Don't miss our interactive post-conference workshop

Legally and Commercially Viable Responses to Generic Competition

20th January, Brussels Hilton, Belgium

08.30 Registration and coffee

I **Brief outline by the workshop leaders on the issues to be dealt with during the workshop and presentation of the case studies**

- how to ensure that you keep on top of the changes in the generics market to react in the most viable way
- establishing ground rules for communication between the registration, marketing and development department to guarantee the most efficient strategy for protecting the margins of your products

II **First case study**

Strategies for products which are still at a relatively early stage of patent protection

Dealing with data exclusivity

- tactics for coping with recent changes in favour of generic companies

SPCs

- setting up your first registration to maximise patent extension

reformulation/delivery technologies

- exploring options
- managing the introduction of a new system

establishing brand identity

- monitoring the generics market
- brand as a pricing factor

Lunch

III **Second case study**

Immediate pre-expiry strategies

Dealing with branding

- differentiation in a substitutable market
- maintaining a price premium without compromising safety

pricing

- managing the transition from monopoly to competition

packaging

- marketing v function

loyalty programmes

- design
- implementation
- monitoring effectiveness

IV **Review and conclusions**

16.30 Workshop closes

During this practical hands-on day you will develop a variety of strategies for dealing with generic competition, using case study material. Working in teams, you will put these strategies into practice and select the most valuable options for your company. Your workshop leaders will encourage cross-fertilisation of ideas and enrich debate, making best use of their vast experience in this field.

Your workshop leaders:

Lorna Brazell is *Senior IP Solicitor* at **Bird & Bird**. After graduating from Edinburgh University she spent several years in scientific research at Cambridge and obtained an LLM from King's College London. Lorna specialises in intellectual property & technology law, with particular expertise in patents and pharmaceutical matters generally. She speaks regularly on legal and procedural issues relating to intellectual property and contributes articles on developments in the law to a variety of publications.

Martin Paltnoi is *Principal Consultant* at **Martin Paltnoi Associates**. Martin advises the pharmaceutical and healthcare industries on an international level in the field of business intelligence. He is best known for work in pharmaceutical patent intelligence in which his consultancy has been involved since its inception in 1973. His clients range from small generic producers to large multi-national ethical drughouses and government agencies. An economic/statistician and professional market investigator by training, Martin first became involved with the industry as part of a small team created by IMS in 1959 to set up audits for the pharmaceutical industry and has remained associated with it ever since.

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NEW REPORT

Why not supplement what you will learn at this event with a brand new report from Vision in Business. "Competitive Intelligence in Pharmaceuticals: The Strategic Advantage", written by Douglas Bernhardt of the Business Research Group in Geneva and will cost £595. It will tell you how competitive intelligence is used to support both strategic and tactical decision -making within the pharmaceutical industry. It will provide both theoretical and practical frameworks necessary to develop competitive intelligence as a core capability of your firm. To purchase an advanced copy please call us on +44 (0) 207 256 5188 or fax this booking form making sure to tick the relevant box, on +44 (0) 207 256 5768

Date & Venue

The conference will take place on Tuesday 18th & Wednesday 19th January 2000 in Brussels. The workshop will take place on Thursday 20th January 2000. Both the conference and the workshop will take place at the Brussels Hilton, Boulevard de Waterloo 38, B-1000 Brussels, Belgium. Tel (+32) 2 504 1111 Fax (+32) 2 504 2111.

Fee

The fee for the 2-day conference is £999. The fee for the 1-day workshop is £599. The fee for all 3 days is £1,598. The fee for the report is £595.
Morning and afternoon refreshments, lunch and documentation as well as the Mussels in Brussels dinner are included in the price. Fees must be paid in advance.

How to Register

Send your registration form with a cheque made payable to Vision in Business Ltd at 30 City Road, London ECIY 2AY, or fax over the form on (+44) 207 256 5768. When we receive your registration and payment we will send confirmation, invoice or VAT receipt and map of the venue. Please note we require payment in advance. If you have not heard from us before the event, please call to ensure we've received the booking.

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Hotel

To book your reduced rate hotel accommodation contact Brussels Hilton, stating that you are a Vision in Business Delegate. Brussels Hilton, Boulevard de Waterloo 38, B-1000 Brussels, Belgium. Tel (+32) 2 504 1111 Fax (+32) 2 504 2111.

Documentation

If you wish to receive a copy of the documentation but cannot attend the conference send £295 + VAT (£346.63) for UK purchasers. All delegates receive a free copy. To order, call our Customer Services on (+44) 207 256 5188 or return the registration form marked Documentation Only.

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Legal and Commercial Strategies for Combating Generic Competition

Tuesday 18th and Wednesday 19th January 2000
Brussels Hilton, Belgium

Protect your research margins

- patent and IP protection strategies to extend your products market exclusivity
- extended data exclusivity to delay generic competition
- outcome and impact of the most important cases on generic competition in Europe
- commercial tips and tricks to minimise the impact of generics on your bottom line: registration, pricing, loyalty schemes and branding
- concrete information about generic regulation and reimbursement in the European countries

Plus . . . Post-conference workshop

One day interactive session

Legal and Commercially Viable Responses to Generic Competition

Conducted by Bird & Bird and Martin Paltnoi Associates
Thursday 20th January 2000
Brussels Hilton, Belgium

Our expert panel:

AstraZeneca
Bayer
Sanofi-Synthelabo
Dr. Michael Burstall
Asta Medica
G. Pohl-Boskamp
Donald Macarthur
Bird & Bird
Baker & McKenzie
Martin Paltnoi Associates
Lovell White Durrant
German Association of Research Based Pharmaceutical Companies (VFA)
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PricewaterhouseCoopers
Cambridge Pharma Consultancy
European Generics Association (EGA)

Official Publications:

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Tuesday 18th January 2000

CHAIRMAN: **Dr. Michael L. Burstall**
CONSULTANT

8.00 Registration and coffee

8.30 Opening remarks by the chair

8.45 **Quantifying the economic aspects of generics in Europe - how does the increased competition from generic drugs affect healthcare and research spending?**

- analysing the European generic market in terms of
  - value – volume – expected growth
- comparing the European generic market with the USA and Japan
- countries which have been affected
  - Germany – Netherlands – UK
- areas for potential growth
  - France – Italy – Spain
- therapeutic areas which have been most affected
  - anti-infectives – CNS – cardiovascular
  - which areas have not been affected and why?
- assessing the factors that promote the use of generics
  - the role of public healthcare systems in Europe
  - the way healthcare systems promote the use of generic - why some succeed and others don't
  - how the USA is moving in the same direction
- the industry's standpoint: how has the use of generics reduced income and profits?
  - calculating the present impact
  - which countries have been most affected
  - which companies are most at risk?
  - to what extent have funds for R&D been affected?
- the standpoint of public health care systems: how has the use of generics reduced public spending on drugs?
  - evidence for savings analysed in the context of health care spending as a whole
  - investigating why public systems are under increasing pressure to restrain expenditure and why every penny counts
  - rising interest in pharmacoeconomic evaluation and its potential impact
- the standpoint of the consumer: what are the gains and losses from the use of generics?
  - reduced tax/insurance contributions vs reduced access to the latest drugs
- could generics take over the European market?
  - is the majority of consumption being out-of-patent drugs likely to continue?
  - what impact is the wave of patent expiries from 2000 onwards going to have?
  - will the pace of innovation on which generic use depend change in the future?
  - is the increased use of generics a self-fulfilling prophecy?

Dr. Michael L. Burstall
CONSULTANT

9.30 **The future of generics and reference pricing in Europe and its implications for the industry**

- analysing the attractiveness of generics and reference pricing
  - pressure on the governments to reduce pharmaceutical expenditure
- why haven't the apparent benefits of such policies been achieved in practice?
- discussing the disadvantages of policies to encourage the use of generics and reference pricing
  - for patients
  - for payers
  - for the pharmaceutical industry, both branded and generic
- what further measures are governments likely to take to reduce costs in addition to keeping up the pressure to increase generic use?
- what will this mean for the research-based pharmaceutical industry?

Jim Furniss
Management Consultant
CAMBRIDGE PHARMA CONSULTANCY

10.15 Morning tea and coffee

10.35 **Regulation and Market Development of Generics in the United Kingdom**

- drivers for generic use
- leading players and levels of generic penetration
- how the drug tariff and clawback systems operate
- brand equalisation deals and other counter strategies by innovators
- the generic patient debacle

Donald Macarthur
CONSULTANT

11.20 **Regulation and market development of generics in Germany**

- legal framework for the registration of generics
  - "reference registration" (Bezugnehmende Zulassung)
- rules of generic substitution
  - legislation (SGB V)
  - objectives of pharmacists and sickfunds
- development of the generics market in Germany and implications for the future of the research based pharmaceutical industry in Germany
  - research budget
  - pricing of innovations
  - change in product lifecycle

Wilhelm Hollenhorst
Special Adviser, Healthcare System Development
VERBAND FORSCHENDER ARZNEIMITTELHERSTELLER - GERMAN ASSOCIATION OF RESEARCH BASED PHARMACEUTICAL COMPANIES

12.05 **Impact of CEE accession on research based companies and generic competition**

- how will our IP be protected?
  - patents
  - trademarks
- will there be an export ban on generics until the patent situation has been solved?
- will CEE companies have to adapt GCP and GMP guidelines before the entry and will that have any consequences for pharmaceutical companies in Europe?
- will there be non-tarif barriers for international companies in CEE?
- prospects for a safeguard measure in the Accession Treaty
  - estimating a timeframe
  - what kind of interim solutions will be implemented if any and to what effect?
  - examples of previous safeguards on accession

Simon Harper
Senior Assistant Solicitor
LOVELL WHITE DURRANT

12.50 Lunch

14.00 **Analysing your most promising strategies to exploit and extend patent protection in Europe**

- Roche Bolar exemption - the status in Europe
- evaluating the scope of the experimental use exemption in Europe
- to what extent does application for regulatory approval constitute infringement of patent?
- assessing patent law development and its effect on pharmaceutical products
  - follow-up to the Green Paper on patents
  - revision of the European Patent Convention
  - implementation of the biotechnology directive
- clarifying the impact of the SKB v Generics BV case
  - importation of compound/sample for a clinical trial before end of patent protection is judged as infringement in the Netherlands
- comparing the situation with other European countries and addressing the question whether this makes the Netherlands a particularly good rapport country for your product registration
- revision of the TRIPS Agreement, Grace Period and Exhaustion

Stephen Jones
Partner
BAKER & MCKENZIE

14.45 **Development and registration strategies which give advantage to your branded products over generic competition**

- analysing strategies which have been used in the past and present to protect branded products
  - what can we learn out of the successful ones and the failures?
- potential approaches (with practical examples)
  - pharmaceutical developments - modified bioavailability, dosage form, patent protected pharmaceutical innovations (examples: glibenclamide, nifedipine)
  - modification of active ingredient (active metabolite, single isomer)
  - enhanced bioequivalence standards - definition of relevant metabolites (example: tramadol)
  - complexity of the product - definition of active principle (examples: herbal extracts, conjugated estrogens)
  - influencing pharmacopoeal monographs
  - protection by specific manufacturing technologies or assays
  - clinical developments - new indications linked with new pharmaceutical formulations, extension of patient population (children, elderly)
- defining the parameters with which I want to protect my product
  - how can I establish differences / identify modifications early enough to protect my product
  - defining optimised time schedules to implement my protective measures
- how does the European Mutual Recognition Procedure work and where are problems for generic products
  - definition of a reference product
  - Mutual Recognition of bioequivalence studies
  - harmonised European SmPCs
- analysing the impact of the European Commission's communication on authorisation procedures
  - will there be an obligation to follow the registration procedure of the reference product?
- how will ICH-developments and guidelines impact on the registration of generics?
- specific regional measures to influence market exclusivity
  - extensions of therapeutic use (US)
- do orphan drug regulations provide potential tools to protect successful products?

Horst Kastrup
Head of Drug Regulatory Affairs
ASTA MEDICA

15.45 Afternoon tea and coffee

16.05 **A viewpoint from the generic pharmaceutical industry**

- counter strategies to boost generics
- patent issues, SPCs and data exclusivity
- what is the generics' role in generating headroom for innovation?
- pricing and reimbursement
- areas of co-operation and mutual interest

Greg Perry
Director General
EUROPEAN GENERICS ASSOCIATION (EGA)

16.50 **Debating legal and commercial options to manage generic competition and its impact on pharmaceutical companies**

PANEL DISCUSSION

Greg Perry
Director General
EUROPEAN GENERICS ASSOCIATION (EGA)

Horst Kastrup
Head of Drug Regulatory Affairs
ASTA MEDICA

This programme is correct at the time of going to press. We reserve the right, however, to alter or cancel the event due to circumstances beyond our control.

Wilhelm Hollenhorst
Special Adviser, Healthcare System Development
VERBAND FORSCHENDER ARZNEIMITTELHERSTELLER - GERMAN ASSOCIATION OF RESEARCH BASED PHARMACEUTICAL COMPANIES

Stephen Jones
Partner
BAKER & MCKENZIE

Donald Macarthur
CONSULTANT

If you have sensitive questions to submit confidentially to our expert panel, please fax them to Sabine Roettgen on (+44) 207 256 9393.

17.20 Closing remarks by the chair

17.35 End of day one

Please join us for a

'Mussels in Brussels'

dinner this evening sponsored by Vision in Business.

You will enjoy a superb dinner in a relaxed and informal atmosphere enabling you to socialise and network with speakers and delegates and ask any remaining questions from the day.

Wednesday 19th January 2000

CHAIRMAN: Dr Gordon Wright
Director, Intellectual Property
SANOFI-SYNTHELABO

8.30 Registration and coffee

9.00 Opening remarks by the chair

9.15 **Maximising the benefits of data exclusivity to defend your product successfully**
- Article 4.8 (a) of Directive 65/65: the abridged procedures
- transformation of Article 4.8 (a) of Directive 65/65 into national laws
- ECJ judgement Norgine/Scotia: possibility of literature applications
- ECJ judgement Generics (UK) Ltd / Squibb & Sons: essential similarity
- what options do companies have to defend data exclusivity after expiry of 6/10 year period?
- combination with other IP rights

Dr Christoph Hiltl
Partner
BOESEBECK & DROSTE

10.00 **New Zealand today, Europe tomorrow? - The New Zealand Generics Programme**
- reviewing the New Zealand healthcare system to date, drawing parallels to European systems
- analysing the details of the New Zealand Generics Programme and its implication for research companies
  - government tenders for 'replacement products'
  - registration for these replacement products strongly supported and simplified
  - sole supplier or preferred supplier system
  - original products struck off reimbursement list
- what options do research companies have to respond to a system like the New Zealand Generics Programme?
  - bringing your case to the regulatory authorities
  - litigation
  - severe price cuts
- is the New Zealand system an exception to the rule or are we soon facing more of these schemes?

Gisela Brinkmeier
Director, International Marketing
G. POHL-BOSKAMP

10.45 Morning coffee and tea

11.05 **Defensive pricing strategies to limit damage from generic competition - is there a way that industry can leverage brand value**
- what are the advantages and disadvantages of generics vs branded products from the government, pharmacist, patient point of view?
  - assessing the balance of price and value-to-customer
- exploring branded vs generic drugs from a health authority point of view in
  - primary care
  - secondary care
- how an understanding of the health authority structure can improve the relationship with research based companies
- improving relationships with health insurance companies and regulatory authorities
- assessing the role of pricing in the context of the competitive advantage of generics vs branded products
- how effective are early entry strategies in combination with price cuts?

Dr Jim Attridge
Government & Economic Affairs
ASTRAZENECA

11.50 **Pros and cons of entering into the generics market**
- what are the benefits in terms of
  - market share
  - value
  - product identity?
- calculating the difference an entry into generics would make to your bottom line
- what legal aspects are involved?
- how important is the timing?
- analysing your product portfolio
  - does it cover the potential for generics?
  - do you limit yourself to generic versions of your own products or do you produce generic versions of other company's products as well?
  - how will that impact on your branded products?
- what are the requirements and needs of a successful generics business?
- how can you incorporate a generics business into your branded company image?
  - overcoming internal resistance and rivalry
  - convincing your brand customers
- should the generic part feature under the same company name?
  - what are the possibilities for opting out under a different name?
- how do you decide your geographic position?
- which factors do you take into account?

Norbert Bangert
Manager Generics
BAYER

12.35 Lunch for delegates and speakers

13.45 **Analysing the latest developments in US regulation of generics and their effects in Europe**
- bioequivalence issues
  - locally acting drugs
  - average versus individual bioequivalence
  - complex drugs
  - rDNA and other biotechnology products
- impact of Food and Drug Administration Modernisation Act
- changes in regulation of generic antibiotics
- 180-day generic exclusivity
- possible changes in regulation of me-too biological products
- manufacturing and control requirements
  - scale-up
  - impurities
  - stability
- effect of US-EC Mutual Recognition Agreement on GMP inspections in Europe and the United States

Richard Kingham
Managing Partner
COVINGTON & BURLING LONDON

14.30 **Clarifying the impact of the Farmitalia Carlo Erba v German patent office and BASF cases on Supplementary Protection Certificates**
- clarifying the current status of SPC regulation in light of the cases
- SPC coverage:
  - patent claims or market authorisation?
  - protection for:
    - second indications
    - new formulations
  - measures to secure more than one SPC
- what constitutes first marketing authorisation?
- minimising the problems arising from SPC differences across Europe
- the effect of the SPC Regulations on:
  - patenting strategy
    - licensing strategy
- the Liechtenstein question

Lorna Brazell
Senior IP Solicitor
BIRD & BIRD

15.15 **Devising the most appropriate marketing strategies to increase the margin of your branded products and succeed in the emerging new marketplace**
- understanding the drivers for change
  - scientific development
  - development of technology
  - increasing consumer empowerment
  - impact of information technology
- implications for the pharmaceutical industry
  - analysing the potential of a new business model
  - acknowledging the need for responding to the new market place
- introducing new competencies
  - using individualised market intelligence
  - redefining product and service development
  - making use of new tools and techniques available in the changed environment
  - analysing the use of portfolio power
- branding and loyalty schemes
- a pragmatic approach to secure your company's competitiveness and position in the new market place

Paul Jones
Principal Consultant
PRICEWATERHOUSECOOPERS

16.00 Closing remarks by the chair

16.15 Join us for tea and coffee to review the findings of the conference

16.35 End of the conference

$15 billion worth of sales in jeopardy

due to loss of patent protection over the next two years

Generic competition is stunting growth and competitiveness of the European pharmaceutical industry.
Are you sure you are doing all you can to defend your profits?

Explore the most effective options for reacting against generic competition

This event offers straight answers and frank discussion in two action packed days - exclusively designed to meet the needs of pharmaceutical manufacturers and their representatives.
Key industry speakers and industry's legal representatives will discuss the key issues and cases as well as revealing legal, ethical, commercially viable solutions to combat generic competition, including:

- data exclusivity
- definition of essential similarity
- SPCs and patent exploitation strategies
- pricing
- the best marketing methods
- development and registration strategies
- and the application of recent judgements and pending cases on your company's situation

Do you have sensitive questions for our expert panel?

You asked for real life examples and the possibility to question people about their experience.
We give you the chance to submit your questions to them in advance and can guarantee complete anonymity should you wish that. Your questions will then be discussed during the panel session with representatives from the industry. If you would like to submit confidential questions, please fax them to Sabine Roettgen on +44 207 256 9393.