



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

## 7<sup>th</sup> EGA Legal Affairs Forum

17-18 March 2011

RENAISSANCE BRUSSELS HOTEL  
(rue du Parnasse 19 - B-1050 Brussels)

Thursday 17 March 2011

EGA Legal Affairs Forum

13:00-14:00 Registrations & Welcome Buffet Lunch

### SESSION I

#### Recent developments on SPCs

Session organised in co-operation with

Chair | *Leighton Howard, CEO, GenericsWeb*



14:00 SPC considerations from a generic perspective

- Multiple SPCs per country/INN
- Inconsistent use of First EU MA date
- Other problems evident in the system

*Leighton Howard, CEO, GenericsWeb*

14:30 The basic patent – Review of relevant case law

- 2<sup>nd</sup> Medical Use
- Physical forms and formulations
- Process patents / Multiple basic patents

*Dr. Duncan Curley, Founder & Head of Patents, Innovate Legal*

14:55 The medicinal product - Review of relevant case law

- The medicinal product defined
- Where/when is the first MA - problems with EU enlargement
- Combination products/ Vaccines and adjuvants

*Dr. Howard Rosenberg, Technical Advisor at Frommer Lawrence and Haug LLP*

15:20 Coffee Break

15:50 Paediatric SPC extensions

- Application and publication in practice
- Negative term SPCs - status quo
- PIP & MA status requirements

*Martijn de Lange, Senior Patent Examiner, Netherlands Patent Office*

EUROPEAN GENERIC MEDICINES ASSOCIATION

Rue d'Arlon 50, B-1000 Brussels, Belgium

T: +32-(0)2-736 8411 F: +32-(0)2-736 7438

E: [info@egagenerics.com](mailto:info@egagenerics.com) [www.egagenerics.com](http://www.egagenerics.com)

VAT: BE 0449 332 209



## EUROPEAN GENERIC MEDICINES ASSOCIATION

*Making Medicines Affordable*

- 16:10      **Review of other case law**  
• Infringement / Abuse  
*Elisabeth Berthet-Maillols, Lawyer at the Paris Bar, Armengaud-Guerlain*
- 16:30      **Debate on possible future models for SPCs**  
• Determining Eligibility / Calculating the Term/ Methods for Challenge  
*Leighton Howard, CEO, GenericsWeb*
- 16:45      **Final debate and conclusions**
- 17:00      End of Seminar and End-of-day Drinks

**Friday 18 March 2011**

**EGA Legal Affairs Forum**

- 08:00      Networking Coffee
- 09:00      Welcome by Greg Perry, Director General, EGA
- SESSION II**      **Practical consequences of the pharmaceutical sector inquiry final report**  
**Chair** | *Lidia Mallo, Legal and Trade Senior Manager, EGA*
- 09:10      **Astra Zeneca case/ Duty of candour and dominant operators/ Patent settlements**  
*Dominik Schnichels, Head of Pharma Taskforce, DG Competition, European Commission*
- 09:30      **Sector inquiry: one year on**  
*Greg Perry, Director General, EGA*
- 09:45      **Court cases concerning patent linkage and pricing & reimbursement procedures: case study in Italy**  
*Nicola Orlandi, Head of Legal and Compliance Generic Business, Sandoz Italy on behalf of Assogenerici*
- 10:00      Debate
- 10.45      Coffee Break
- SESSION III**      **Patent enforcement in Europe**  
**Chair** | *Gyorgy Thaler, Chair Legal Affairs Committee, EGA*
- 11:15      **Views of the generic industry**  
*Yehudah Livneh, VP Corporate IP and Legislative Affairs, Teva*
- 11:30      **A review of key cases affecting generic companies**  
*Kristof Roos, Attorney, Crowell & Moring*
- 11:45      **To be confirmed**

### EUROPEAN GENERIC MEDICINES ASSOCIATION

Rue d'Arlon 50, B-1000 Brussels, Belgium

T: +32-(0)2-736 8411 F: +32-(0)2-736 7438

E: [info@egagenerics.com](mailto:info@egagenerics.com) [www.egagenerics.com](http://www.egagenerics.com)

VAT: BE 0449 332 209



## EUROPEAN GENERIC MEDICINES ASSOCIATION

*Making Medicines Affordable*

- 12:00      **Developments on the EU Patent Court and EU patent: How close are we to the implementation of the EU patent reform?**  
*Oliver Varhelyi, DG Internal Market, Head of Unit D2, Industrial Property Rights, European Commission*
- 12:15      Debate
- 13:00      Networking Buffet Lunch
- SESSION IV      “Raising the bar” at the European Patent Office**  
**Chair** | *Greg Perry, Director General, EGA and Member of EPO SACEPO*
- 14:00      **Update on EPO changes to the guidelines/ Recent decisions from the EPO Technical Board of Appeal: how these “raise the bar”.**  
*Dieter Tzschoppe, Director, Pure and Applied Organic Chemistry Cluster, EPO*
- 14:20      **Views of Academia**  
*Prof. Dietmar Harhoff, Director Institute for Innovation Research, Ludwig-Maximilians University, Munich and Member of EPO SACEPO Committee*
- 14:40      **EGA’s paper on “How to improve the European patent system” submitted to the EPO SACEPO Committee:**
- Acceleration of examination and opposition procedures
  - Reform of divisional applications
  - Improve quality of applications: Information disclosure statement
- Julia Pike, Head Global IP Litigation, Sandoz*
- 15:00      Debate
- 15:45      Close of forum and end-of-forum coffee

### EVENT SPONSORS

**crowell**  **moring**  
*experience. creativity. results.*

 **GENERICSWEB**  
THE SEARCH IS OVER

**GENERIC**  
*bulletin*  
www.generics-bulletin.com

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)

Cristina Romagnoli - T: +377-93-501348 - F: +44-208-0825368 - E: [info@gpaconferences.com](mailto:info@gpaconferences.com)

Registrations close officially on 4 March 2011 & are subject to availability.

### EUROPEAN GENERIC MEDICINES ASSOCIATION

Rue d'Arlon 50, B-1000 Brussels, Belgium  
T: +32-(0)2-736 8411 F: +32-(0)2-736 7438  
E: [info@egagenerics.com](mailto:info@egagenerics.com) [www.egagenerics.com](http://www.egagenerics.com)  
VAT: BE 0449 332 209