



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

7th 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

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

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

Howard Rosenberg, Scientific Advisor, 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

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- 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**
Harald Mische, Case Handler, 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**
Alia Knight, Senior Patent Litigator, Teva EU
- 11:30 **A review of key cases affecting generic companies**
Kristof Roos, Attorney, Crowell & Moring
- 11:50 **Preliminary injunctions; recent cases and practice**
Sabine Rojahn, Partner, Taylor and Wessing

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- 12:10 **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
- 12:25 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 developments in the EPO**
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

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