5th Annual Biosimilars Conference

Innovations, developments, and controversy- what the future holds?

19th - 21st October 2009, BSG Conference Centre, London, UK

BOOK NOW!

Key Speakers
Ray Cresswell, VP R&D Legal Operations, GlaxoSmithKline
Dr. Michael Muenzberg, Global Head of Medical Affairs, Sandoz International GmbH
Vinay Ranade, CEO, Reliance GeneMedix
Rasmus Rojkjaer, Vice President, Head of Global Biologics R&D, Mylan GmbH
Dr. C Jane Robinson, Principal Scientist, Biotherapeutics, National Institute for Biological Standards & Control (NIBSC)
Dr. David Goldsmith, Consultant Nephrologist, Guy’s Hospital and St Thomas’ NHS Foundation Hospital
Tommy Erdei, CFA, Executive Director, Healthcare Banking, UBS Investment Bank
Dr Frank Moffatt, Product Manager Biopharmaceutical and DNA Analysis, Solvias
Jo Pisani, Partner, Pricewaterhousecoopers
Ashish Menocha, Head of International Markets, Abdi Ibrahim
Cecil Nick, Vice President (Biotechnology), Parexel Consulting
Dr. Daryl Fernandes, Chief Executive, Ludger
Gerben Moolhuizen, Chief Business Officer, OctoPlus N.V.
Mateja Urlep, Director, TikhePharma
Keith Powell, CEO, Polytherics
Duncan Curley, Director, Innovate Legal

Pre conference Workshop, Monday 19th October 2009
Understanding the developing biosimilars framework in the United States and European Union
led by: Daniel A. Kracov, Partner and Chair, FDA and Healthcare Practice, David R. Marsh, Partner and Co-Chair, Intellectual Property Practice and Lincoln Tsang, Partner from Arnold & Porter LLP
Dear Colleague,

The biological drug market is one of the fastest growing sectors of the pharmaceutical industry which corresponds to over 15% of the total pharmaceutical market. However, due to the patent expiry of many drugs, and increasing pressure from government, insurers and patient advocacy groups to reduce expenditure a number of opportunities for biosimilars have been created.

The biosimilars market is currently highly fragmented with many favorable circumstances for new or potential market entrants. With conducive regulatory developments, the biosimilars sector should pick up significantly; forming an important developing pharma market. With the new bills being passed, this is the time for progress.

Following the success of our previous Biosimilars conferences with high attendance and positive feedback, we are happy to announce the 5th Annual Biosimilars Conference. This event aims to provide a detailed analysis of the recent developments in the current market and regulatory environment for biosimilars. Join us to learn, network, benchmark against the strategies and participate in our open discussions and provide your valuable inputs.

Why Attend?
- Examine the key issues for development of biosimilars regulations
- Gain a clearer insight on how US environment differs from Europe
- Discover the acceptance criteria for immunogenicity of biosimilars
- Discuss the legal and regulatory considerations for clinical trials
- Analyse the emerging partnerships between big pharma and smaller biosimilars companies
- Investigate the factors affecting biosimilars market access
- Network and discuss ideas with the leaders in the field

I look forward to meeting you at the conference

Best regards

Pranita Nangia
Conference Producer
Understanding the developing biosimilars framework in the United States and European Union

Led by:
Daniel A. Kracov, Partner and Chair, FDA and Healthcare Practice, Arnold & Porter LLP, Washington, D.C.
David R. Marsh, Ph.D., Partner and Co-Chair, Intellectual Property Practice, Arnold & Porter LLP, Washington, D.C.
Lincoln Tsang, Ph.D., Partner, Arnold & Porter LLP, London

Timings: 09:30 - 10:00 Coffee & Registration
10:00 - 15:00 Workshop
Timing includes lunch and refreshment breaks

Agenda:
Session 1 by Daniel A. Kracov: Overview of U.S. biosimilars legislation: FDA standards, processes and exclusivity
This session will look at the standards and mechanisms for biosimilar licensure under pending legislation (or statute if enacted).
- Biosimilars application review processes
- Requirements for FDA guidance
- Standards for biosimilar and interchangeability determinations
- Data requirements and FDA waiver authorities
- Exclusivity for innovator biologics
- Exclusivity for interchangeable biosimilars
- Nomenclature for biosimilars
- Potential innovator and biosimilar strategies

Session 2 by David R. Marsh: Biosimilar patent issues
This session will examine the mechanisms for handling patent disputes in pending legislation (or statute if enacted), and the impact on biotech patent litigation.
- Processes for handling biosimilar patent disputes
- Impact on strategies for innovator biologic product patenting, patent disputes and resolution
- Potential biosimilar patent strategies
- Potential changes in the biologic product patent litigation dynamic

Session 3 by Lincoln Tsang: Comparing the developing US framework to biosimilars in the EU
This session will provide an overview of the EU framework for biosimilars, including:
- Key differences in the developing US and EU biosimilar framework and pathways
- Biosimilars exclusivity and patent issues in the EU
- Applications and data requirements for EU biosimilars
- Experience to date under the EU biosimilars framework
- Developing global innovator and biosimilar strategies

About your workshop leaders:
Daniel A. Kracov
Dan Kracov heads the FDA and healthcare practice. He assists clients, including start-up companies, trade associations, and large manufacturing companies, in negotiating the challenges relating to the development, approval and marketing of drugs, biologics, and medical devices. His experience in US Food and Drug Administration (FDA) strategic advice and crisis management won him a spot on the Fall 2005 Legal Times list of “Leading Lawyers in Food & Drug Law.”
Mr. Kracov regularly handles product and compliance-related investigations, the development of regulatory corporate compliance programs, and due diligence in financings, mergers and acquisitions. He has a widely-recognized experience in biomedical product-related public policy matters, including Congressional investigations and FDA-related legislative strategies.

David R. Marsh
Dr. David Marsh is co-chair of Arnold & Porter’s intellectual property practice. He focuses extensively on intellectual property counseling, interferences and patent procurement, predominantly in the chemical, pharmaceutical, and biotechnology areas. He has argued multiple matters before the United States Patent and Trademark Office’s Board of Patent Appeals and Interferences. He also manages multiple European Opposition proceedings, and represents clients in patent and other intellectual property litigation or dispute resolution proceedings. Dr. Marsh is also an American Arbitration Association and World Intellectual Property Organization neutral arbitrator. As an adjunct professor at Georgetown Law School, Dr. Marsh teaches “Biotechnology and Patent Law.” He has also written numerous articles on patent law, is a frequent speaker at conferences in the US and Europe, and is an editor of BioScience Law Review. The Legal Times recognized Mr. Marsh as a “Leading Life Sciences Lawyer in Washington, DC” for 2006. He was ranked by Practical Law Companies “Cross-border Life Sciences Handbook 2006/2007 as “Highly Recommended in Patent Counselling” and “Recommend in Intellectual Property” in both Washington, DC and in the USA. He is also a Fellow of the Royal Society for the encouragement of Arts, Manufactures and Commerce.
Dr. Marsh carried out his graduate work in molecular biology at Cambridge, England and his post-doctoral work at Yale University. His research experience includes molecular biology, immunology, biochemistry, and mammalian and plant genetics.

Lincoln Tsang
Dr. Lincoln Tsang is a partner in the firm’s London office. He is both a lawyer and a registered pharmacist with post-graduate qualifications in toxicology and biochemistry. His practice relates to life sciences industry including pharmaceuticals, biotechnology, medical devices, in vitro diagnostic devices, cosmetics and food with particular emphasis on the intersection of the law and public policy relating to life sciences. He assists clients in developing strategies for research and development including product life cycle management, product acquisition, risk and crisis management.
In addition to advising industry, Dr. Tsang also advises foreign governments, various trade associations and not-for-profit and/or charity organizations. He maintains an active pro bono practice. He presents and writes widely on regulatory law and public policy.

About: Arnold & Porter LLP
Arnold & Porter LLP is an international law firm with nearly 700 attorneys practicing worldwide in more than 25 practice areas spanning a broad spectrum of the law, with a primary focus on litigation, transactional matters, and regulatory issues. Our attorneys, many of whom have previous government agency experience, routinely counsel pharmaceutical, biotechnology, medical device, and diagnostic companies, as well as other healthcare entities, in responding to complex legal challenges in the US and Europe. Arnold & Porter professionals work together to provide our clients with seamless, comprehensive, and sophisticated analyses, and strong and zealous advocacy.

For further information, please visit: www.arnoldporter.com
Day 1
5th Annual Biosimilars Conference
Tuesday 20th October 2009, London, UK

09:30  Registration and refreshments

10:00  Opening address from the chair

10:10  Opportunities and challenges for biosimilars in the global market
- Commercial drivers for the biosimilar market
- Competition faced by potential biosimilars from second-generation products
- Impact of pricing strategies of originator products
  Jo Pisani
  Partner
  Pricewaterhousecoopers

10:50  Attractiveness of next generation biosimilars or similar
- Latest advantages in biological research
- Examining the key dynamics of future biosimilars
  Rasmus Rojkjaer
  Vice-president, Head of Global Biologic
  Mylan

11:30  Morning refreshments

11:50  Biosimilars meeting the challenges & lessons learned
- Economic factors market potential
- Status of regulations EUR & USA
- Risks - biologics versus small molecule drugs
- Comparability - CMC Quality - Case studies
- Lessons learned
  Dr Frank Moffatt
  Product Manager Biopharmaceutical and DNA Analysis
  Solvias

12:30  EU legal framework for biosimilars
- Examining the legal basis for generics and biosimilars in the EU
- Specific guidelines for EU product
- Comparison of EU and US law on biosimilars
  Ray Cresswell
  VP R&D Legal Operations
  Glaxosmithkline

13:10  Networking lunch

14:30  Development of biosimilar medicines - intellectual property issues
  - Originator patent landscapes for biologicals
  - The importance of process patents
    - method of use patents
    - supplementary protection certificates
    - upcoming patent and SPC expiries
  Duncan Curley
  Director
  Innovate Legal

15:10  Emerging partnerships between Big Pharma and smaller biosimilars companies
  Ashish Menocha
  Head of International Markets
  Abdi Ibrahim

15:50  Afternoon refreshments

16:10  Differentiating between biosimilars and innovators’ biopharmaceutical products by their glycosylation patterns
  - How innovators and designers of biosimilars can enhance their drugs by engineering glycosylation
  - How designers of biosimilars can avoid infringing innovators’ patents that involve glycosylation
  - How to demonstrate comparability of glycosylation between different drugs
  - What potential buyers should consider regarding biopharmaceutical glycosylation when choosing between an innovator’s drug and biosimilars or follow-on biologics
  Dr. Daryl Fernandes
  Chief Executive
  Ludger

16:50  Biosimilar Erythropoietins - Challenge vs opportunity
  - Assessing the opportunities in biosimilar erythropoietins
  - Discussing the recent applications for biosimilar erythropoietins
  Dr David Goldsmith
  Consultant Nephrologist
  Guy’s Hospital and St Thomas’ NHS Foundation Hospital

17:30  Closing remarks from the chair

17:35  17:35 Networking Drinks
Take your discussions further and build new relationships in a relaxed and informal setting.
Day 2
5th Annual Biosimilars Conference
Wednesday 21st October 2009, London, UK

09:30 Registration and refreshments

10:00 Opening address from the chair

10:10 Analysing the global biosimilars market
- Identification of the most important biologic drugs with potential for commercial biosimilar development
- Examination of strengths, weaknesses, opportunities and threats facing major stakeholders in the industry

Mateja Urlep
Director, Tikhe Pharma
Former Global Head of Marketing and Medical, Sandoz

10:50 Use of bioassays for testing biosimilars
- Regulatory requirements for bioassays
- Logistical and scientific issues
- Why bioassays are particularly problematic
- Examples of bioassays used for approved biosimilars

Dr. C Jane Robinson
Principal Scientist, Biotherapeutics
National Institute for Biological Standards & Control

11:30 Morning refreshments

11:50 Presentation to be announced

Tommy Erdei
CFA, Executive Director, Healthcare Banking
UBS Investment Bank

12:30 Biosimilars: Applying EU lessons to new targets, new challenges in a global market
- Key lessons from the EU experience
- Is the prevailing view of biosimilarity too narrow?
- The challenges of monoclonal biosimilars
- Formulating a global biosimilar program
- Ingredients for success

Cecil Nick
Vice President (Biotechnology)
Parexel Consulting

13:10 Networking lunch

14:30 Biosimilars and pharmacovigilance
- The EMEA Biosimilar Pathway allows a submission with less clinical data compared to the originator - e.g. no Phase II data required
- The Pharmacovigilance Programme of a Biosimilar does not differ in complexity from an originator
- The Post Approval Commitments are a massive burden for the manufacturers of Biosimilars

Dr. Michael Muenzberg
Global Head of Medical Affairs
Sandoz International GmbH

15:10 All potential biosimilars are under threat from improved products
- Interferon alpha – longer dosing interval /improved activity/reduced side effects
- EPO – Cost of goods reduction
- Interferon beta – Cost of goods and as for alpha
- GCSF – A ready made biobetter

Keith Powell
CEO
Polytherics

15:50 Afternoon refreshments

16:10 Biosimilar, biobetter, biosuperior: how to differentiate follow-on biologicals with controlled release technology
- The added value of drug delivery technologies for follow-on biologicals
- What are the success factors for effective long-acting drug delivery?
- Phase II clinical proof of concept case study

Gerben Moolhuizen
Chief Business Officer
OctoPlus

16:30 Emerging biosimilars opportunities in Asia
- What are the challenges?
- What are the advantages of outsourcing the development of biosimilars?

Vinay Ranade
CEO
Reliance GeneMedix

17:30 Chair’s closing remarks

17:40 End of Conference
Conference title

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