



GENERIC MEDICINES A GLOBAL MARKET A GLOBAL INDUSTRY

Hotel Hilton
Prague - Czech Republic
28 - 29 - 30 June 2004



Sponsored by **ZENTIVA** and



OFFICIAL CARRIER



JUNE 27, 2004 • 09.00-17.00 • HOTEL HILTON, PRAGUE • CZECH REPUBLIC

STRATEGIC GENERIC DRUG DEVELOPMENT FOR THE UNITED STATES MARKET

This past year, laws and regulations relating to approval of generic drugs saw their most significant changes in almost 20 years. Added to this are the branded companies' continual efforts to take advantage of legal loopholes in efforts to keep generics at bay, and increasing inter-generic competition for exclusivities. In order to remain competitive (or become competitive) generic companies must understand recent changes in order to effectively predict and respond to the strategies of branded and generic companies. The prepared generic company should be able to actively use the legal system to its advantage.

This full-day seminar – now in its fourth year – is intended to provide generic companies with information and insights into strategies for new product introduction into the U.S. market. The interplay between patent and regulatory issues will be closely examined. Orange Book issues will be discussed as they apply to patent litigation, litigation avoidance, and long term planning, with an eye to not only gaining market entry, but also

responding to, and anticipating, strategies of branded companies. Also covered are recent developments and trends – judicial, legislative and regulatory – and possible future changes.

Topics to be Covered Include:

- The Orange Book and patent certification
- The Hatch-Waxman Amendments
- Recent changes to patent and FDA law
- Patent term extensions
- Marketing and information exclusivities
- Planning for strategies of rival brands and generics
- Developing pro-active generic strategies

The seminar is a lively, interactive meeting that presents information critical for generics. In order to maintain the informal atmosphere, **attendance is limited to 50 people.**

Last year's seminar sold out, so sign up early!

ABOUT THE SEMINAR FACULTY

• **Yehudah Livneh, Ph.D.**, is the Director of the Patent Department of Teva Pharmaceutical Industries, Ltd., and was formerly director of the patents at Biotechnology General (Israel) Ltd. Dr. Livneh is a registered Patent Attorney in Israel, and is registered to practice before the United States Patent and Trademark Office. He has a Ph.D. in Biochemistry from Brandeis University in the U.S. and a Bachelor of Science from The Hebrew University of Jerusalem, Israel. Dr. Livneh is the Chairman of the Intellectual Property Committee of the IGPA, on the editorial board of the *Journal of Generic Medicines*, and a member of the AIPPI. He played an active role in the passage of Hatch-Waxman type amendments to the Israeli Patent Law.

• **Neil F. Greenblum, Esq.**, founding partner at Greenblum & Bernstein, P.L.C., received a Bachelor of Science in Chemical Engineering from City College of New York, and a Juris Doctor degree from American University. He has been admitted to the Bar of the District of Columbia, the Bar of the Commonwealth of Virginia, is a member of the bar of the Court of Appeals for the Federal Circuit, and

is registered to practice before the United States Patent and Trademark Office. Mr. Greenblum advises generic pharmaceutical companies in all aspects of intellectual property, and is experienced with the special strategic, legal, and litigation aspects of patent law particular to generic pharmaceuticals. He is US Legal Update Editor of the *Journal of Generic Medicines*, and regularly lectures on U.S. litigation strategy and practice at the University of Strasbourg, France (CEIPI).

• **Paul A. Braier, Ph.D., Esq.**, associate at Greenblum & Bernstein, specializes in patent law, with emphasis in drug law and regulation as they relate to marketing and patent law, and frequently lectures on the subject for organizations and conferences. Dr. Braier received a Bachelor of Science in Chemistry with High Honors from the College of William and Mary, a Ph.D. in Chemistry from the University of Chicago, and a Juris Doctor degree from the Georgetown University Law Center. While at Georgetown University, Dr. Braier was a staff member of the *Journal of Legal Ethics*. Dr. Braier has been admitted to the Virginia State Bar and is registered to practice before the United States Patent and Trademark Office.

THE SEVENTH ANNUAL IGPA CONFERENCE

A MUST - ATTEND EVENT!

The IGPA conference has now become the single most important annual event for the global generic medicines industry. The seventh conference provides a unique opportunity for networking and for gaining the latest information on the commercial, regulatory and legal fields affecting our industry. Numerous ideas, findings and key people in the industry... all under one roof! In the magnificent city of Prague.

HERE IS HOW YOU WILL BENEFIT...

- You will gain an independent and accurate insight into critical markets, customers and competitors.
- You will receive the latest market and regulatory intelligence, enabling you to take full advantage of the opportunities emerging in the generic medicines industry.
- You can maintain and develop a network of industry contacts.
- And... you will return to your company informed and updated with new ideas to assure your competitiveness in the growing generic market.



Prague, the Žofín Palace

WHO SHOULD ATTEND

- CEO'S and senior management from the generic pharmaceutical industry
- Regulatory experts, patent lawyers, market specialists, and senior sales managers from generic companies worldwide
- Senior staff in Research & Development
- Corporate analysts, strategists and academics
- API manufacturers and suppliers
- Clinical Research Organizations



JUNE 28, 2004: MONDAY

10.00 - 12.00

Registration and pre-conference coffee

13.30 - 18.30

IGPA Pre-Plenary Sessions

13.30 - 15.45

Science and Regulatory Session

Chairman: **Mike Spino**

(President ApoPharma Inc)

- Key developments in the regulatory procedures for the registration and marketing of generic and Bio-similar medicines in the EU, USA, Canada, and India. Presentations by experts from EGA, GPhA, CGPA and IPA.
- Key developments at ICH affecting generic medicines - **Nick Cappucino** (IGPA Coordinator for ICH issues)
- Does the current level of science permit a proper comparison for establishing therapeutic equivalence for bio-similar products?

John Langstaff (President of Cangene Inc)

15.45 - 16.15

Coffee Break

16.15 - 18.30

Intellectual Property Session

Chairman: **Yehudah Livneh**

(Director of Patent Dept, TEVA)

- Regional Updates on IP Issues by IGPA Members USA, Canada, EU, India, (This covers data exclusivity,

18.30 - 20.00

Bolar, patent extensions, compulsory licences and IP enforcement). Presentations by experts from GPhA, EGA, CGPA and IPA.

- Recent Developments in PLT/SPLT and TRIPS **Rajeev Ranjan** (Director, Department of Industrial Policy & Promotion, Ministry of Commerce & Industry Government of India)
- Pharmaceutical Patents - An incentive to innovate or litigate - **Yehudah Livneh** and **Dilip Shah** (Secretary General IPA)

Welcome Cocktail Reception

sponsored by  NEWPORT

JUNE 29, 2004: TUESDAY

09.00 - 10.45

Opening of the Conference

Chairman: **Rory O'Riordan** (Chairman EGA)

- Welcome address by President of Czech Association of Pharmaceutical Companies
- Keynote speech by **Czech Ministry of Health**
- Operating as leading company in Central and Eastern European market - **Jiří Michal** (CEO Zentiva)
- Impact of EU Enlargement on generic companies **Gorazd Hladnik** (Chair EGA Accession Committee)

10.45 - 11.15

Coffee Break



11.15 - 13.00

Market Projections and Developments

Chairman: **Greg Perry** (EGA)

- A global view of the generic medicines market
Graham Lewis (Vice President IMS Health)
- USA - **Kathleen D. Jaeger** (President GPhA)
- EU - **Rory O'Riordan** (Chairman EGA)
- Canada - **Jim Keon** (President CGPA)
- India - **Dilip Shah** (Secretary General IPA)

13.00 - 14.30

Buffet Lunch

14.30 - 16.00

Market Projections and Developments

Chairman: **Jim Keon**

- China - **Susan Capie** (Principal Consultant, Pharma Vantage Consulting)
- Japan - Japan Generic Pharmaceutical Group (speaker TBA)
- Middle East - **Dr. Moh'd Fityani** (President, Jordanian Association of Manufacturers of Pharmaceuticals)
- Brazil - **Jorge Bermudez** (Director of the National School of Public Health)

16.00 - 16.30

Coffee Break

16.30 - 18.00

How market analysts view the future of generic medicines?

Chairman: **Dilip Shah**

- **Richard B. Silver** (Senior Vice President, Lehman Brothers)
Mergers & Acquisitions in the Generics Industry: the road towards globalisation of the sector
- **Tommy Erdei** (Vice President Health Care ABN AMRO Corporate Finance)

20.00 - 24.00

Conference Gala dinner at Žofin Palace
sponsored by **ZENTIVA**

JUNE 30, 2004: WEDNESDAY

09.00 - 10.45

New Frontiers for Generic Producer

Chair person: **Kathleen D. Jaeger**

- What future for Bio-comparable generics?
Paul Edwards (CEO Genemedix plc)
- Stepping into NCEs - **Mike Spino** (ApoPharma Inc)

10.45 - 11.15

Coffee Break

11.15 - 13.00

CEO Panel - Maximizing the future challenge and opportunities for the generic pharmaceutical industry

Chair person: **Greg Perry**

- **Claudio Albrecht** (CEO Ratiopharm)
- **H. F. Khorakiwala** (Chairman of Wockhard Group)

13.00



Close of Conference: Jim Keon



VENUE AND EVENTS

The conference is taking place at the Hilton Hotel Prague, Probezní 1, 186 00 Prague 8 (30 minutes drive from Prague Ruzyně Airport). Please view the hotel and its facilities by accessing their website at www.prague.hilton.com. The hotel boasts one of the city's largest Health Club & Spa. A variety of memorable sights including Prague castle and St Vitus Cathedral, Charles Bridge and the Old Town Square with its famous astronomical clock, are all within walking distance.

There will be extensive networking opportunities throughout the conference and during the following events:

- Pre-conference coffee from 10.00 to 12.00 on the 28th June
- A welcome cocktail reception on the 28th June at the Hilton Hotel. Sponsored by  NEWPORT
- An exclusive concert followed by a gala dinner on the 29th June at the lavish 19th century Žofín Palace located on the banks of the Vltava river just opposite Prague Castle. Sponsored by  ZENTIVA
- A farewell cocktail on the 30th June at the Hilton Hotel

EXHIBITION

Exhibition space is also available for registered Delegates. For cost, see **registration form**. Please contact Cristina Romagnoli (cristina@gpaconferences.com).

CONFERENCE DRESS CODE

Casual but smart for daytime engagements. Elegant for evening events, including gala dinner.



The Hilton Hotel

BOOK HOTEL NOW!

Hotel rooms and facilities at the Hilton Hotel Prague, 5 star rating, will be guaranteed for IGPA delegates until 30th April 2004 at a special price from € 170. So book now, by using the hotel group/convention code: GPA. Booking can be done via www.hilton.com page or via toll free call to reservation central:

- US bookings +1-800-774-1500
- EUROPE bookings + 800 44 45 86 67

For other hotels in the area, please contact:

- CSA Airtours by emailing Katerina.benesova@csa.cz.

FLIGHTS - CZECH AIRLINES OFFICIAL CARRIER

Please contact your Travel Agent or Czech Airlines Office and on presentation of a copy of the confirmation of your registration, Czech Airlines will apply a discount of 15% on the regular fare and 25% on the business fare (for the period 26th June to 1st July 2004 exclusively). For further information please consult their website at www.czechairlines.com

REGISTER NOW TO AVOID DISAPPOINTMENT AND PAY AFTER THE 1st OF MAY 2004 (IGPA 2003 WAS SOLD OUT ONE MONTH BEFORE THE CONFERENCE)

CONFERENCE REGISTRATION FORM to send back by fax at +39-02 66804297 or register on line on www.gpaconferences.com

CONFERENCE REGISTRATION FORM

Title: First Name: Family Name:

Company: Job title:

Company VAT No and/or Country:

Billing Address:

Postal Code: City: Country:

Tel: Fax N°:

Personal E-mail: Website:

Assistant E-mail: Names Invitee(s):

• **PRE-CONFERENCE SEMINAR (27 JUNE 04) – 50 places available only for IGPA Conference participants**

Please note the Seminar price is inclusive of coffee breaks & lunch

- I would like to register for the Sunday 27 June 04 Pre-Conference Seminar "Strategic Generic Drug Development for the United States Market" and I will pay € 580 (+ expected rate of 22% VAT*)

• **IGPA CONFERENCE (28 JUNE 04 – 30 JUNE 04)**

Please note all prices are inclusive of coffee breaks, buffet lunches, welcome cocktail & conference dinner on the 29 June 04

- My Company/Association is a DIRECT Member of CGPA or EGA or GPhA or IPA and will pay the IGPA Member Fee of € 1,599 (+ expected rate of 22% VAT*)
- My Company/Association is not a IGPA Member and I will pay the normal Non-Member Fee of € 1,899 (+ expected rate of 22% VAT*).
- I am registered for the conference and I would like to invite 1 2 3 people to join me for all the Buffet Lunches, Welcome Cocktail & Conference Dinners at a cost of € 350 per person (+ expected rate of 22% VAT*) - *This registration does not include entrance at the conference.*
- I am registered for the IGPA conference and I wish to apply for a table top in the conference area from the 28 June 04 to the 30 June 04
- Normal (height 3mt - width 2 mt -depth 1mt) for € 1,999 (+ expected rate of 22% VAT*)
- Extra (height 3mt - width 3 mt -depth 1mt) for € 2,499 (+ expected rate of 22% VAT*)

The two options will include both a table with 2 chairs.

Once you register your place will be reserved. After the 1st of May 2004 you will receive an invoice by e-mail which will ask you to pay within five days after receipt (after this date your reservation will be automatically released). Registrations close officially on the 1st June 2004 and they are also subject to availability.

PLEASE NOTE THAT THE ORGANISERS ARE NOT RESPONSIBLE FOR TRAVEL AND ACCOMMODATION BOOKING!

- Please tick here if you DON'T want to be contacted for our next events

Date and Place: Signature:

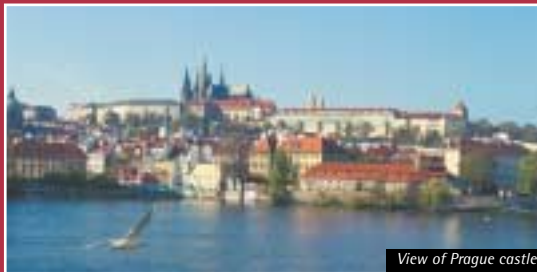
** The VAT rate is subject to changes, therefore it will be finalised by a new Czech VAT Act which will come into force on the 1st May 2004*

If you need any information please contact:
Cristina Romagnoli (cristina@gpaconferences.com) Tel/Fax: +39-02 66804297 or visit www.gpaconferences.com





THE SEVENTH ANNUAL IGPA CONFERENCE



View of Prague castle

THE ORGANISERS



THE SPONSORS



The updated Conference programme and the registration form can also be found on the Internet on www.gpaconferences.com