This 15th Generics, Supergenerics and Patent conference will address the newest challenges and issues faced by the generics industry. With the patent cliff now upon us, generics companies are looking forward to a future with few blockbuster small molecule drugs to be imitated. There is a need for significant changes in the way many generics companies approach their business.

PLUS TWO HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 16th May 2012, The Copthorne Tara Hotel, London

Innovative Regulatory Strategies for Generics
Workshop leader: Maureen Graham, Managing Director & Regulatory Affairs Consultant, Diamond BioPharm Ltd
9.00am-12.30pm

Developing patent litigation strategies for EU markets
Workshop leader: Duncan Curley, Director, Innovate Legal
1.30pm-5.30pm
8.30 Registration and Coffee

9.00 Chairman’s opening remarks
Richard Dicicco, Chairman, Harvest Moon Pharmaceuticals

9.10 A Global Outlook for the Generics Industry: from Commodity to Value Added Generics
- An overview of global generics investments and the next level of development in generic drugs
- Trends and the future market environment – how will this hinder or enhance growth and profitability?
- What are the main opportunities and/or threats which are pushing entry into this intensely competitive industry?
- How will the industry change with increased competition faced by new entrants?
Richard Dicicco, Chairman, Harvest Moon Pharmaceuticals

9.50 A New Frontier: Commercialization of Super Generics
- What are super generics?
- What are the success stories?
- Strategic considerations for developing a value added generic
- Future potential for supergenerics
Deepak Murpani, Vice President, Product Development, GenePharm Group

10.30 Morning Coffee

11.00 Branded generics and emerging market- why all the fuss?
- Where are they?
- Where is the money?
- Untapped potential?
- What to do and when?
- Local market strategies?
Paul Mendelsohn, Managing Director, Pharmawise

11.40 Moving into new countries: European market profiling
- What makes a market attractive?
- Will your business model fit a new market?
- Risk management of forays into new regions
- Acquisition vs. Start up
Ewan Livesey, Senior Vice President Corporate Development, Country Manager Switzerland, Lupin (Europe) Ltd

12.20 Networking Lunch

1.50 How can smaller companies survive in the European generics industry?
- Pressures facing the generics industry
- Competitive advantages of small and large companies
- Opportunities for smaller organisations
- Outlook for the future of the European generics industry
Guy Clark, Director Business Development, Goldshield Group Limited

2.30 A future perspective of the UK generics market
- How long can the UK maintain the current levels of generic competition?
- What can companies who operate in the UK do to profit from this market?
- Forecasts for the future of the UK generics market
Rex Clements, Country Head UK, Sandoz Biopharmaceuticals

3.10 Afternoon Tea

3.40 Effects of Chinese companies entering European markets
- How will these moves impact the already saturated markets?
- What advantages to Chinese companies have that makes them believe they can succeed in foreign markets?
- Will Chinese companies look to partner with existing operations in Europe?
Douglas Andrews, CEO, Stravencon Ltd

4.20 European Generics Regulations
- Are simple generics simple?
- What are chemisimilars?
- The importance of assay sensitivity
- Trends for biosimilar guidance
John Warren, Director, Medicines Assessment Ltd

5.00 Chairman’s Closing Remarks and Close of Day One
Generics, Supergenerics and Patent Strategies
Day Two | Tuesday 15th May 2012

8.30 Re-registration and Coffee

9.00 Chairman’s opening remarks
Richard Dicicco, Chairman, Harvest Moon Pharmaceuticals

9.10 Assessment of the growing trend of big pharma moving into generics
• Why are innovators showing an active interest in the generics market?
• What are the obstacles that stand in their way?
• Is the model of big pharma suited to the generics industry?
• What effect will this movement into an already competitive market place have on existing generics companies?
Alan Sheppard, Global Head Generics, Thought Leadership, IMS Health

9.50 Can partnerships between big pharma and generics companies work?
• Procedural issues where management conventions clash
• What aspects of partnerships are the most valuable and how can they be enhanced?
• A look at the profiles of recent collaborations and what they have achieved
Yariv Hefez, Director Global Business Development & Alliance Management, Merck Serono International S.A.

10.30 Morning Coffee

11.00 Patent settlement agreements, a generic standpoint
• What are the relevant principles and potential pitfalls?
• How do recent developments affect how generics companies approach patent disputes in the future?
• What strategies are available to avoid concerns?
Sean-Paul Brankin, Partner, Crowel & Moring

11.40 Efficient European Regulatory Maintenance for Generics
• How to reduce the regulatory burden
• Strategic options and innovative approaches for variation submissions
• License and documentation organisation: A best practice guide
Nick Littlebury, Regulatory Affairs Manager, Diamond Pharma Services

12.20 Networking Lunch

1.50 An update on European case law
• What are the effects of recent changes to generics regulations
• Open healthcare reforms and their impact.
• Overview of recent litigation
Paul Csizsar, Director, European Commission

2.30 Recent developments in supplementary patent certificates
• What is the criteria for being awarded an SPC?
• What effect have recent IP and patent rulings had on the industry?
• A look at recent and ongoing cases
Duncan Curley, Director, Innate Legal

3.10 Afternoon Tea

3.40 Patent Strategies in view of Generic Landscape and changing legal landscape
• Session details to be confirmed
Aman Trehan, Deputy General Manager, Intellectual Property, Zydus Cadila Healthcare Ltd

4.20 Generics response to Big Pharma’s defensive moves
• An overview & case studies of legal, regulatory and marketing tactics employed by originators
• Employing well strategized legal and marketing moves to keep out the competition
• Generic evergreening – how do generic companies compete in the evergreening race?
Julie Barrett-Major, Director of Intellectual Property, Norgine Ltd

5.00 Chairman’s Closing Remarks and Close of Conference

Who should attend:
Chief Executives, Executive Directors, Vice Presidents, Heads, Senior Scientists, Team leaders of:
• Intellectual Property
• Regulatory Affairs
• Business Development
• Licensing
• Manufacturing

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Overview of workshop
This workshop will share knowledge of innovative regulatory strategies and provide practical advice of how they can be implemented in a generics organisation. Case studies and practical examples will be worked through demonstrating route to market strategies that ensure maximum value and speed to market. Competitive positioning strategies will also be discussed and these will include how to potentially use orphan designation to extend market exclusivity periods.

Reasons to attend:
• Understand innovative regulatory strategies to allow you to move your products forward in the most efficient way
• Practical advice through the use of case studies that can be applied for your organisation
• Understand the routes to market: MRP, DCP & Centralised procedural routes discussed and explained
• Understanding the routes to market strategy for generics: MRP, DCP & Centralised procedure.
• Creative regulatory strategies to extend market exclusivity for generic products: Including orphan designation in your strategy
• Competitive positioning fixed dose combination development products: Understanding the regulatory implications

Programme
9.00 Welcome and introductions
9.10 Understanding the routes to market strategy for generics: MRP, DCP & Centralised procedure
9.50 Creative regulatory strategies to extend market exclusivity for generic products: Including orphan designation in your strategy
10.40 Morning Coffee
11.10 Competitive positioning fixed dose combination development products: Understanding the regulatory implications
11.50 Discussion Session / Q&A
12.30 Close of workshop

About the workshop host
Maureen Graham, Managing Director & Regulatory Affairs Consultant, Diamond BioPharm Ltd
Dr. Graham has over 25 years’ experience within the pharmaceutical industry and has worked for several different companies including Glaxo, Merck & Co, IVAX and Amgen. Dr. Graham has held a number of Directorships including European Director of Regulatory Affairs at Amgen. Dr. Graham founded Diamond Pharma Services in 2005, which is a leading technical and scientific consulting group of companies serving the biotechnology and pharmaceutical industry. Dr. Graham has direct experience with many types of products including biotechnology, advanced therapies and chemical entities. Dr. Graham also has a wealth of experience and expertise when it comes to the regulatory and product development issues associated with generics.

About the organisation
Diamond Pharma Services is a leading technical and scientific consulting group with an emphasis on the following areas:
• Regulatory Affairs: Product Concept to Registration and Beyond
• Product Development: Nonclinical, CMC and Clinical Aspects
• Pharmacovigilance: Clinical trial (Phase I-IV), Post-Marketing and QPPV Services
• Compliance: GLP, GMP, GCP and QP Services

The organisation has extensive experience across European Regulatory Affairs including New Chemicals, Biotechnology, Advanced Therapy products and Generic products.
About the workshop

The aim of this Executive Briefing is to discuss patent litigation strategies as a means of securing market access for small molecule generic pharmaceutical products in EU markets. This briefing is aimed at manufacturers of generic pharmaceutical medicines who may be targeting products for development for European markets and who wish to learn more about litigation options, in order to leverage a first-to-market or unique position with respect to the existing IP landscape.

Benefits of attending – this Briefing will enable you:
• To gain insight into patent litigation in the EU
• To develop strategies for circumventing potential patent obstacles
• To understand innovator patent litigation tactics
• To discuss and exchange experiences with fellow professionals

Programme

1.30 Registration and Coffee
1.40 Welcome and Introduction
• Basic legal concepts  
  - novelty  
  - inventive step  
  - sufficiency  
  - added subject-matter
2.10 European Patent Office vs. the National Courts
• oppositions  
• litigation  
• timelines and costs
3.00 Morning coffee
3.20 Exploring novelty in detail
• anticipatory disclosure - documents  
• prior use
4.10 Exploring obviousness in detail
• Preparing an obviousness case  
• Choosing the prior art  
• Use of experts  
• Commercial success and other issues
4.40 Discussion and questions
5.20 Close of Executive Briefing

About the workshop host

Dr Duncan Curley is an English solicitor and the founder of Innovate Legal. He obtained his PhD in Medicinal Chemistry at University College, London in 1992. Duncan trained and qualified in the Intellectual Property department of a magic circle law firm in London, before becoming a partner in 2003 at a US law firm, where he specialised in pharmaceutical and biotech patent litigation. He formed the boutique patent law practice Innovate Legal in 2007. Duncan now principally advises on patent issues for companies operating in the generic pharmaceuticals sector.

About the organisation

Innovate Legal is a London-based law firm specialising in patents, intellectual property and litigation. The firm undertakes patent clearance and freedom to operate opinions and provides legal services to companies wishing to develop a patent strategy. Its lawyers are highly experienced dispute resolution specialists, operating from offices close to the Law Courts in London. Rather than operating according to rigid hourly rate billing arrangements, Innovate Legal can offer fixed fees and ‘success based’ billing for certain client projects. www.innovatelegal.co.uk

The firm’s website contains further information on intellectual property issues, as well free downloads of articles and other patent briefings.
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**Cancellation:** If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee less a £50 administration charge, providing that cancellation is made in writing and received at least 28 days prior to the start of the event. Regrettably cancellation after this time cannot be accepted. We will however provide the conference documentation via the Document Portal to any delegate who has paid but is unable to attend for any reason. Due to the interactive nature of the Briefings we are not normally able to provide documentation in these circumstances. We cannot accept cancellations of orders placed on the Document Portal less than 28 days prior to the start of the event. Substitutions will be allowed up to the day of the event. Substitutions will be allowed up to the day of the event. If a delegate has been registered for the event and their name does not appear on the list at the event, we will not accept any liability.

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