



10th EGA Legal Affairs Forum

18 - 19 March 2014

Thon Hotel EU

Rue de la Loi/Wetstraat 75 - B-1040 Brussels

Tuesday 18 March 2014

EGA Legal Affairs Forum

13:00 Registrations & welcome buffet lunch

14:00 Welcome by *Lidia Mallo, Government Affairs & IP Advisor, EGA*

Session I - SPCs: case law update and strategic considerations

Chair | *Leighton Howard, CEO, GenericsWeb*

Session organised in co-operation with GenericsWeb



14:10 **Introduction and review of current issues in SPCs**

- Summary of hot topics
- Combination SPC update - how the patent offices are reacting
- Date of grant vs date of notification for SPC date calculation

Leighton Howard, CEO, GenericsWeb

14:20 **Case law updates**

Combination products

- Case C-484/12 *Georgetown* - one SPC per patent?
- Update on the irbesartan/HCTZ reference (Sanofi/Actavis)
- Update on Case C-493/12 Eli Lilly
- Telmisartan/HCTZ - reference from the English Patents Court

Andy Brown, Head of IP, Pharmathen

14:40 **Other references to the Court of Justice**

- Case C-310/11 *Neurim*
- Case C-617/12 *AstraZeneca* (Lichtenstein issue)
- Case C-210/13 *GlaxoSmithKline Biologicals* (vaccine adjuvants)

Howard Rosenberg, Scientific Advisor, Frommer Lawrence and Haug LLP

15:10 Questions & answers

15:15 Coffee break

15:45 **Using SPC case law to strategic advantage - discussion and debate**

*Led by Duncan Curley, Founder & Head of Patents, Innovate Legal
Marleen H.J. van den Horst, Attorney at law, BarentsKrans*

16:55 **Final debate and conclusions**

Moderator: Leighton Howard, CEO, GenericsWeb

17:00 End-of-day cocktail



Wednesday 19 March 2014

EGA Legal Affairs Forum

- 08:00 Networking coffee
- Session II - Legal issues that affect the industry**
Chair | *Suzanne Smith, Executive Director Legal, Actavis plc*
- 09:00 **The pros and cons of arbitration**
Patrick Heneghan, Partner, Skadden, Arps, Slate, Meagher & Flom (UK) LLP
- 09:20 **Advanced manufacturing during SPC to manufacture in the EU and export to other countries with inexistent or expired patents**
Thomas Kolzau, Head of Patents Affairs, Helm AG
- 09:40 **Patent Settlements and reverse payments: Lundbeck and Servier decisions**
Christophe Humpe, Partner, King & Wood Mallesons SJ Berwin
- 10:00 Debate
- 10:30 Coffee break
- Session III - The Unified Patent Court**
Chair | *György Thaler, Chair Legal Affairs Committee, EGA*
- 11:15 **Implications for the generic medicines industry and views of the preparatory committee on the UPC rules**
- *Fiona Bor, Director of Intellectual Property, Mylan*
 - *Alexander Ramsay, Deputy Director, Division for Intellectual Property and Transport Law, Ministry of Justice, Sweden and Vice Chairman of the UPC Preparatory Committee*
 - *Kevin Mooney, Chairman of the Drafting Committee advising the Preparatory Committee on the Rules*
 - *Duncan Curley, Founder & Head of Patents, Innovate Legal*
- 12:30 Debate
- 12:45 Networking buffet lunch
- 14:00 **Update on the latest trends at the EPO**
Heli Pihlajamaa, Director of the Patent Law Department, EPO
- 14:20 Questions & answers
- 14:30 **Update on court cases that impact the industry**
Kristof Roox, Partner, Crowell & Moring LLP
- 14:50 **Biosimilars patent litigation**
Jan-Diederik Lindemans, Counsel, Crowell & Moring LLP
- 15:10 Questions & answers
- 15:30 End-of-forum coffee

SPONSORS AND MEDIA PARTNERS



For further information please visit: www.egagenerics.com

EUROPEAN GENERIC MEDICINES ASSOCIATION AISBL (EGA)

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