

New course

IP and the GENERICS INDUSTRY

Topics covered at this seminar:

- Why IP matters
- Differences between patent and data exclusivity
- Contrasts between Europe and the USA
- Patent types and their impact on generics
- Patent and SPCs
- How generic companies use IP
- Data exclusivity and registration
- EU pharmaceutical legislation

**5.5 CPD
HOURS**
SOLICITORS
REGULATION
AUTHORITY

Course Leader:

Peter Wittner

Interpharm Consultancy

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16 May 2014
The Rembrandt Hotel, London



AIMS OF THE COURSE

- This seminar will give an overview of the European generic market and the legal and regulatory environment in which it functions.
- Intellectual Property (IP) plays an extremely significant role in the generic world, but important matters such as patent issues and data exclusivity are often confused, even though there are significant differences between them.
- Generic companies are also increasingly aggressive in their use of patents against each other. Anyone who wants to make progress in the generic world needs to ensure that they have a good understanding of the basic issues, which this course is designed to provide.
- The legal and regulatory environment in which EU generic companies operate is very complicated, and it is important for those working in regulatory affairs to understand how the legal and Intellectual Property framework can have an impact on their own work.

Any misunderstanding of the mixture of factors that influence the time and speed of registration can lead to regulatory delays. These in turn can have an adverse impact on the launch of new products.

WHO SHOULD ATTEND

- Marketing, business development and sales personnel
- Regulatory personnel
- Production personnel
- IP/patent managers and engineers
- Managers involved with generics
- Directors of generic companies
- Legal advisers, executives and assistants
- Anyone involved with the effective development, regulation and marketing of generic products

DOCUMENTATION

Participants will receive a course material folder containing comprehensive documentation provided by the course leader, which will be a valuable source of reference for the future.

COURSE LEADER

Peter Wittner has worked in the pharmaceutical industry for over 35 years, of which the major part has been mainly in the area of generics. He worked for both the former Evans Medical and then Norton Pharmaceuticals (later part of IVAX) where he was responsible for European Sales & Marketing. After leaving Norton, Peter set up his own consultancy in 1993 and operated independently until 1996 when he joined the Indian company Ranbaxy to set up the infrastructure of their new UK subsidiary. After spending two years with them he returned to his consultancy work, and for the last 15 years he has been providing consultancy, market intelligence and training services, mostly to non-EU companies specialising in the field of generics.

Peter is a regular speaker at generic conferences and frequently runs training sessions for companies on a wide variety of topics relating to the generic industry and biosimilars.

Reserve your place at the course by registering online now at www.management-forum.co.uk or by fax +44 (0)1483 730008

Any questions? e-mail josephine.leak@management-forum.co.uk

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all **MANAGEMENT FORUM** seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

A Certificate of Attendance for Professional Development will be given to each participant who completes the course

PROGRAMME

09:30 ► Introductions and opening remarks

09:40 ► **IP, PATENTS AND DATA EXCLUSIVITY**

- **Overview - Why IP matters - an introduction**
 - Why IP matters to Big Pharma
 - Why IP matters to generics
 - Patent exclusivity and data exclusivity - aren't they the same?
- **The differences between patent and data exclusivity**
 - Definition of patent / SPC exclusivity periods
 - Explanation of data exclusivity
- **Contrasts between Europe and the USA - a quick look**
 - USA - Hatch Waxman Act 1984
 - Europe - Directive 2004/27/EC
 - Roche-Bolar (US) and Bolar Clause (EU)

11.00 ► Coffee

11.15 ► **PATENTS – A CLOSER LOOK**

- **Patent Types and their impact on generics**
 - Patent types - Molecule, synthesis, usage
 - The importance of priority - SmithKline Beecham vs Synthron (*Seroxat*)
 - SPCs - why do they exist, how do they alter expiry dates?
 - US patent system and US Patent extensions
- **Patents and SPCs**
 - Patent extensions in Europe and USA
 - Negative SPCs in the EU and paediatric exclusivity
 - Big Pharma and patent extensions - 'evergreening'
- **European Generic *Clopidogrel* launch ahead of patent expiry**
 - Will it set a trend?
 - How did it happen? Generic definition

12.30 ► Lunch

13.30 ► **MORE ABOUT PATENTS**

- **Some case studies - patent cases and SPC decisions**
 - AstraZeneca vs. Ratiopharm (*Nexium*)
 - Pfizer vs. Ranbaxy (*Lipitor*)
 - Medeva SPC - are combinations protected?
- **How generic companies use IP**
 - Generic vs Big Pharma - getting one step ahead
 - Generic vs Generic - blocking tactics
- **Patents and Biosimilars - a new jungle**
 - Submarine patents - a US problem
 - Antibody technology patents
- **The new Unitary European patent**
 - What was wrong with the previous system?
 - What has changed?

15.00 ► Tea

15.30 ► **DATA EXCLUSIVITY and EU LAW**

- **Data exclusivity and registration**
 - What does it mean?
 - Why does it exist?
 - Impact on registration
 - Possibility of overlap - data exclusivity after patent expiry
 - Registration of Biosimilars
- **EU Pharmaceutical legislation**
 - New EU legislation - Directive 2004/27/EU
 - Changes introduced - Data exclusivity, Bolar Clause, Definition of a generic, European Reference Product, Sunset Clause

16.30 ► **Closing Remarks and Questions/Answers**



IP and the GENERIC INDUSTRY



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16 May 2014
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Dates
16 May 2014
Start 09.30 – Finish 17.00

Registration & Coffee
16 May 2014 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
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Subject to availability, a limited number of bed-
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**All bookings should be made directly with the
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Directions
Opposite V&A Museum. Nearest underground
station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee
£575 + VAT if applicable. The fee includes
course documentation as well as mid-session
refreshments and lunch. Invoice and confirmation
will be forwarded to you.

Conference No. H5-3414

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Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee of
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For further information please contact **Robert Sinclair**
(email: robert@management-forum.co.uk)