Business Information In A Global Context

All New for 2008!

"Excellent event with extremely valuable information for the practitioner. Will definitely recommend to colleagues"

Thomas Lehmeir, Senior Patent Attorney, Novartis Pharma AG (Munich, April 2008)

15th Forum on

Biotech Patenting

The Latest Developments and Newest Strategies for Protecting Biotech Innovations

23 – 24 September 2008 | Radisson SAS Portman Hotel, London, UK

Distinguished Speakers for 2008 Include:

Judge Randall R. Rader
Circuit Judge
United States Court of Appeals for the Federal Circuit

Ursula Kinkeldey
Chairperson
Technical Board of Appeal
European Patent Office

Lawrence Cullen
Deputy Director (Biotechnology & Pharmaceuticals), Patents Directorate,
UK Intellectual Property Office

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Jones Day
Kilpatrick & Stockton
Powell Gilbert
Strategem IPM
Vossius & Partners
Wragge & Co

Leading biotech patent practitioners and experienced in–house counsel will provide practical and tactical advice on how to:

- Analyse the practical impact of recent changes at the UK-IPO, EPO and USPTO
- Increase your knowledge of developments in follow-on biologics and antibody technologies in the patent area
- Manage the challenges posed by the conflicting legal approaches to gene patenting
- Establish a successful global patent strategy and successfully protect biotech patents in China and India
- Get the latest information on second medical use claims
- Tackle inventorship and patent entitlement disputes

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A Advanced Practical Workshop on Successfully Evaluating Freedom to Operate

B How to Conduct Effective IP Due Diligence

see inside for full details

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To register call +44 (0) 20 7878 6888 or register online at www.C5-Online.com/biotechpatenting

"I would highly recommend this conference to colleagues. The presentations and presentation material were very helpful."

Gabriel McCool, Edwards Angell Palmer & Dodge (Munich, April 2008)

Analysis, Insights and Strategies for the New Challenges in Biotech Patent Practice

"Level of detail was just right. Very Useful."

M Rees, IP Manager, Podermed (Munich, April 2008)

With Big Pharma increasingly reliant on biotechnology for its product pipeline and with biotech drugs now accounting for 15% of the global pharmaceutical market, the importance of biotechnology inventions and their patents is more important than ever. But the unique nature of biotechnology patents, the intense scrutiny involved with obtaining biotech patents and with patent standards constantly in flux, means that lawyers involved in obtaining and protecting patents in this high stakes arena, must have up-to-the-minute information.

C5 has specifically developed the **15th Annual Forum on Biotech Patenting** to provide you with complete and in-depth information on current legal developments impacting your biotech patent practice. This the event that biotech patent lawyers attend year on year to get updates on the changes shaping biotech patents today, including recent scientific advances, developments in US patent practice, current discussion on the the novelty of biotech inventions and further therapeutic use in Europe, EPC 2000, the growth of biologics, emerging case law and what is happening with biosimilars legislation.

The expert panel of regulators, in house counsel and their legal and other advisors, will provide you with the key information and insights you need now on:

- How the EPC 2000 will affect medical use claims and other areas of patent practice
- How the growth of biologics in the newly approved medicines space is increasing the potential for litigation
- Case law developments including *re Kubin*, *Monsanto*, *KSR*, *Medimmune*, *Aeomica* and more
- What can you expect from government initiatives and what will be influencing the EPO, UKPTO and USPTO in the coming year?

Who Will You Meet?

- From Pharma and Biotech Companies
  - Patent Attorneys and In-House Counsel for Pharma and Biotech Companies
  - Directors of Patent Departments and Patent Managers
  - IP Managers
- Patent Attorney, Agents and IP Lawyers
- IP Consultants
- Technology Transfer Officers

New for 2008:

- Keynote judicial address by Judge Randall Radar
- Interactive case studies to gain insight into corporate perspectives on biotech patent litigation and patent entitlement disputes
- Two pre-conference workshops designed to add value to your conference experience
- Networking opportunities to help you create new industry contacts
- Patent examiner's insights on what biotech patent examiners really look for at the EPO

Speaker Faculty Includes:

John Whealan
Associate Dean for IP Law
George Washington University Law School

Rouget F. (Ric) Henschel
Partner
Foley & Lardner (US)

Aliki Nichogiannopoulou
Examiner, Biotechnology/ Patent Law, **European Patent Office (Germany)**

Peter de Weerd
VP and Head of Patents
Novartis Pharma AG (Switzerland)

Rob J Aerts
Principle Patent Attorney
Solvay Pharmaceuticals B.V. (Netherlands)

Ian B Bryan
IP Counsel
GE Healthcare (UK)

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MONDAY | 22 September 2008
PRE-CONFERENCE WORKSHOPS

A
8.30 a.m. – 12.00 p.m. *(Registration Opens at 08.00 a.m.)*

Advanced Practical Workshop on Successfully Evaluating Freedom to Operate

Adam Cooke, Partner, **Wragge & Co** (UK)

Nicola Baker-Munton, Chief Executive Officer, **Stratagem IPM** (UK)

This workshop will cover the successful preparation and conduct of FTO searches, including how to analyse FTO search results and communicate them for the purposes of patent procurement and company reporting. To ensure that this workshop is practical, your workshop leaders will use a real-life FTO case study to highlight key strategic points, including design of the FTO search and drafting of the FTO report. Key areas to be covered include:

- How to define the scope of your FTO analysis
- Using effective search parameters and identifying key sources of information
- Identifying restrictions presented by research tools and platform technologies
- Commonly overlooked sources of key information you must be aware of
- When to use research outsourcing and how to make it successful
- FTO limitations to look out for such as territorial patent protection and unpublished patent applications
- Key strategic and business considerations including managing time constraints
- Assessment of whether the risk of litigation can be tolerated and at what level

For the purposes of this workshop, an overview of the prior art will be given, as will a product description.

(Lunch is served for attendees of both workshops)

B
1.00 p.m. – 4.30 p.m. *(Registration Opens at 12.45 p.m.)*

How to Conduct Effective IP Due Diligence

Nina White, Partner, **Boulte Wade Tennant** (UK)

Patrick Duxbury, Partner, **Wragge & Co** (UK)

This classroom-style workshop is designed provide step-by-step guidance on how to conduct thorough due diligence and ensure that costly mistakes that erode IP value are avoided. As well as providing valuable information on the key legal and business issues impacting IP due diligence, your workshop leaders will provide insights on the essential components of a due diligence review, spotting IP red flags and managing the reporting process. Particular focus will be put on the following areas:

- How to recognise investor goals in an acquisition and how this affects your due-diligence strategy
- Evaluating the scope, validity and enforceability of the target's patents
  - identifying if the target owns or has adequate rights in its patent estate
  - have the patents been maintained in fact?
  - are the patent applications in good standing and in compliance with statutory requirements
  - have any prior investors encumbered the target's intellectual property?
  - have all the important filings been made in all commercially important countries?
- What parties can expect from outside counsel and how corporate counsel can assist the due diligence process
- Drafting the due diligence report
  - structure and essential elements and how they differ according to transaction type
  - what the executive summary must contain
  - presenting FTO search results and analysis
  - liability provisions

TUESDAY | 23 September 2008

8.00 Registration and Coffee

8.45 Opening Remarks from Conference Chair

Peter de Weerd
VP and Head of Patents, **Novartis Pharma AG** (Switzerland)

EUROPE

9.00 Critical Update on Legislative and Policy Developments at the UK-IPO and EPO

UK-IPO

<u>UK-IPO</u>

Lawrence Cullen
Deputy Director (Biotechnology & Pharmaceuticals),
Patents Directorate, **UK Intellectual Property Office** (UK)

- Update on UK Patent Rules and practice developments affecting biotech patenting, including
  - supplementary protection certificates (SPCs)
  - paediatric medicines
  - IPO office facilitated litigation and dispute resolution
  - divisional applications
  - stem cells and cybrids
- How the EPC 2000 is changing practice at the UK-IPO
  - post-grant amendments
  - second medical use claims

EPO

<u>EPO</u>

Ursula Kinkeldey
Chairperson, Technical Board of Appeal
European Patent Office (Germany)

- Assessing the impact of EPC 2000 changes on practice at the EPO
  - petition for review of decisions by the Enlarged Board of Appeal
  - central limitation procedure
  - second medical indication (referral to the EBA)
  - diagnostic and surgery methods (referral to the EBA)
- What do these developments mean in practice?

10.45 Morning Refreshments

11.00 EPO Insight: An Examiner's Perspective On Biotech Patent Applications

EPO

Aliki Nichogiannopoulou
Examiner, Biotechnology/Patent Law
European Patent Office (Germany)

- Increasing your chances of meeting the patentability criteria required for biotech applications
  - what trends are emerging in light of the EPC 2000?
- Discussion of the application of the morality clause when examining biotech applications
- Examination practice post-implementation of Biotech Directive 98/44/EC into the EPC 2000
- How implementation is affecting examiners' attitude towards the patentability of
  - higher life forms
  - genes
  - human embryonic stem cells

11.45 Review of Recent EPO and EU National Court Biotech Decisions

Ian B Bryan
IP Counsel, **GE Healthcare** (UK)

Nina White
Partner, **Boult Wade Tennant** (UK)

Simon Cohen
Partner, **Taylor Wessing**

- Impact of recent case law on drafting and filing strategies
  - claim scope for DNA and polypeptide molecules
    - *Monsanto v Cargill*
    - *Monsanto v Cefetra*
    - *Celltech v MedImmune*
  - sufficiency of disclosure
    - *H. Lundbeck A/S v Generics (UK) Ltd* and others
  - inventive step and utility
    - Aeomica Inc.
    - T1329/04 and the requirement for "plausibility"
    - *Angiotech v Conor Medsystems*

12.30 Networking Lunch

1.45 Impact of the EPC 2000 on Medical Use Claims

Hans-Reiner Jaenichen
Partner
Vossius & Partner (Germany)

- How is the introduction of the revised Article 54 (5) EPC 2000 affecting patent practice?
- Summary of the newly available claim language under the EPC 2000
- How can you sufficiently prove the claimed medical use now?
- Ways to establish novelty of second medical use claims
- Examining the treatment regimen and related jurisprudence
  - EPO
  - UK
  - Netherlands
  - Germany
- Will medical use claims enforcement be easier under the EPC 2000?

UNITED STATES

2.30 Analysis of the Latest Decisions of the US Courts and Their Implications

Anne Dollard
Chief Patent Counsel and Assistant Secretary
Xoma (US)

Jamie Greene
Partner
Kilpatrick & Stockton (US)

- Can a company be sued in the EU even if it includes a patented inactive gene that does not express its function?
  - *Monsanto v Cafetra*
- Does the term "blocking nucleic acids" include PNAs?
  - *Regents of the University of California v Dakocytomation*
- Expansion of research use exceptions
  - *Integra LifeSciences I, Ltd v Merck KGaA*
  - *Benitec Australia v Nucleonics Inc*
- Obviousness considerations in gene patenting
  - *In re Kubin*
- Inequitable conduct in data selection
  - *Aventis Pharma S.A. v Amphaster Pharmaceuticals, Inc.*
- Is the Federal Circuit encouraging unwarranted charges of inequitable conduct?
  - *McKesson Information Solutions v Bridge Medical*

3.15 Afternoon Refreshments

3.45 Implications and Status of the Patent Reform Act

John Whealan
Associate Dean for IP Law
George Washington University Law School
Former Counsel to the Senate Judiciary Committee and former Deputy General Counsel for IP Law and Solicitor USPTO

Phil Kiko
Of Counsel
Foley & Lardner (US)
Former General Counsel/Chief of Staff House Judiciary Committee
Former Deputy Chief of Staff/Counsel House Committee on Science

- Understanding the US Congress legislative process and the role of the lobbyist
- Genealogy of the Patent Reform Act from start to today
- Reviewing the major issues of the Patent Reform Act
  - where does disagreement appear to remain?
- Identifying possible scenarios for the passage of the Patent Reform Act in the next 6 to 18 months
- Examples of opportunities to "tweak" a bill

4.15 Obviousness Determinations After *KSR v Teleflex*

Rouget F. (Ric) Henschel
Partner
Foley & Lardner (US)

- In-depth review of *KSR v Teleflex*
- Federal Circuit case law post *KSR*
- Developments in gene sequence claims: *In re Kubin*
  - can the USPTO Board "over rule" *In re Deuel*?
  - will *In re Kubin* survive the Federal Circuit appeal?
- Obvious to try standard revived
  - broad scope suggested by *KSR*
  - the Federal Circuit's reaction
- Re-emphasis on *Graham v Deere* factors
  - scope and content of prior art
  - difference between prior art and claimed invention
  - level of ordinary skill in the art
  - objective indicia of non-obviousness

CHINA AND INDIA

5.15 How to Successfully Obtain and Enforce your Biotech Patents in China and India

Tony Chen
Partner
Jones Day (China)

Rajeshkumar Acharya
Proprietor & Advocate, Patent & Trademark Agent
H.K. Acharya & Company (India)

- Review of patent laws in China and India
- What are the patent offices looking for in relation to biotech patents?
  - tackling the peculiar provisions of each patent system
- Successfully overcoming common prosecution challenges
  - resolving conflicts between local and international laws
  - recent case law
  - remedies available
- Navigating the dual system of enforcing your patent rights in China
- Key bureaucratic restrictions and civil v criminal enforcement issues to be aware of in India

6.00 Conference Adjourns

NETWORKING DRINKS AT THE HOTEL BAR AND PIANO LOUNGE

WEDNESDAY | 24 September 2008

8:30 Registration and Coffee

8.45 Opening Remarks from Conference Chair

Peter de Weerd
VP and Head of Patents
Novartis Pharma AG (Switzerland)

9:00 Keynote presentation: Judicial Address

Judge Randall Rader
Court of Appeals
Federal Circuit (US)

RANDALL R. RADER is a Circuit Judge of the United States Court of Appeals for the Federal Circuit. Before his appointment to the Bench, Judge Rader worked with members of the House of Representatives (1975-1980) and as counsel to the Senate Judiciary Committee (1980-88). He was Chief Counsel and Minority Chief Counsel for the Subcommittee on the Constitution and the Subcommittee on Patents, Trademarks, and Copyrights.

Take this unique opportunity to hear about the most exciting emerging topics in biotech patenting, directly from a US Court of Appeal, Federal Circuit Judge.

Judge Rader's keynote presentation will be followed by an extended Q&A session.

10.30 Morning Refreshments

STRATEGY

11.00 Developing Your Patent Strategy Develop Competitive Advantage, Obtain Maximum Revenue and Extend Patent Lifecycles

Nicola Baker-Munton
Partner
Strategem IPM (UK)

- Identifying and managing core patents and working around third party patents
- Developing your IP commercialisation strategy
  - enhancing product development through the licensing and acquisition of third-party IP
- Ensuring full integration with research and development to ensure that research focuses on outcomes that may be protected as IP

GENE PATENTS

11.45 Unravelling the Legal Conflict in Gene Patenting in Europe

Rob J Aerts
Principal Patent Attorney
Solvay Pharmaceuticals B.V. (Netherlands)

- Requirement of industrial applicability for gene patenting under the EC Biotechnology Directive
  - relationship between Directive provisions and provisions regulating industrial applicability in the Convention
  - clarification of how the new gene patenting provision should be interpreted
- Clarification of issues raised by recent case law, including those at the EPO Board of Appeal
- What is the Board of Appeal's approach to fulfilling the industrial applicability of invention requirements?
  - biotech patents and the question of industrial applicability
- Do gene and protein patents differ from patents in general?

12.30 Networking Lunch

BIOSIMILIARS

1.45 Comparison of the US and European Legal Issues Surrounding Biosimilars: Legislation, Case Law and Approvals to Date

Anthony Tridico
Partner
Finnegan, Henderson, Farabow, Garrett & Drunner (USA)

Liz Fuller
Director
Wragge & Co (UK)

- What is the approach to biosimilars in the US?
  - current status of biosimilar legislation
  - crucial strategies for protecting your invention
    - claim drafting strategies
    - use of method and process claims to maximise protection
  - identifying the advantages of disadvantages of trade secret protection
- Current state of play for biosimilars in the EU
  - historical background and current legislation
  - risks and benefits of in the biosimilars category
  - experience, case law and approvals to date
    - what has been approved and why?
    - what has been rejected or withdrawn and why?
  - key strategic issues

2.30 Afternoon Refreshments

CASE STUDIES

3.00 Case Study on Bringing and Defending Inventorship and Patent Entitlement Actions

Tim Powell
Partner
Powell Gilbert (UK)

Disputes about inventorship and entitlements to patents are becoming increasingly common and can have major commercial ramifications. This was illustrated in the dispute between Yeda (the technology transfer arm of the Weizmann Institute of Israel) and Sanofi Aventis and ImClone about the rights to patents covering the monoclonal antibody combination therapy Erbitux ®. Entitlement actions were brought in US and four European countries, leading to a recent worldwide settlement.

This session will illustrate the principles followed by patent offices and the courts in determining inventorship and entitlement disputes by reference to a hypothetical case study. There will also be a discussion on the potential pitfalls in structuring collaborative research and the tactical and strategic issues that need to be considered in bringing or defending entitlement actions.

4.00 Managing your Biotech Patent Litigation: In-House and Outside Counsel Perspectives

Peter de Weerd
VP and Head of Patents
Novartis Pharma AG (Switzerland)

Anthony Trenton
Partner
Denton Wilde Sapte (UK)

- In-house counsel experiences in litigating life sciences patents
  - who should be on your litigation team?
  - cost control
- Putting together your litigation strategy: key considerations
- How do outside litigators approach the practical and strategic challenges of biotech patent litigation?
  - co-ordinating litigation
  - managing client expectations

4:45 Closing Remarks and Conference End

15th Forum on

Biotech Patenting

The latest critical developments and practical strategies for protecting your biotech innovations

23-24 September 2008 | Radisson SAS Portman Hotel, London, UK

Business Information In A Global Context

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ADMINISTRATION DETAILS

CONFERENCE

Date: 23-24 September 2008
Time: 9:00am (Registration and distribution of documentation from 8:15am)
Venue: Radisson SAS Portman Hotel
Address: 22 Portman Square, London, W1H7BG, United Kingdom
Tel: +44 (0)20 7208 6000 Fax: : +44 (0)20 7208 6001
Tube: Marble Arch

WORKSHOPS

Date: 22 September 2008
Time: Workshop A: 8:30am – 12:00pm Workshop B: 1.00pm – 4:30pm

HOTEL ACCOMMODATION

An allocation of bedrooms is being held for delegates at a negotiated rate until 20 September 2008. Please call Venue Search on +44 (0) 20 8541 5656 or email beds@venuesearch.co.uk. Please note that lower rates may be available when booking via the internet or direct with the hotel, but different cancellation policies may apply.

CONTINUING EDUCATION

12.75 hours (conference only) plus 3.5 hours per workshop towards Continuing Professional Development hours (Law Society Reference No: BJEUFO).

DOCUMENTATION

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