government Relations, EGA

- **Injunctions and cross-undertakings**  
**Speaker** | Anna McKay, Independent Consultant, UK
- **Implementation of the Intellectual Property Rights Enforcement Directive 2004/48/EC into Hungarian Legislation.**  
**Speaker** | Michael Ficsor, Vice President of Hungarian Patent Office
- **New EU proposal for a Directive on criminal measures to enforce Intellectual Property rights**
  - Key points of the proposal, procedure and timetable for approval.  
**Speaker** | Daniel Fontanaud, Seconded Expert Judge, Unit on the Fight against Organised Crime, DG Justice, Freedom and Security, European Commission.
  - What will be the implications for generic manufacturers?  
**Speaker** | Veronica Lowe, Mayne Pharma, UK

**15:30**   **Coffee Break**

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

- **EU Regulation on medicinal products for paediatric use**
  - Key points of the Regulation, status and timetable for approval
  - Implications for generic manufacturers**Speaker** | Nadene McClay, Director of Policy, EGA.
- **EU Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems**
  - Key points of the Regulation, status and timetable for approval
  - Implications for generic manufacturers**Speaker** | Liz Coleman, formerly Industrial Property Unit, DG Internal Market and Services, European Commission - Director of IP Policy, UK Patent Office.

**17:00**   **Closure of FORUM**

**For further 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 21 January 2006 and are subject to availability.