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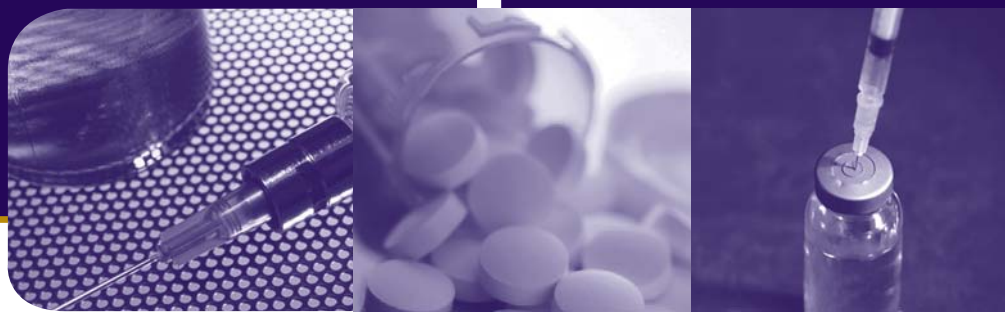
"Conference provided overview on FTO-related issues. To me, such an overview was unprecedented" *Franky Terras,* **Innogenetics (Freedom to Operate, February 2006)**

"Good balance in the range of issues addressed and the depth in which each was discussed" *Dr Richie Paul,* **Elan Pharma International Ltd (Freedom to Operate, Summer Edition 2006)**

5th International

Freedom to Operate Forum



Analysis, Opinion Writing, and Strategies for Minimising Risk in the Pharmaceutical and Biotech Industries

10 & 11 June 2008 • Millennium Hotel Knightsbridge, London, UK

Hear from the experts, including:

UCB, S.A.
Stratagem IPM
Fitzpatrick, Cella, Harper & Scinto
Lovells
Bird & Bird
Bristows
Squire Sanders & Dempsey L.L.P
Elkington & Fife LLP
Ablynx N.V.
Prosidion
Wragge & Co
Powell Gilbert
Jones Day
Dechert LLP
Edwards Angell Palmer & Dodge LLP
Vossius & Partner

Top patent practitioners and experienced in-house counsel will cut through the complexities of:

- Landscaping, FTO searching and competitor analyses
- Risk evaluation and claim interpretation, focusing on best practices
- How the latest EPO and European national case law on validity could impact your assessment
- Supplementary protection certificates and how they will affect your FTO assessment
- How the latest legal & regulatory developments will affect your freedom to operate
- Potential blocking patents and how they are best addressed
- Strategies for licensing your way out of trouble
- The role of FTO in M&A's and what you need to do to prepare
- Privilege and confidentiality in FTO opinions: when are they preserved and when are they waived?
- The disputes and infringement issues that may impact your FTO

Attend the Practical, Interactive Post-Conference Master Class on

Drafting a Legally Sound Opinion on Invalidity and Non-Infringement – US and European Perspectives

Conference Chairs

Allen Norris
Vice-President, Head Group IP
UCB, S.A.

Penny Gilbert
Partner,
Bristows

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With millions of future euros, dollars, pounds and yen at stake, and the constant threat of litigation, it is absolutely critical that patent counsel and executives for pharmaceutical, biotech and chemical companies and their advisors, have the tools and knowledge they need to make a sound and competent freedom to operate determination.

Just how do you correctly determine if you truly have freedom to operate in a given area of research?

Building on the success of our previous events in London and Munich, **C5** is proud to present the **5th International Freedom to Operate forum**. This event will bring together an outstanding faculty of leading in-house counsel and expert attorneys to share important information on the latest developments in your industry.

They will provide you with practical information and insights from their own experiences on:

- Devising an effective search strategy and evaluating the output
- Construing the claims of the third party patents that you find
- The latest legal & regulatory developments both in Europe and the US
- How supplementary protection certificates will affect your FTO
- The role of FTO in M&A's: what you need to do to prepare?
- What communications subject to an FTO opinion remain confidential: both US and European perspectives
- The major disputes and infringement issues that may impact your FTO

You cannot afford to miss out on this **C5** event – proven to be the best Freedom to Operate forum on the market today.

You will also benefit from:

- an industry discussion on how best to address blocking patents; and
- our Post-Conference Master Class on Drafting a Legally Sound Opinion on Invalidity and Non-Infringement. This in-depth master class offering both European and US perspectives will give you practical and tactical advice for drafting opinions that will provide well-reasoned legal analysis within the context of freedom to operate.

If you have ever attended our past events, you will know that this event is the **Freedom to Operate** event.

Take this opportunity to hear from and network with your colleagues and industry leaders at the fantastic **Millennium Knightsbridge Hotel** in **London on 10 & 11 June 2008.**

Meet the speakers including:

Penny Gilbert
Founding Partner, Powell Gilbert

Patrick Duxbury
Partner, Wragge & Co (UK)

Trevor Cook
Partner, Bird & Bird

Marie Manley
Partner, Bristows (UK)

Kathleen Madden Williams, Ph.d, JD
Chair of Life Sciences Practice and Partner, Edwards Angell Palmer & Dodge LLP (Boston, MA)

WHO SHOULD ATTEND

In-house Patent Counsel at Pharmaceutical, Biotech and Chemical Companies

Patent Attorneys

Patent Agents

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TUESDAY 10 JUNE 2008

8.00 Registration and Coffee

9.00 Chair's Opening Remarks

Allen Norris
Vice-President, Head Group IP, UCB, S.A.

9.10 Comprehending Landscaping, FTO Searching and Competitor Analyses

Nicola Baker-Munton
Chief Executive Officer, Stratagem IPM

Sarah Boxall
Senior Patent Attorney, Stratagem IPM

- Focusing your objectives on acquiring competitive intelligence and determining whether you have FTO
- Setting search strategies: the key questions and other considerations
  - defining the product or service
  - setting the parameters of the search
  - which databases should you use?
  - what does the attorney really need?
  - what information must be considered?
- Analysing the search
  - what should be kept in and what discarded?
  - how to effectively mine the output?
  - dealing effectively with geography, language and dates
  - what are the limitations of the search?
- What is prior art and how do you analyse it effectively?
- The what, when and how of monitoring
- Costs: budget and time frame considerations
  - how can you keep down your costs and speed up time?
  - research outsourcing: how to ensure you do this successfully
- Outcomes: reporting, storing and retrieving data from the searches

9.50 Best Practices for Evaluating Your Infringement Risk and Interpreting the Claims

Raymond Mandra
Partner, Fitzpatrick, Cella, Harper & Scinto (US)

Bert Oosting
Partner, Lovells (Netherlands)

- How do you interpret the claims of third party patents that you find?
- What are the national positions on claim construction in Germany, France, the UK and US?
- Analysing the changing practice of the USPTO and EPO when it comes to (overly) broad claims and/or claims that cover future embodiments
- What are the current positions on "equivalence" and "purposive construction" in Europe?
- Assessing the relevance of prosecution history and opposition proceedings for claim interpretation
- Evaluating the revision of the Protocol on Article 69 EPC and its impact on the doctrine of equivalents
- Evaluating the impact of EPC 2000
- The ab initio effect of Central EPO-Post-Grant amendments

10.40 Morning Refreshments

11.00 Accounting for the Latest EPO and European National Case Law on Validity in Your Assessment

Trevor Cook
Partner, Bird & Bird

- Identifying the areas of difference between the EPO and national jurisdictions
- Comparing the liberal German approach to novelty to the photographic approach
- Questioning whether the UK has come back in line on inventive step
- Exploring the UK attachment to insufficiency
- Evaluating the EPO's attempts at bringing national jurisdictions into line on medical use claims
- Assessing the impact of recent high profile controversies
  - Lundbeck Escitalopram
  - Merck Alendronate

11.45 Discovering How the Latest Regulatory Developments Will Affect Your Freedom to Operate

FOCUS ON EUROPE
Regulatory Data Protection and the "Bolar-type provision" in the EU Legal Framework

Marie Manley
Partner, Bristows (UK)

- Assessing the extent to which Regulatory Data Protection (RDP) is an obstacle to your freedom to operate
  - what does RDP add to patent protection?
  - what is the scope of the "global marketing authorization concept"?
  - recent relevant cases and upcoming issues examined
- Analysing the effectiveness of the measures being taken for the implementation of the Paediatric Regulation
- The "carve-out" provision: why does it make it easier for generics to enter the market?
- Examining the scope and effect of the "Bolar-type provision"
  - is it merely confined to generic applications or does it have a wider application?
  - what types of studies are covered?
  - how is it being implemented throughout Europe and what problems have emerged?

FOCUS ON THE US
Research Patent Exemptions, Patent Term Extensions, Patent Linkage, and Non-Patent Market Exclusivity

Cameron Kerrigan
Partner, Squire Sanders & Dempsey L.L.P

- What vehicles exist for generic competition in the US market and how do they operate?
- What non-patent market exclusivity is available under US law?
  - 5-year data exclusivity
  - 3-year market exclusivity
  - Orphan Drug exclusivity
  - Pediatric study exclusivity
- How does patent linkage work in the US?
  - "Patent listing"
  - 30-month delays in product approval linked to patent infringement litigation
- Update on the exemption for the use of products for research
- What is covered by a patent term extension granted to compensate for delays in the FDA approval process?

1.00 Lunch

2.15 Repositioning FTO Strategies in Light of Recent Changes in SPC Law

Gordon Wright
Partner, Elkington & Fife LLP

- Attempts to protect an old active ingredient under the SPC regulations
  - the ECJ ruling in the MIT case
  - the Yissum case on the definition of product
- Other controversies on aspects of SPC law, including the references to the ECJ in Health Research and in AHP Manufacturing
- Impact of the Paediatric Regulations on SPCs
- Current debate on whether the patent term extension afforded by an SPC is adequate or whether should it be extended?

- SPC provisions in different jurisdictions and the new member states
  - consideration of the implementation of SPCs in the new accession countries
  - practical difficulties of SPCs in "new" Europe

2.45 Discovering How Potential Blocking Patents Are Best Addressed

Allen Norris
Vice-President, Head Group IP, UCB, S.A.

Frank Landolt
IP and Legal Counsel, Ablynx N.V.

Alison Blakey
Patent Counsel & Director of Intellectual Property, Prosidion Limited

- Knowing when you are faced with a "potentially relevant" patent
  - who should you consult?
- What strategies can you adopt to deal with the risks stemming from pending applications?
- What should you be looking for in your searches
  - avoiding "getting lost in the paper"
  - leading examples of infringing "prior art"
- Questioning what you can do if the patent is blocking
  - oppositions and third party observations
  - designing around
  - making the case for invalidity
  - contractual options
  - licensing or purchasing the patent (see later session for more detail)
  - collaborative agreements
- When should you ask for a supplemental search?
- What are the problems associated with supply and other collaborative agreements and how can you overcome them?
  - is generic entry being prevented, and, if so, what are the competition law considerations you should bear in mind?
- Assessing the impact of the recent clamp-down by the USPTO and EPO on (overly) broad claims and/or claims that cover future embodiments
  - will patent applications that contain such claims be granted?
  - to what extent will such applications lead to "blocking patents" in the future?

3.45 Afternoon Refreshments

4.00 How Freedom to Operate Licensing Can Be Used to Clear Your Developmental Path

Patrick Duxbury
Partner, Wragge & Co (UK)

- At what stage should you consider taking a licence?
  - what are the pros and cons of early/late stage licensing in the context of blocking patents
- How an option to licence can be used to circumvent your problem
- What are the key competition issues you should be aware of?
  - how is the technology transfer block exemption likely to impact your licence?
- How actual and potential litigation can be resolved through cross-licensing

4.45 Chair's Closing Remarks and Conference Adjourns

WEDNESDAY 11 JUNE 2008

8.30 Coffee

9.00 Chair's Opening Remarks

Penny Gilbert
Founding Partner, Powell Gilbert

9.15 Where is Privilege and Confidentiality in FTO Opinions Preserved and When is it Waived?

Neil Coulson
Of Counsel, Jones Day (London)

Daniel M. Becker, M.D.
Partner, Dechert LLP

- The Seagate change in "willfulness" opinions
- Distinguishing FTO and non-infringement/invalidity ("willfulness") opinions
- What communications subject to a freedom to operate opinion remain confidential?
  - communications with R&D
  - communications with outside counsel
  - litigation v opinion counsel
- Privilege waiver: what can we learn from a review of the recent case law on the scope of waiver?
- Damage control: how to minimise what needs to be produced in litigation?
- What of multiple party privilege/confidentiality issues?
  - collaborations
  - joint defence agreements
- What are the main jurisdictional differences between the US, Europe, Japan and China?

10.15 Morning Refreshments

10.35 Pinpointing the FTO Considerations Involved and the Preparatory Steps to Take Prior to an M&A

Kathleen Madden Williams, Ph.d, JD
Chair of Life Sciences Practice and Partner, Edwards Angell Palmer & Dodge LLP (Boston, MA)

Dr Joachim Wachenfeld
Partner, Vossius & Partner (Germany)

- Asking the right questions: what is the target co's own IP and can it exclude others in the market place?
  - weighting the target co's IP
  - how to use effective search parameters and strategies
  - how to assess the validity of a co's IP
- How much effort should you put into FTO and does the timing of the deal permit an effective FTO?
- Don't forget about:
  - compounds, compositions, methods of treatment and use claims
  - screening assays
  - reach through claims
- Critical forget-me-nots:
  - does the company own its patents?
  - critical differences of ownership issues in the US and Europe
- Important recent case law from the US and Europe
- Dissecting a real deal:
  - how does IP fit into the deal?
  - working effectively with the deal team to add value

11.35 Highlighting the Disputes and Infringement Issues That May Impact Your FTO

Bert Oosting
Partner, Lovells (Netherlands)

Morag Macdonald
Partner, Bird & Bird

Kenneth R. Adamo
Partner, Jones Day

- What has brought about the European Commission's investigation into competition practices in the EU's pharmaceutical sector?
- Are companies misusing the patent system in order to exclude potential competition?

- if so, how are they doing so?
- how is a "patent minefield" created and how far can you go?

- What is the downside if you get your risk assessment wrong?
- What remedies are available to a patentee (and infringement proceedings)?
  - what is the latest on cross-border injunctions
- Damages, lost profits, reasonable royalties
  - in what circumstances can treble damages in the US still be incurred?
  - are damages and lost profits/reasonable royalties possible?
  - is there a punitive element to the award of damages in Europe?
- What if the infringement involves a research tool?
  - could you be liable for reach-through royalties?
- How do freedom to operate opinions affect liability and damages?

12.45 Lunch (for Master Class Attendees)

Post-Conference Master Class
2.00pm – 5.30pm

Drafting a Legally Sound Opinion on Invalidity and Non-Infringement – US and European Perspectives

Ralph A. Loren
Partner, Edwards Angell Palmer & Dodge

Elizabeth N. Spar, Ph.D.
Technology Specialist, Edwards Angell Palmer & Dodge

Frank Landolt
IP and Legal Counsel, Ablynx N.V.

Opinions of counsel take many forms and are prepared for a variety of different purposes. In the context of freedom to operate, the two most common opinions relate to non-infringement and invalidity. Each of these opinion forms has, as its basic purpose, to provide the client with a reasoned legal analysis of the scope of rights, and the limitations on those rights, accorded by third party patents and, to the extent possible, pending applications.

In this practical and interactive Master class, you will get three hours of in-depth instruction on how to analyse, research, and draft non-infringement and invalidity opinions in the aftermath of Knorr. You will be able to take away from this session a checklist of the key points to consider when preparing and drafting an opinion.

Topics to be covered include:

1. The impact of Knorr and Seagate on Opinion Writing
   - Have the Knorr and Seagate decisions changed how and when non-infringement and invalidity opinions are prepared?

2. Why are Non-Infringement Opinions Prepared?
   - Preliminary considerations
   - When is a verbal opinion sufficient?
   - Why put it in writing?
   - What do you include in a written opinion?
   - Do you document everything?
   - Is an opinion by in-house counsel sufficient?
   - Why get an opinion from outside counsel?

3. Drafting the Non-Infringement Opinion
   - What are the essential elements?
   - What case law do you use?
   - Examples of non-infringement opinions

4. Why are Invalidity Opinions Prepared?
   - Preliminary considerations
   - When is a verbal opinion sufficient?
   - What do you include in the written opinion?
   - What about the inequitable conduct and unenforceability?
   - Is an opinion by in-house counsel sufficient?
   - Why get an opinion from outside counsel?

5. Drafting the invalidity opinion
   - What are the essential elements?
   - What case law do you use?
   - When do you draft separate opinions for non-infringement and invalidity?
   - How do you present your best case for invalidity?
   - Do you include both strong and weak points as to invalidity in an opinion?
   - Examples of invalidity opinions

5th International

Freedom to Operate Forum

Analysis, Opinion Writing, and Strategies for Minimising Risk in the Pharmaceutical and Biotech Industries

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CONFERENCE

Date: 10 and 11 June 2008
Time: 9.00am – 12.45pm
Registration and distribution of documentation from 8:00am
Venue: Millennium Knightsbridge Hotel
Address: 17 Sloane Street, Knightsbridge, London, UK SW1X 9NU
Tel: +44 (0) 20 7235 4377 **Fax:** +44 (0) 20 7235 3705
Tube: Knightsbridge

MASTER CLASS

Date: 11 June 2008 **Time:** 2.00pm – 5.30pm
Registration and distribution of documentation from 1.30pm

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DOCUMENTATION

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