Business Information
In A Global Context

7th Annual
International Conference on

Pharma Patent Lifecycles

The premier international event on new developments and winning strategies to extend revenue streams and manage generic competition

26 & 27 June 2008
Charing Cross, Guoman Hotel, London, UK

Led by Industry Experts from:

Novartis International
Merck Serono International
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Bird & Bird (UK)
Bristows (UK)
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Simmons & Simmons (UK)
Reimann Osterrieth Kohler Haft (Germany)
Ropes & Gray (US)
Veron & Associes (France)
Wragge & Co (UK)

Top industry players will provide insight into the hottest issues, including how to:

- UNDERSTAND the practical impact of recent European and US case law developments
- NAVIGATE the interface between patent law and competition law
- TACKLE the complexities of the EPC 2000 and its effects on patent lifecycle planning
- FORMULATE effective strategies and tactics to successfully litigate against generic opposition
- EXPLORE the impact of *KSR* on primary and secondary patents
- MASTER the challenges of global patent lifecycle management

Plus!

Benefit from our expert-led pre-conference Master Class on:

A Step-by-Step Guide to Ensuring your Patent Settlements Meet EU Anti-Competition Law Guidelines

.....see inside for full details

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DID YOU KNOW …

It is estimated that pharma patent expirations equalling 140 billion USD in losses will occur over the next 10 years. Upon generic entry into the market place branded pharma risk losing more than 80% of their market share.

Escalating pipeline burdens and the latest legal developments are radically changing the landscape for pharma patent lifecycles in Europe and the US. As a private practice lawyer or in-house counsel, you need to be alert to all the latest legislative and case law developments affecting lifecycle management in order to stay ahead of the game.

With the patent endgame stakes being higher than ever before for the pharma industry, this event is not to be missed.

Since 2001, 1000s of life sciences patent professionals have made **C5's Pharma Patent Lifecycles** Conference their source of information for the most up-to-date legal developments surrounding **patent lifecycle management**. As a pharma patent professional, this is the must-attend event for 2008 aimed at giving you advanced practical guidance on maximising and leveraging your or your client's global patent portfolios.

The 2008 programme is designed not only to highlight key legal issues, but also to align your patent management strategy to business needs. Meet and network with the experts as well as your peers and competitors as you get the latest information on increasing patent lifecycle and optimising revenue from your portfolio.

Participants will also receive a comprehensive set of written materials prepared by the speakers for the conference. These are invaluable reference materials which you will use again and again long after the conference is over.

Seats at this popular annual are sure to go quickly. REGISTER NOW! Call +44 (0) 20 7878 6888, fax the registration form to **+44 (0) 20 7878 6896** or register online on **www.C5-Online.com/ppl.**

Who Should Attend

From Pharma and Generic Companies

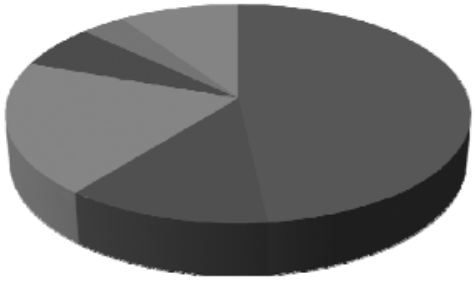
- In-House Counsel and Legal Directors
- Heads of IP, IP Counsel and IP Managers
- Heads of Patents, Patent Counsel, Patent Directors and Managers

Private Practice Lawyers specialising in

- Life Sciences/Pharma
- Patents
- IP

Patent agents and consultants

Delegates who have attended in the past per title:



	Total Count
Patent Attorney/Patent Professional	40%
Patent Director/Manager	20%
Partner/Outside Lawyer	17%
General Counsel/Senior Counsel/VP	11%
Department Head	8%
CEO/Advisor	4%

GLOBAL SPONSORSHIP OPPORTUNITIES

C5, along with its affiliate organisation based in New York, American Conference Institute (**ACI**), works closely with sponsors to create the perfect business development solution. With over 500 conferences in the US, Europe, Russia and CIS, Canada and China, **C5/ACI** provides a diverse portfolio of first-class events tailored to the senior level executive. For more information about this event or our global portfolio, please contact: Colin Carter on +44 (0) 20 7878 6933 or email c.carter@C5-Online.com

Pre-Conference Master Class

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Wednesday 25 June 2008

2.30pm – 6.00pm (Registration Opens at 2.00pm)

Patent Settlements Master Class: A Step-by-Step Guide to Meeting EU Anti-Competition Law Guidelines

Facilitated by Partners from Arnold & Porter

The recent EU probes on pharma patents mean that anti-competition liabilities and risks for brand name and generic pharmaceutical manufacturers have never been more real. The European Commission raids on some of the world's largest pharmaceutical companies, spurred by an inquiry into patent use and anti-competitive practices are only the start of a sector-wide review into current barriers to generic competition. Regardless of whether you represent an innovator or generic, this workshop will help you ensure that your patent agreements do not infringe the EU Treaty's ban on restrictive business practices. Get practical guidance on:

- Assessing the impact of reverse payment rules and court's views on patent settlements
- Weighing up the role of authorised generics in the market
- Determining when bundled discounts and exclusive contracts are illegal
- Understanding which antitrust pitfalls to avoid when entering into licenses and consolidations

This master class has been designed to give you a forum to benchmark your know-how and discover how to resolve complex anti-competition matters affecting the protection and exploitation of your products. You will learn how to successfully and carefully draft and execute collaborative settlement agreements that pass competition law scrutiny. Your session leaders will revisit patent settlements, including reverse settlements and take you through the intricacies developing defensive and offensive strategies in this critical time, including:

- Managing the fall out from the European Commission's dawn raids
- Minimising anti-competitive risks of generic alliances
  - addressing potential threats to competition and economic effects, including control of market share and pricing issues
  - structuring strategic alliances to minimise anti-competitive risk and avoid criminal exposure through effective contract drafting
- Successfully avoiding illegal monopolisation: the latest on product improvement and switching strategies
  - ensuring caution when taking action that reduces competition or excludes generics
    - what conduct truly deprives generic companies of the ability to have their product substituted for the branded product at the pharmacy?
  - viewing product improvements from an anti-trust perspective
  - protective against potential investigation or litigation with regard to product improvements
    - whether product improvements by the patent holder and alleged monopolist are exclusionary post- *Abbot v Teva*
  - understanding the boundaries of market switching
- Anti-competition considerations in pricing and distribution
- Anticipating and avoiding anti-competition dilemmas in M&A
  - choosing deal structures that maximise value and minimise anti-trust risk
  - ascertaining competitive effects of overlaps in the merging parties' development pipeline
- Complying with competition law guidelines for IP licensing and collaborations among competitors
  - what you must know about potential competition and innovation, and exclusive in-licenses
  - drafting antitrust-sensitive royalty agreements
  - deal structures that maximise values and minimise anti-trust risk
- Antitrust implications in co-promotion, co-marketing and licensing agreements (including resale price maintenance issues and improper information-sharing)

The master class also includes a hands-on, interactive and problem based exercises on Drafting and Executing Collaborative Agreements that Pass Competition Law Scrutiny.

(Refreshments will be served to delegates during the master class)

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

THURSDAY 26 JUNE 2008

8.00 Registration and Coffee

8.45 C5 Welcome

8.50 Opening Remarks from Conference Chair

Kevin Mooney
Partner
Simmons & Simmons (UK)

CHAIR'S COMMENTARY

9.00 A Bird's Eye View of the Future for Pharma Patent Lifecycle Enforcement

Kevin Mooney
Partner
Simmons & Simmons (UK)

- Reviewing the future evolution of pharma patents globally
  - how many pharma patents are coming under threat?
  - how aggressive will the generics be?
  - what will be the impact of a centralised enforcement procedure?
  - what is the impact of the competition authorities?

EUROPEAN UPDATE

9:30 Critical Update on European Case Law and Legislative Developments

Part One: Case Law Review

Ian Karet
Partner
Linklaters (UK)

- Identifying key developments in generic applications for negative declarations
  - *Arrow v Merck*
- How claims of entitlement are being decided now
  - *Yeda v Rorer*
- Recent stays of proceedings in the UK pending EPO Opposition Proceedings
  - *Glaxo Group v Genentech*
- Comparison between the German and other European approach to automatic stay of the validity proceedings
- Update on significant interim injunctions currently pending appeal
  - *Pozzoli*; *Servier v Apotex*
- Understanding the current application of the test for obviousness in the UK
  - *Angiotech* and *Pozzoli*

Part Two: Assessing the EPC 2000 in the Context of Pharma Products

Harvey Adams
Partner
Mathys & Squire (UK)

- Review of some of the substantial changes implemented by EPC 2000 and how they are affecting patenting strategy in the field of pharmaceuticals, including:
  - getting there early
    - reduced requirements for a filing date
  - downstream problems of a lack of unity in the international phase
    - the loss of Rule 112 EPC
  - further medical uses – different claim formats under different circumstances
    - Article 54(5) EPC
  - centralized post-grant amendment and/or correction
    - Articles 105a and 105b EPC
  - petitions for review by the Enlarged Board of Appeal
    - Article 112a EPC and Article 113 EPC
- EPO fee increases for large specifications
  - how to save money whilst maximising your protection

10.30 Morning Refreshments

11.00 Status Update on the Execution of the IP Enforcement Directive and Implications for Pharma Patent Lifecycle Management

Interactive Q&A Discussion

<u>Panel Moderator</u>

Penny Gilbert
Partner
Powell Gilbert (UK)

<u>Panelists</u>

Christine Kanz
Partner
Reimann Osterrieth Kohler Haft (Germany)

Thomas Bouvet
Advocat
Veron & Associes (France)

Simon Dack
Barrister
De Brauw Blackstone Westbroek (The Netherlands)

Carlos Valls
Partner
Iuris Valls Abogados (Spain)

With the IP Enforcement Directive now implemented in most member states, its impact on patent practice is under increased scrutiny. This comparative panel will bring together experts from key jurisdictions to discuss current challenges highlighted by the Directive and the corresponding effect on the patent endgame. In particular, discussion will focus on matters arising in respect to litigation and settlement proceedings as well as offering insight into:

- The scope and enforceability of second medical use claims
  - *Teva v Aventis*
  - *Actavis v Merck* (UK)
  - *Carvidilol II* (Germany)
- Determining the scope for *ex parte* seizures under the Enforcement Directive in Holland
  - *Teva v Abbott*

Following commentary from the panel, the discussion will be opened to the audience for Q&A, allowing all attendees to share ideas and concerns.

12:15 Networking Lunch

REGULATORY DEVELOPMENTS

1.30 The Impact of Regulatory Data Protection on Lifecycle Management

Marie Manley
Partner
Bristows (UK)

- Understanding the useful role of regulatory data protection in the product life-cycle management strategy
  - how to successfully obtain exclusivity for protected categories of data
    - filing with competent authority issues
  - what can you do to protect your rights when faced with a generic company seeking generic approval based on your innovator data
- Assessment of the current EU position
  - regulatory data protection and market exclusivity provisions under the Community Code
  - what if further indications are sought in relation to the original product? Status of the jurisprudence in relation to:
    - new dose
    - new indication
    - new pharma form
  - interpretation of the scope of the global marketing authorisation concept
- Data exclusivity incentives for paediatric and orphan indications
  - what is impact on research based and generic clients?
- What are the other instances where regulatory data protection may be available?
- Comparing the approach to the regulatory data protection in various Member State

2.15 Recent Trends and Developments in Supplementary Protection Certificates and Paediatric Extensions

Peter Bogaert
Partner
Covington & Burling (Belgium)

- Breaking down SPC Protection: how is it working in practice?
  - determining scope
  - key requirements
  - tackling the uncertainty surrounding duration
- What you need to know about national and EC case law differences
- Reviewing recent case law and identifying outstanding issues
- Breaking down the Paediatric Regulation
  - paediatric obligation provisions
  - understanding the paediatric investigation plans
  - waiver and deferral issues
- Examining the Paediatric Rewards Requirements
  - products in development and patent protected products
  - orphan designated products
  - off-patent products
  - outstanding issues currently raising questions
- Learning how to successfully obtain a paediatric extension

3:15 Afternoon Refreshments

EXTENSION STRATEGIES

3:45 Successful Evergreening Strategies to Compete with Generics and Obtain PTC's

Lori-Ann Johnson
Partner
Finnegan Henderson Farabow Garrett & Dunner (Belgium)

- What are the early steps you can take to facilitate lifecycle management later?
  - r&d considerations and early steps to take
  - benchmarks in the drug's development and patent timelines
  - claim drafting considerations
- What should you do upfront and how much should you disclose?
- What works and doesn't work in lifecycle applications?
- How can you successfully extend patent terms?
- Is it possible to co-ordinate lifecycle management globally?
- Tactical methods to strengthen secondary protection
  - formulations
  - polymorphs
  - salts
  - crystals
  - review of courts increasing reluctance to enforce secondary use patents
- Revising patent strategy to circumvent over-reliance on follow-on patents

4.30 Effective Use of Second Medical Use (Swiss-Type) Claims to Extend Patent Lifecycles

Luke Kempton
Director
Wragge & Co (UK)

- Recap of key facts in the Enlarged Board of Appeal's decision in EISAI/Second Medical Indication and subsequent effects on EPO practice
- Applying the EPC2000 in relation to second medical use claims
  - allowance of purpose-limited product claims for second medical use
  - obviation of need for claims to be in 'Swiss' form
- Achieving patentability of second medical use claims
  - what is the role of prior art?
  - article 54(5) novelty considerations to be aware of
  - key patient subgroups and their consequences
  - understanding dosing regimen issues
- Update on enforcement of second medical use claims
  - when are 2nd medical use claims infringed, and what are regulatory implications?
  - off-label uses
  - lessons from recent high-court cases
    - *Aventis* and *Sepracor Inc's* – fexofenadine
    - *Actavis UK v Merck* decision – finasteride

5.15 Conference Adjourns

6.00 DRINKS RECEPTION

FRIDAY 27 JUNE 2008

8:30 Registration and Coffee

8.45 Opening Remarks from Conference Chair

James Haley
Partner
Ropes & Gray (USA)

US REVIEW

9.00 US Legislative and Regulatory Developments Impacting Pharma Patents

Thomas J. Kowalski
Partner
Frommer Lawrence & Haug (US)

Naomi Halpern
Partner
Frommer Lawrence & Haug (US)

- Examining new prospective legislative changes
  - how will they impact pharma patent practice and life cycle management individually and collectively?
  - the FDA Revitalisation Act and related legislative proposals
    - understanding their impact on pharma patent lifecycles
    - what has stayed in the bills and what has been left out?
    - Medicare Modernisation Act
    - Access to Life Saving Medicine Act
- Impact of the act's pro-generic tendencies on innovators
  - assessing the Patent Reform Act in the context of pharma products: analysis of key provisions
    - effect on first to file v end of first to invent
    - impact on opposition practice
    - does it mean the potential elimination of interference practice?
  - update on GlaxoSmithKline lawsuit blocking the rules package
  - latest news on the proposed IDS rules
  - evaluation of the extent to which continuation and designated claims practice for pharma patents will change under the proposed USPTO rules
- Determining collectively how these changes impact pharma patent practice and lifecycles

9.45 Recent US Case Law Developments Affecting Primary and Secondary Pharma Patents

Part One: Interpreting the New Standard for Obviousness under *KSR*

Gregory Sephton
Partner
Fitzpatrick Cellar Harper Scinto (US)

- Examining the *KSR v Teleflex* decision and the new test for obviousness
  - follow-effects emerging from Federal Circuit decisions
  - reaction of the United States Patent & Trademark Office
  - what is the impact on innovators?
  - increased difficulty for second generation applications and obtaining of patents covering improvements on known drugs
- Reviewing the typical bases for secondary patents
  - are the following modes now all obvious?
    - new formulations
    - polymorphs
    - enantiomers
    - combinations
    - new indications
    - new salts
- What are the implications of *KSR* on these modes and are they all now obvious?
- Has the *KSR* standard now rendered all modes for obtaining secondary patents obsolete?
- Understanding the implications of *KSR* on brand longevity

Part Two – Recent Supreme Court Decisions

Brian Slater
Partner
Fitzpatrick Cellar Harper Scinto (US)

- Review of the forces driving the unprecedented number of cases going to the Supreme Court
- New developments concerning paragraph IV challenges relating to pharma patents
  - update on 180-day first to file exclusivity
- Declaratory judgement actions following the Supreme Court's Medimmune decision
  - *Teva v Novartis*
- Consideration of developments regarding inequitable conduct
  - *Monsanto v Bayer Bioscience*

10.45 Morning Refreshments

ANTI-TRUST AND COMPETITION LAW DEVELOPMENTS IMPACTING LCM

11.00 Successfully Navigating the Intersection between Patent and Competition Law

Marleen van Kerckhove
Partner
Arnold & Porter (Belgium)

- Going behind the EC's recent probe into agreements between brand name and generic drug manufacturers
- Re-examining where it all started
  - *AstraZeneca* case
  - has it opened the floodgates?
- Examining the on-going European Commission sector inquiry
- Discussing which practices might constitute infringement
- patenting behaviour
- litigation settlements
- vexatious litigation
- product switches
- Comparison with the US anti-trust status
  - key FTC enforcements initiatives to be aware of
  - recent FTC amicus brief and citizen petition filings
- The practical impact of these developments into your patent lifecycle management policies

MANAGING GENERIC COMPETITION

11.45 Strategies for Managing Increased Generic Sophistication and Related Threats

Duncan Curley
Director
Innovate Legal (UK)

- How is the market changing for generics?
  - key European legal developments affecting innovator/generic litigation
- The latest trends in patent revocation actions
  - applications against first generation patents vs. second generation patents
  - how are innovator companies blocking generics successfully from market entry?
- Lessons learned from recent drug-specific cases
  - insight into how generics can circumvent innovator patents and trends in the development of 'new' drug formulations
    - atorvastatin
    - perindopril
    - escitalopram

12.30 Networking Lunch

2.00 Brand Name and Generic Litigation as a Defence or Delay Tactic? UK and US Comparative

James Haley
Partner
Ropes & Gray (USA)

Gerry Kamstra
Partner
Bird & Bird (UK)

- Investigating current trends in innovator v generic patent litigation
  - changing standards of obviousness
  - increased use of declaratory relief
  - role of preliminary injunctions
- Key cases being looked at and strategies being used
  - US: *BMS v Apotex*
  - UK: *Arrow v Merck*
- How frequently are settlements being used and what are the key associated challenges/pitfalls?
  - exploring settlement options from innovator and generic perspective
  - recent actions by the ITC and the European Commission
- Anticipating and defending against attacks on protection
  - effective preparation of defence of market
  - choice of forum and co-ordination across multiple jurisdictions

CORPORATE CASE STUDIES

2.45 How to Optimise Your Product's Lifecycle Through Successful Global Patent Lifecycle Management

Brian Cordery
Partner
Bristows (UK)

- Insight into one of the world's leading pharma products global lifecycle management strategy
- Identifying practical hurdles in obtaining your lifecycle objectives and determining how to best optimise your product's lifecycle
- When and how to build a team to manage the lifecycle of your key products
- Building and maintaining an effective competitive intelligence picture – making the most of available sources of information
- How to get the best from local litigation teams and co-ordinate outside counsel
- Achieving the three 'C's: communication, co-ordination and consistency
- Learning how to expect unexpected and to deal with issues before they arise

3.30 Afternoon Refreshments

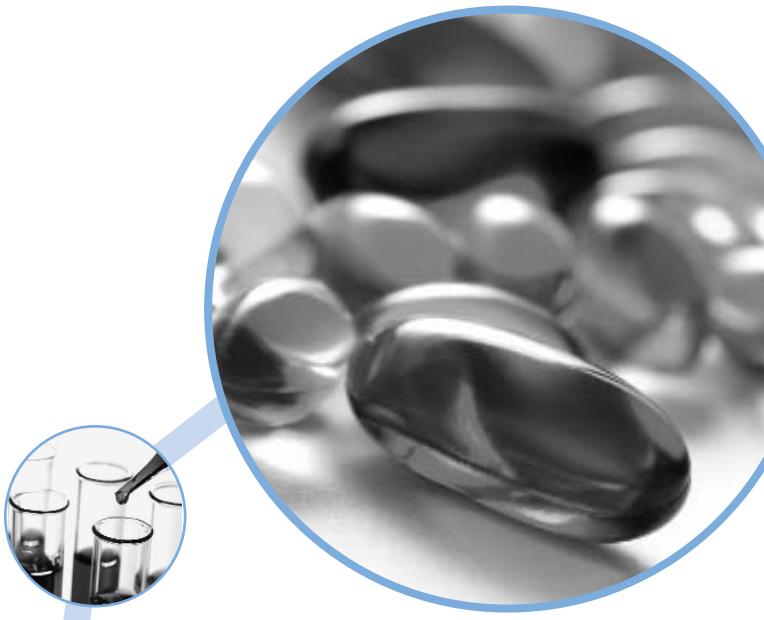
4.00 Industry Case Study and Break Out Session: Insight into Pfizer's European Lipitor Litigation

Robert Williams
Partner
Bird & Bird (UK)

In 2003 Ranbaxy attempted to break into Pfizer's 10 billion dollar market by challenging the patents on its extremely successful cholesterol reducing drug, Lipitor. The global litigation led to different considerations and outcomes around the world. Hear from the lead counsel for Pfizer in the UK in its global litigation against the Indian Pharma giant Ranbaxy and benefit from discovering how procedural and substantive differences between European countries had a significant impact upon the end results of this pharma patent litigation. This session will outline the major developments from the litigation and discuss the actions that were brought by Ranbaxy, and Pfizer's responses.

The presentation will be followed by round table groups discussing the pros and cons of Pfizer and Ranbaxy's actions and what can be learnt by other industry players.

5:00 Closing Remarks and Conference End



7th Annual International Conference on

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The premier international event on new developments and winning strategies to extend revenue streams and manage generic competition

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ADMINISTRATION DETAILS

CONFERENCE

Date: 26 & 27 June 2008
Time: 9.00am - 5.00pm (Registration and distribution of documentation from 2.00am)
Venue: Charing Cross, Guoman Hotel
Address: The Strand, London. WC2N 5HX
Tel: +(44) 871 376 9012 Fax: +(44) 871 376 9112

MASTER CLASS

Date: 25 June 2008
Time: 2.30pm - 6.00pm
(Registration and distribution of documentation from 2.00 pm)

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Up to 15.5 hours (Master Class 3.5 hours) towards Continuing Professional Development hours (Law Society Reference No: BJEUFO).

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