2nd Annual

PHARMA & BIOTECH PATENT LITIGATION

Effective Litigation Strategies for Protecting Your Market Share and Maximising Product Revenue

27 and 28 January 2010 | Radisson Blu Hotel, Amsterdam, Netherlands

Special Address by Judge Randall R. Rader, United States Court of Appeal, Federal Circuit

Leading practitioners will share their insights and experience in complex, cross-border patent litigation, including strategic guidance on:

- Is the Enforcement Directive an effective tool for brand name pharma in enforcing patents: analysis of post Directive case law
- The latest European Patent Office decisions and their implications: hear directly from the EPO’s Legal Member to the Boards of Appeal
- SPCs and paediatric regulation: recent decisions and varying application requirements across Europe
- Pharma Sector Inquiry Final Report: what lessons can both innovators and generics companies draw?
- European Standards on sufficiency of description post Lundbeck and Novartis v Johnson & Johnson
- Enforcing IP rights in China, India, Russia and Israel: local practitioners’ guide to the facilitative provisions and stumbling blocks

Post-conference Master Class: 29 March 2010

Winning Strategies for Enforcing Your Life Sciences Patents in China and India

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Litigation across the life sciences industry is increasing in volume, complexity and in the number of multi-jurisdictional cases. 2009 has been a watershed year, having witnessed a number of cases in very complex areas such as Supplementary Protection Certificates (SPCs), paediatric extensions, and there have been a succession of landmark decisions with conflicting outcomes in different European jurisdictions. Furthermore, the Final Report of the European Commission’s Sector Inquiry has raised a number of difficult questions and the impact on both brand name pharma and generics companies is considerable. These developments have dramatically altered the litigation landscape across Europe and pharma and biotech companies, and their litigators, must have an up-to-the-minute understanding not only on the key developments, but also the implications for their companies and patent practices.

C5’s 2nd Annual Pharma & Biotech Patent Litigation brings together eminent in-house counsel from the world’s largest pharma and biotech companies and their expert advisors in an outstanding panel of speakers. Based on their first-hand experience, the distinguished panel will provide you with invaluable information and insights that will help you ensure your company can protect its inventions, effectively challenge infringement and maximise its market share.

A notable highlight of C5’s conference this year will be the Special Address by Judge Randall R. Rader, United States Court of Appeal, Federal Circuit “How Have Recent Landmark Decisions Impacted on the US Litigation Landscape?”

Be sure to attend this year’s practical and interactive Post-Conference Master Class on “Winning Strategies for Enforcing Your Life Sciences Patents in China and India”, on 29 January 2010. Led by local expert practitioners, this workshop offers a deep dive into optimal routes for enforcement and protection of patents in two key jurisdictions, it addresses the industry’s key concerns in deciding whether to pursue infringers in China and India.

Be where your industry will be on 27-28 January 2010 in Amsterdam, and don’t miss out on this unique opportunity to hear from and network with your industry peers and experts. Book your place at this essential conference today, by calling +44 (0) 20 7878 6888, by faxing your registration form to +44 (0) 20 7878 6896 or by registering online at www.c5-online.com/patentlitigation

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C5, along with its affiliates in New York, American Conference Institute (ACI) and in Toronto, The Canadian Institute (CI), works closely with sponsors to create the perfect business development solution. With over 500 conferences in the US, Europe, Canada, Russia and CIS and China, C5/ACI/CI 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: Jonathan Price on +44 (0) 20 7878 6907 or email j.price@C5-Online.com

C5’s events in pharma and biotech are recognised by your colleagues and competitors industry as the market leader in providing the most comprehensive and sophisticated coverage of key industry developments. Our distinguished alumni include:

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Micromet
Nerviano Medical Sciences
Bioinvent
Roche Diagnostics
ISIS Innovation
and many more…

The 2nd Annual Pharma & Biotech Patent Litigation is a must for:

- In-house patent counsel, patent attorneys and IP counsel in from biotech and pharma companies
- Directors of patent departments and patent managers
- Patent attorneys and external counsel specialising in life sciences, IP and patent litigation
08.15 Registration and Coffee

08.45 Chairman’s Opening Remarks

Frank-Erich Hufnagel, Partner /Rechtsanwalt, Freshfields Bruckhaus Deringer LLP (Germany)

09.00 Highlights from Pharma and Biotech Patent Litigation in 2009 and Trends for the Future

Fiona Bor, Senior Patent Counsel, Teva Europe Patent Department (UK)

Michael Burdon, Partner, Head of Biosciences Group / Joint Head of IP Group, Olswang (UK)

This session will review recent major decisions in the life sciences arena from the UK, Netherlands, France and Germany, address emerging litigation trends and include a critical overview of litigation hotspots such as:

- Dosage regimens - the next instalment of Kos Life Sciences (EPO: G2/08)
- Paediatric extensions to SPCs - for example Losartan (du Pont)
- The Occlutech decisions in the German, Dutch and UK courts
- How and to what extent (if at all) have major 2008 European decisions like Conor vs Angiotech and Olanzapine been applied in subsequent litigation?
- Compensation for employee inventions – the UK position as exemplified by Kelly & Chiu v. GE Healthcare Limited vs the situation in Germany / Sweden.
- Is there an increasing trend to uphold rather than revoke life sciences patents?

09.45 The Generics (UK) v Lundbeck case and Subsequent Conflicting Decisions in the Netherlands and Germany: What is the European Position on Sufficiency Today?

Bas Berghuis van Woortman, Partner Simmons & Simmons (Netherlands)

Scott Parker, Managing Associate Simmons & Simmons (UK)

- The House of Lords decision in Generics (UK) v Lundbeck and its impact on subsequent cases
- The decisions in Lundbeck in Germany and the Netherlands
- The conflicting decisions of courts in the Netherlands, Germany, France and the UK in Novartis v Johnson & Johnson
- Consequent to the decisions under review, how does the law deal with claims that are broader in scope than the description/data in the patent?
- To what extent is the UK still out of step with the rest of Europe?

10.30 Morning Refreshments

10.45 Post-Enforcement Directive Case Law Across Europe: New Opportunities for Effective Enforcement of IP Rights by Innovators?

Dirk Schüller-Langeheine, Partner Hoffmann Eitle (Germany)

Gertjan Kuipers, Partner, De Brauw Blackstone Westbroek (Netherlands)

Frédérique Faivre Petit, Partner, Cabinet Regimbeau (France)

Andrew Waugh QC, Three New Square Chambers (UK)

- Post Enforcement directive case law on hitherto unfamiliar aspects of litigation in major European jurisdictions:
  - disclosure/discovery
  - confidentiality
  - ex parte injunctions, pre-emptive injunctions
  - seizure/inspection orders, including cross-border seizures
  - gathering evidence
  - product recall
  - reimbursement of legal fees
- In this context the panel will discuss recent decisions including:
  - UK High Court decision in L’Oreal SA v Ebay International AG
  - German Federal Court of Justice decision in Pollutant Residue Removal
  - provisional injunctions granted in Olanzapine urgency proceedings
  - inspection and confidentiality orders in Laser Welding Method and Brick Veneers II
  - cross border seizures in the Synthol/Astellas case
  - Abbott v Medtronic (The Hague District Court decision and the Court of Appeal Hertogenbosch 2009)
  - Friederichs vs Novartis
  - Wellcome Foundation Ltd & Glaxo Group Ltd vs Pharmachemie B.V.
  - Octrooihouder sas vs Gerekwestreerde International B.V.
  - Procter & Gamble Company vs Reckitt Benckiser
  - Ezendam v Lommer
- Is the statement that harmonisation is occurring in favour of innovators justified?

12.15 In Discussion with the European Patent Office: Update on Recent Decisions

Rainer Moufang, Legal Member, Boards of Appeal, European Patent Office (Germany)

Rainer Moufang is a senior representative of the EPO’s Boards of Appeal, with close involvement in cases running through the patent office. He will provide an informative and authoritative overview of the major decisions recently made and pending before the EPO. There will be ample time for participants to address their questions and concerns, as well as discuss implications of recent EPO cases with Dr Moufang.

13.15 Networking Lunch

14.30 SPC Litigation: Recent Case Law and Varying Requirements for SPCs Across Europe

Panelists to be confirmed

- Grant of SPCs – is it possible to interfere?
  - Dutch Patent Office Syntho- Merz, 26 March 2009
  - Syntho v Merz Pharma [2009] EWHC 656 (Pat) – referral to the ECJ
- How and why are negative or zero term SPCs obtained?
  - Dutch Patent Office, 23 January 2009
  - French Patent Office decision
- Requirements for obtaining SPCs across major European jurisdictions:
  - general requirements
  - vaccines
  - enantiomers and combination products
- What is the “first market of authorisation” in the EU, for the purposes of SPCs?
- Key issues in litigating SPCs claims: novelty, obviousness and sufficiency
- Scope of protection of SPCs: combination products, enantiomers and crystalline forms

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15.10 Critical Analysis of Key Issues and Recent Case Law Involving Paediatric Extensions

Tony Rollins, Managing Counsel - European Patents
Merck, Sharp & Dohme Ltd (UK)

- Paediatric regulation - to what extent is the application for paediatric extensions a balancing act for patent owners?
- the issues arising including combination products and negative term SPCs
- different interpretations of the regulation
- Latest update on Patent Office interpretation of paediatric regulation
- the English Court of Appeal September ’09 ruling – the El du Pont Nemours case
- inconsistent Patent Office decisions
- What does the future hold?

15.40 Afternoon Refreshments

15.55 Pharma and Biotech Infringement Litigation in China, India, Russia and Israel

Anthony Chen, Partner, Jones Day (China)
Eugene A. Arievich, Principal, Baker & McKenzie CIS Limited (Russia)
Eran Bareket, Senior Partner/Advocate
Gilat, Bareket & Co. (Israel)
Hari Subramaniam, Partner
Subramaniam, Nataraj & Associates (India)

China
- Proliferation of patent litigation in China: statistics and reasons
- Interplay of infringement lawsuits and invalidation actions
- Impact of the Patent Law Amendment Act on patent litigation
- Case studies of pharmaceutical patent litigation in China

India
- Specific features of patent litigation in India
- Different fora for revocation actions and for infringement actions
- Judicial processes, ex parte and interim reliefs
- Burden of proof
- Disclosure requirements
- Price related parameters and their role in the grant of interim and/or final injunctions - the Tarceva litigation

Russia
- Specific features of Russian patent litigation
- no discovery
- importance of forensic examination
- different fora for infringement and nullity actions
- Manufacturing samples for getting a marketing authorisation - infringement or exemption?
- The final analysis on experience of litigating patents in Russia - tangible results or a wild goose chase?

Israel
- Facilitative provisions
- availability of a wide rage of effective temporary remedies
- Anton Piller orders
- ex-parte injunction available in urgent cases
- patents presumed valid for the purpose of temporary injunction
- effective remedies as part of final judgment
- permanent injunction- the primary remedy
- effective damages: restitution of profits of the infringer and award of damages at large
- double damages for wilful infringement

17.15 Chairman’s Closing Remarks and Conference Adjourns

Thursday, 28 January 2010

08.45 Chairman’s Opening Remarks

Tony Rollins, Managing Counsel - European Patents
Merck, Sharp & Dohme Ltd (UK)

09.00 Special Address: How Have Recent Landmark Decisions Impacted the US Litigation Landscape?

Judge Randall R. Rader
United States Court of Appeal, Federal Circuit (USA)

Before his appointment to the Bench, Judge Randall R. Rader was Chief Counsel and Minority Chief Counsel for the Sub-committee on the Constitution and the Subcommittee on Patents Trademarks and Copyrights.

The past 12-18 months witnessed several landmark cases, including Re Bilski and Ariad vs Lilly, as well as a series of conflicting decisions in key areas such as patent term extensions. Judge Rader’s address will provide a unique opportunity to receive an authoritative view of the actual impact of these decisions in the months that followed.

Judge Rader’s address will be followed by an extended Q&A session

10.15 Pharma Sector Final Report: What Are the Implications for Industry?

Fabio Domanico, Pharmaceuticals Sector Inquiry Task Force, European Commission (Belgium)

David H Rosenberg, Industry Affairs Manager, Corporate IP Department GlaxoSmithKline PLC (UK)

- Summary of Final Sector Inquiry Report and implications for industry
- policy recommendations
- enforcement mechanisms envisaged for the near future
- what follow on investigations are likely to result?
- Does it change existing innovators’ practice in prosecuting or litigating pharma patents? If so, to what extent?
- Does the Final Report offer generics companies more comfort or a new defence line vs originators? Or is it less than was expected after the Preliminary Report?

11.15 Morning Refreshments

11.30 Settlement Agreements Post Pharma Sector Inquiry: What Can and Cannot be Done?

Fabio Domanico, Pharmaceuticals Sector Inquiry Task Force, European Commission (Belgium)

Denis Schertenleib, Partner, Patent Litigation & Licensing, Hirsch & Associates (France)

- Main objections to settlement agreements, flowing from the sector inquiry
- Industry view on practical usefulness of settlement agreements – are they really any different from licence agreements?
- Drafting the most common clauses in settlement agreements: when are they likely to be deemed anti-competitive?
- market sharing
- customer sharing
- reverse payments
13.45 **Beyond the Injunction: The Battle for Damages in Pharma Patent Litigation**

*Frank-Erick Hufnagel, Partner, Freshfields Bruckhaus Deringer LLP (Germany)*

- How are damages calculated in pharma patent litigation: the alternatives
- Recovery of lost profit - a viable/attractive option?
  - approach in different European jurisdictions
  - level of proof required
- Calculating damages in the case of multiple infringers
  - can damages be claimed against each infringer in a distribution chain?
  - can a “mix” of calculation models be applied vis-a-vis different infringers?
  - must damages against one infringer be set off against damages recovered from another?
  - can the patent owner be over-compensated

14.45 **Using Experiments in Pharma and Biotech Patent Litigation: Key Legal and Practical Considerations**

*Gerry Kamstra, Partner, Bird & Bird (UK)*

*Eyal Barash, Chief Patent Counsel, Aptuit (USA)*

- Legal considerations
  - evidential permissibility and weight
  - legal privilege
  - obtaining samples
- Tactical considerations
  - risk of disclosure of unexpected results
  - risk of unexpected interpretations of results
  - impact on procedural timelines
- Practical considerations
  - involvement of independent experts
  - design of experiment having regard to whether infringement or invalidity is being proved
  - choice of laboratory equipment and reagents
  - conduct of observed experiments

15.30 **Afternoon Refreshments**

15.45 **Strategies and Best Practice for Conducting and Managing Complex Multi-Jurisdictional Litigation**

*John Nevard, Senior IP Manager, Unipath Medical (UK)*

*Martyn Fish, Partner, Harrison Goddard & Foote (UK)*

- Reaching the decision to litigate: what factors must be considered when deciding whether to sue or settle?
- What patents to assert (when the choice is available)?
- Making effective preparations to litigate
- When to involve external counsel/local counsel in each jurisdiction
- Are there any reliable means of assessing likelihood of success?
- Choice or law and forum: pros and cons to note in each major European jurisdiction
- How do you manage differing timelines in different jurisdictions?
- Factors to consider when selecting multi-national legal teams
  - advantages of having local counsel
  - how and to what extent should an in-house team be involved?
  - how can they ensure they retain control over the case?
- Effective cost management strategies
  - how do you ensure your forecast budget is realistic and that you adhere to it thereafter?

16.45 **Chairman’s Closing Remarks**

*optional post conference master class*

**Friday, 29 January 2010 – 09.00-12.30**

**Winning Strategies for Enforcing Your Life Sciences Patents in China and India**

*Anthony Chen, Partner, Jones Day (China)*

*Hari Subramaniam, Partner, Subramaniam, Nataraj & Associates (India)*

Practically focused and interactive, this master class will offer a deep dive into patent enforcement in two jurisdictions which, for the European pharma and biotech industry, are crucially important given the strong presence of local generics companies. Led by highly regarded local practitioners, this workshop is far from being just a general overview of patent litigation in China and India, but is designed especially to address specific questions, concerns and issues raised by pharma companies when assessing whether to pursue infringement actions in these countries.

**China**

China’s rapidly growing pharmaceutical market has attracted a great deal of competition among international pharmaceutical companies and domestic generic drug makers. The result: patent litigation has become a critically important competition tool. While China’s nascent patent system is modeled after the West, it has developed distinctive features that could entrap unwary users. This part of the master class is designed to help you prepare, plan, and manage patent litigation in China, considering the specific characteristics of China’s patent infringement lawsuits and patent invalidation actions. In particular, the following topics will be addressed:

- Where to file patent infringement lawsuits in China
- Declaration of non-infringement action by accused infringer
- How to obtain evidence for patent infringement lawsuits in China: preservation of evidence and reversal of burden of proof
- How to obtain and enforce injunctions
- Damages assessment

**India**

India occupies a strategic position in the pharma and biotech sectors due to its market size, long-standing presence of most international pharmaceutical companies which co-exist alongside a strong domestic generics presence. Indian patent law contains unique provisions that have been used by industry to prevent grant of patents on commercially important products. This litigation and the interpretation given by Indian Courts also plays a role in at least partially influencing policy in other jurisdictions such as Brazil, South Africa, and other Asian countries. This part of the master class will cover the following areas:

- Where to file patent infringement lawsuits in India
- How to obtain evidence for patent infringement lawsuits
- The use of interim and ex parte injunction orders as a tool to prevent infringement
- Defences in infringement actions
- Declaration of non-infringement action by accused infringer
- Revocation actions and choice of jurisdictions
- Pre-grant and post-grant oppositions
- Assessment of damages
- Time factors and costs
- Litigation in India - case studies
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ADMINISTRATIVE DETAILS

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Time: 8:15 am to 17:15 pm
Venue: Radisson Blu Hotel
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An allocation of bedrooms is being held for delegates at a negotiated rate until 15 December 2009. Please visit the conference website www.C5-online.com for more information.

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The documentation provided at the event will be available on CD only.

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