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Biotech & Pharmaceutical Patenting

17th – 18th February 2010
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- ➔ **Ian Forrester QC**, *Partner*, **White & Case LLP** (Belgium)

- **Prepare for upcoming changes** with updates directly from the decision-makers at key patent offices
- Examine the effect of recent case law on **patent term extensions and paediatric data exclusivity**
- Increase your success in cases relating to **single enantiomers, biosimilars** and **second medical use claims** with a critical review of the latest decisions of courts around the world
- Update on latest developments in **DNA patenting** with insights from the agrochemical sector
- Overcome the challenges of **patenting diagnostic methods** now and in the future
- **Select your litigation forum wisely** with a comparative examination of litigation across Europe, the US and the BRIC territories

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BIOTECH & PHARMACEU

CONFERENCE DAY ONE

08:30 Registration and Coffee

09:00 Chair's Opening Remarks

Peter de Weerd, Vice President & Global Head of IP Optimisation, Novartis (Switzerland)

09:15 **Keynote Critical Update: Patent Filing and Prosecutions: What You Need to Know!**

Hear first hand how recent and upcoming changes will affect your patenting strategy, with updates directly from senior representatives at the major patent offices. Come armed with your questions as you get the opportunity to ask for the answers you need.

Dr. Dieter Schneider, Head of Division, German Patent & Trademark Office

Senior representative from European Patent Office invited

Senior representative from World Intellectual Property Organisation invited

10:45 **Top Competition Law Concerns**

- The phenomenon of parallel trade and its legal status after GSK
- The implications of the Commission's sector inquiry
- Settlement of patent disputes
- Article 82 EC and abuse

Ian Forrester QC, Partner, White & Case LLP (Brussels)

11:30 **Patenting Single Enantiomers**

- Convergence of the decisions of the UK and German courts
- The approach adopted by the Australian courts
- Data exclusivity considerations
- Selection inventions

Kevin Mooney, Partner, Simmons & Simmons LLP (UK)

Peter Klusmann, Partner, Hoffmann Eitle (Germany)

Matthew Swinn, Partner, Corrs Chamber Westgrath (Australia)

12:30 Networking Lunch

13:30 **Patent Term Extensions and Paediatric Data Exclusivity**

- Legal opportunities for market exclusivity in the pharmaceutical field
- Patent term extensions in different jurisdictions
- Requirements for getting patent term extensions
- Case law related to patent term extensions

- Granting negative term SPCs in the wake of Merck
- Paediatric data exclusivity in light of the Losartan case
- Impact of ECJ's decision in AHP

Dr. Frank Burkert, European Patent Attorney, Bayer Healthcare (Germany)

Bert Oosting, Partner, Lovells (The Netherlands)

14:15 **Second Medical Use Claims**

- Kos case: Discussion of likely impact of the decision of the EPO's Enlarged Board of Appeal

Adam Cooke, Partner, Lovells (UK)

15:00 Networking Break

15:20 **Stem Cells Revisited**

- General overview on stem cells: The technology and its assessment before the patent offices - is the term "stem cell" clear?
- WARF and beyond: What do we learn from G2/06 and how do we proceed before the EPO?
- The British and the German View: Will the European Court of Justice bring the desired clarity?

Dr. Jürgen Meier, Partner, Vossius & Partner (Germany)

16:00 Panel Discussion: **Patenting Biosimilars: Global Perspectives from Industry**

- Navigating the strict regulatory hurdles to get products to market
- Comparing the approaches taken by the regulators in Australia, Europe and the US

Naomi Pearce, Patent Director, Hospira (Australia)

Marc Markus, European Biology Patent Lead, Pfizer (France)

US industry expert to be confirmed - download the latest brochure at www.ibclegal.com/biopharma for updates

17:00 Chair's Closing Remarks

From 17:15



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CONFERENCE DAY TWO

08:15 **Breakfast Briefing: What is Going on in the Pharmaceutical Patents in Brazil?**

- Patent litigation – a new reality at the Brazilian courts
- Linkage – is it feasible?
- Data protection: A scenario
- Is the biosimilar a reality in Brazil?

Joaquim Goulart, *Partner*, **Dannemann Siemsen Advogados** (Brazil)

Gustavo Morais, *Partner*, **Dannemann Siemsen Advogados** (Brazil)

09:00 Registration and Coffee

09:15 **Chair's Opening Remarks**

Peter de Weerd, *Vice President & Global Head of IP Optimisation*, **Novartis** (Switzerland)

09:30 Panel Discussion: **Key Issues to be Aware of when Patenting Pharmaceutical and Biotech Products in the BRIC Territories**

- An overview of recent developments in the pharmaceutical patent area in Brazil
- The developing practice of post-grant oppositions in India
- The effect of the 3rd amendment on patenting in China
- Patent litigation trends in Russia - overview and recent developments

Joaquim Goulart, *Partner*, **Dannemann Siemsen Advogados** (Brazil)

Gustavo Morais, *Partner*, **Dannemann Siemsen Advogados** (Brazil)

Vladislav Ugryumov, *Partner*, **Lovells** (Russia)

Dr. Benjamin Bai, *Partner*, **Jones Day** (China)

Pravin Anand, *Managing Partner*, **Anand & Anand** (India)

10:30 **How to Protect your Innovations in Emerging Markets: An Industry Perspective**

- What can be done by Novartis in the BRIC territories and other emerging markets?
- How to cope with counterfeit products in emerging markets

Peter de Weerd, *Vice President & Global Head of IP Optimisation*, **Novartis** (Switzerland)

11:15 Networking Break

11:35 **Latest Challenges in Patenting Diagnostic Methods**

- Biomarkers
 - Where do you get them from?
 - Are they patentable?
- How are antibodies produced?
- What do you need to be prepared for in the future?
 - Telemetry: Remote access diagnostics
- Compare and contrast with procedures for patenting chemical inventions

John Nevard, *Chief IP Counsel*, **Inverness Medical** (UK)

12:15 **Inventor Compensation: A Comparative Approach**

- *Kelly v GE Healthcare*

- Jurisdictional approaches

Alan Johnson, *Partner*, **Bristows** (UK)

Klaus Haft, *Partner*, **ROKH IP** (Germany)

13:00 Networking Lunch

14:00 **Litigating Patents in Europe: A Comparative Viewpoint**

- Update on the move towards a unified patent court and the European Patent Litigation Agreement (EPLA)
- Are interim injunctions still always commercially viable in the light of *Smith & Nephew* and *Servier v Apotex*?
- Why are the national courts differing in their opinions?

- *Lundbeck*

- *Conor v Angiotech*

Moderator: Simon Cohen, *Partner*, **Taylor Wessing LLP** (UK)

Nigel Stoate, *Partner*, **Taylor Wessing LLP** (UK)

Pierre Véron, *Founding Partner*, **Véron & Associés Avocats** (France)

Christoph de Coster, *Partner*, **Taylor Wessing LLP** (Germany)

Otto Swens, *Partner*, **Vondst Advocaten** (The Netherlands)

15:00 Networking Break

15:15 **Litigating Patents in the US Courts**

- Developments in post-KSR obviousness / invalidity law
 - In *Re Kubin*
 - *Bayer v Barr*
 - USPTO guidelines/KSR application during prosecution
- Developments that may effect biotech and pharmaceutical patents generally
 - US Supreme Court *Bilski* decision
 - USPTO reaction to *Bilski*
 - "Stay away/stay out" provisions/ payments to generics
 - *Centocor Inc. v Abbott Labs* ("Humira"), \$1.7billion verdict (Eastern District of Texas) and the potential Federal Circuit treatment

Ken Adamo, *Partner*, **Jones Day** (US)

16:00 **No Performance – No Protection? Protection of DNA Sequences Under Directive 98/44/EC**

Implications of the referral to the European Court of Justice in the case *Monsanto v Cefetra*

Dr. Michael Kock, *Global Head of IP*, **Syngenta** (Switzerland)

16:45 **Question & Answer Panel**

Address any remaining questions you have on patenting in the pharmaceutical and biotech sectors to a selection of speakers from the 2 day conference.

Naomi Pearce, *Patent Director*, **Hospira** (Australia)

Peter de Weerd, *Vice President & Global Head of IP Optimisation*, **Novartis** (Switzerland)

Marc Markus, *European Biology Patent Lead*, **Pfizer** (France)

Matthew Swinn, *Partner*, **Corrs Chamber Westgrath** (Australia)

17:15 Chair's Closing Remarks

17:30 Close of Conference

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17th – 18th February 2010 • Hilton Munich Park, Munich, Germany

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