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In A Global Context

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C5's 4th Annual Conference on

Pharma & Biotech Patent Litigation

Practical and Commercial Litigation Strategies for Protecting Your Global Patent Portfolio and Maximising Revenues

31 January – 1 February 2012 • Crowne Plaza City Centre Hotel, Amsterdam, The Netherlands

Get Vital Information from Leading Experts:

European Patent Office (Germany)
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Petr Kusý, Patent Attorney, ermák a spol. Law and Patent Offices (Czech Republic)
Judge at the Federal Patent Court Munich (Germany)
Vertex Pharmaceuticals (UK)

Key regulators, distinguished in-house counsel from the world's largest pharma and biotech companies, and their expert legal advisors from across the globe will address the following key issues:

- The enforceability of **gene sequence patents** in light of *Lilly v HGS*
- SPC references and recent opinion by the Advocate General of the ECJ: **what you need to know for your SPC applications**
- **EPO update** on biotech patenting and the EU patent reform
- The impact of **recent launch strategies by generics** on preliminary and interim injunctions across Europe
- The interplay between insufficiency of disclosure and future embodiments in **biotech inventions**
- Patent litigation strategies in **Central and Eastern Europe** and lessons to be learned
- **Instructing scientific experts** in your patent litigation proceedings in light of recent case law
- Developing a successful **strategy for pan-European patent enforcement** following recent case law developments on **cross-border injunctions**
- The latest **US developments** in pharma and biotech patent litigation
- Disclosure of prior art and **forthcoming antitrust issues**
- The **stem cell patent landscape**: overcoming the legal and regulatory challenges
- **Second medical use and dosing regimens claims**: back in the spotlight
- Patentability and enforcement of **research tool patents**: how broadly should reach-through claims be applied?
- Avoiding patent infringements in **clinical trials**
- Managing the practical implications of **EU border enforcement of IP rights**
- **Patent litigation in India** for pharma & biotech products

Up to 16.25 CPD

Add practical value to your learning experience by attending the programme's pre-conference workshop on Monday, 30 January 2012:

Part A: Successful Patent Drafting Tips and Techniques in Light of Recent Case Law Developments

Part B: Practical Considerations for your 2012 Pan-European Patent Litigation Strategies

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Pharma and Biotech patent law continues to evolve rapidly, with numerous significant case law developments arising from new tactics being employed by generics in recent times. Given the highly competitive and lucrative nature of the industry, it is more important than ever that IP/patent departments and patent attorneys stay abreast of recent court decisions on a global level, as well as current litigation tactics, to ensure they are implementing the most competitive strategies to protect and defend their patent portfolios and maximise revenues on inventions.

The 2012 Pharma & Biotech Patent Litigation forum will focus on the latest case law developments on pharma and biotech patents across Europe and the US and how decisions in the various national courts will inevitably impact on the litigation strategies you employ. You will walk away with fresh insights, tactics and tools to strategise your litigation techniques and remain competitive in today's constantly changing patent landscape.

C5's 4th Annual Pharma & Biotech Patent Litigation conference brings together key regulators, distinguished in-house counsel from the world's largest pharma and biotech companies, and their expert legal advisors from across the globe. Based on their first-hand experience in recent pharma and biotech patent litigation, the expert panel will provide you with important case law updates and invaluable strategies to combat the latest challenges for more effective and satisfactory results.

Must-attend practical, interactive and intensive pre-conference workshop sessions on: Monday, 30 January 2012:

Part A: Successful Patent Drafting Tips and Techniques in Light of Recent Case Law Developments

Part B: Practical Considerations for your 2012 Pan-European Patent Litigation Strategies

Be where your industry will be on 31 January – 1 February 2012 in Amsterdam and reserve your place at this invaluable conference today! Register now by calling **+44 (0) 20 7878 6888** or registering online at **www.c5-online.com/patentlitigation.**

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Lakshmikumaran & Sridharan (L&S) is a full service law firm. Founded in 1985, L&S has six offices across India with 219 professionals including 31 Partners. The IP Team has expertise in patents, designs, trademarks, copyrights & PVP laws and work closely with clients for contentious and advisory issues. L&S enjoys more than 80% share in filings under the PVP Legislation. The Patent Litigation team achieved greater heights in the year 2010-11 by successfully defending interest of a wind energy company in a highly publicized patent litigation. The team is also representing an automobile company in spark plus technology related litigation.

CONFERENCE CHAIRS:

Gareth Morgan, Partner, Winston & Strawn

Colleen Tracy, Partner, Fitzpatrick, Cella, Harper & Scinto

EXPERT FACULTY:

Eleni Kossonakou, Directorate Patent Law, European Patent Office

Juergen Dressel, Head of Patent Litigation ex USA, Novartis Pharma AG

Fiona Bor, Director and Head of IP, Mylan

Julia Pike, Head of Global IP Litigation, Sandoz

Michael Kock, Global Head IP, Sygenta International AG

Dr. Ewan Nettleton, Senior Patent Counsel, CVM, Novartis Pharma AG

James Horgan, Assistant Counsel, European Patents, Merck & Co. Inc

Bernard McDonald, Global IP Manager, Legal Affairs Group, Emergent BioSolutions

Gareth Morgan, Partner, Winston & Strawn

Philip Carey, Associate, Winston & Strawn

Colleen Tracy, Partner, Fitzpatrick, Cella, Harper & Scinto

Gertjan Kuipers, Partner, De Brauw Blackstone Westbroek

Paul Inman, Partner, Wragge & Co.

Simon Dack, Partner, Hoyng Monegier

Alan Johnson, Partner, Bristows

Sean-Paul Brankin, Counsel, Crowell & Moring

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Vladislav Ugryumov, Partner, Gowlings

Ewa Rutkowska, Partner, Baker & McKenzie Krzyzowski & Partners

Dr. Árpád Petho, Partner, Danubia Patent & Law Office LLC

Petr Kusý, Patent Attorney, ermák a spol. Law and Patent Offices

Karin Friehe, Judge, Federal Patent Court, Munich

R. Parthasarathy, Senior Partner, Head of IPR Division, Lakshmikumaran & Sridharan Attorneys

Jan Pieter Hustinx, Partner, De Brauw Blackstone Westbroek

Lisa Dixon, Senior Patent Counsel, Vertex Pharmaceuticals

Dr. Duncan Curley, Director, Innovate Legal

Marleen H.J. van den Horst, Partner, Head of IP & Technology Practice Group, BarentsKrans

WHO SHOULD ATTEND?

C5's 4th Annual Pharma & Biotech Patent Litigation conference is a must for:

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

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Pre-Conference Workshop – 30 January 2012

13.45 **Coffee and Registration**

14.00 **Part A: Successful Patent Drafting Tips and Techniques in Light of Recent Case Law Developments**

Nick Bassil, Partner, Kilburn & Strode (UK)

Lisa Dixon, Senior Patent Counsel, Vertex Pharmaceuticals (UK)

The workshop leader will examine the practical and strategic tips for drafting successful patent applications, ensuring you can effectively claim a commercial product in the patent every time, whilst balancing early patent filing with sufficient data.

- Ensuring you claim a commercial product in the patent
- Early filing vs. adequate data
  - how much data needs to be included in the patent application?
- Determining what is already on the market: adopting a thorough approach
- Practical tips on claim drafting for SPCs in light of recent decisions
  - how far do you need to describe invention story / technical prejudice?
  - when is it safe to publish?

15.30 **Part B: Practical Considerations for Your 2012 Pan-European Patent Litigation Strategies**

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

Jan Pieter Hustinx, Partner, De Brauw Blackstone Westbroek (Netherlands)

The workshop leader will walk you through important considerations for your upcoming patent litigation strategies based on developing trends in the pharma and biotech industry. This workshop will present the opportunity to benchmark your current strategies with your peers and discuss practical solutions to both existing and future challenges.

- Boiler plate considerations
  - prior art against competitor patenting vs. prior art against your own patenting
- Recent amendments to the guidelines for examination
- Revising your approach to instructing scientific experts
  - selecting the right expert for opinion evidence
- Launch strategies by generics: what can we expect in 2012?
  - contrasting the current approaches across Europe

17.00 **End of Pre-Conference Workshop**

Main Conference Day One: 31 January 2012

8.30 **Coffee and Registration**

8.50 **Chair's Opening Remarks**

Gareth Morgan, Partner, Winston & Strawn (UK)

9.00 **KEYNOTE ADDRESS**
Recent Case Law Developments in Pharma and Biotech Patent Litigation in Germany

Karin Friehe, Judge, Federal Patent Court, Munich (Germany)

9.30 **SPC References and Recent Opinion by the Advocate General of the ECJ: What You Need to Know for Your SPC Applications**

Juergen Dressel, Head of Patent Litigation ex USA, Novartis (Switzerland)

- Recent AG opinion in *Medeva/Georgetown*
  - practical implications if the Court of Justice follows the recent opinion
  - the wider consequences: how will other referred SPC cases be impacted by the outcome of *Medeva*?
- Other CJEU references: what is the scope of SPCs for combination products?
  - *Daiichi*
  - *Novartis*
  - *Yeda*
  - *University of Queensland*
- *Neurim Pharma v Comptroller*: referral to the CJEU
  - entitlement to a new SPC for a patented new human indication
- Emerging SPC issues
  - reach through claims: *Novartis v Medimmune*
  - single enantiomers: *Pfizer v Teva* (Atorvastatin)

10.15 **The Enforceability of Gene Sequence Patents in Light of Lilly v HGS**

Gareth Morgan, Partner, Winston & Strawn (UK)

- What satisfies industrial applicability for gene based patents in the UK?
  - to what extent will a patent need to describe utility/ application?
- Contrasting the decisions of UK national court and the EPO Technical Board of Appeal
  - considering questions of industrial applicability, sufficiency and inventive step
  - pan-European implications
- The EU Biotech Directive: guidance on how the requirement of industrial applicability should be applied to gene sequences
- Practical effects of Monsanto in light of *Lilly v HGS*
- Current EPO guidelines as to what point in the development process you can successfully make an application for a gene patent
- Gene-based patents in the US
  - *Prometheus*
  - *Myriad*

11.00 **Refreshment Break**

11.15 **EPO Update on Biotech Patenting and the EU Patent Reform**

Eleni Kossonakou, Directorate Patent Law, European Patent Office (Germany)

- Recent amendments to the guidelines for examination
- Progress in the creation of unitary patent protection (EU patent reform)
- Legality of a single EU patent court
  - roles of the ECJ and the EPO
  - practical and constitutional considerations: how would a single patent court be administered?
- Latest developments on stem cell based inventions
- Patentability of gene sequences

12.00 **Limiting Protection for Biotech Inventions – a Trend?**

BIOTECH FOCUS SESSION

Michael Kock, Global Head IP, Syngenta International AG (Switzerland)

- Recent referrals to the CJEU on the scope of claims for nucleic acids
  - impact of new interpretation on EU national laws relating to the scope of protection
  - how can practitioners circumvent the decision for patents granted that are based on such claims?

- Patentability of biological processes for breeding plants
  - G2/07 ("Broccoli Case")
  - G1/08 ("Tomato Case")
  - exemptions for essentially biological processes
- Impact on swine breeding and breeding of animals
- Achieving improved plants based on smart breeding (breeding based on molecular analysis)

12.45 **Lunch**

13.35 **The Impact of Recent Launch Strategies by Generics on Preliminary and Interim Injunctions Across Europe**

PANEL SESSION

Moderator: Philip Carey, Associate, Winston & Strawn (UK)

Julia Pike, Head of Global IP Litigation, Sandoz (Germany)

Marleen H.J. van den Horst, Partner, Head of IP & Technology Practice Group, BarentsKrans

- Critique on recent case law on clearing the way
  - *Pfizer v Teva*: immediate ex parte preliminary injunction alive and well
  - *Ranbaxy v AstraZeneca* (Esomeprazole): Ranbaxy sought to clear a path
  - *Cephalon v Orchid*: questions the automatic right to preliminary injunctions
- Under what circumstances do generics not have to clear the way?
- Legal and commercial benefits/implications for the generic when launching at-risk
- To what extent have recent case developments influenced the decision practice of national courts across Europe?
  - what does *Pfizer v Teva* suggest about the way courts will respond to at-risk launches?
- Launch strategies adopted by generics in different countries and how to combat them

14.40 **Recent US Developments in Pharma and Biotech Patent Litigation**

Colleen Tracy, Partner, Fitzpatrick, Cella, Harper & Scinto (US)

- New higher standard of proving inequitable conduct following *Therasense*
  - overcoming the practical implications of proving materiality independently of intent
  - patent prosecution and due diligence considerations
  - how will the USPTO need to adjust their guidelines in response?
  - the impact of the *Therasense* decision on European case law
- Adopting a competitive patent prosecution strategy in the US in light of imminent new patent prosecution rules on the "first to file"
- The impact of companion diagnostics for biosimilars
  - using antibodies to get the greatest commercial advantage from your biosimilar products
  - overcoming the patent challenges for different types of biosimilars

15.30 **Refreshment Break**

15.45 **Patentability and Enforcement of Research Tool Patents: How Broadly Should Reach-Through Claims be Applied?**

Huw Evans, Partner, Allen & Overy LLP (UK)

- Recent decisions on the sufficiency of reach-through claims in the UK
  - *Lundbeck v Norpharma*
  - *Novartis v Medimmune*
- The position elsewhere and the relevance of Bayer/reach-through claim (*T1063/06*)
- Reach-through claims from an infringement perspective
  - product "obtained directly" from a patented process
  - relevance to general manufacturing claims
- Filing and enforcement of research tool patents
  - what protection should they be entitled to?
  - how far are research tool patents likely to extend?
- Platform technology: the way of the future?

16.30 **Patent Litigation in India for Pharma & Biotech Products**

R. Parthasarathy, Senior Partner, Head of IPR Division, Lakshmikumaran & Sridharan Attorneys (India)

- How does the patent litigation framework differ in India?
- Strategies and tips to protect IP rights in India
- Managing the infringement of IP rights
  - what can pharma companies do when their rights have been infringed in India?
- How recent case law developments in India may impact on patent law developments across the globe

17.15 **Chairman's Closing Remarks and End of Day One**

Main Conference Day Two: 1 February 2012

8.45 **Chair's Opening Remarks**

Colleen Tracy, Partner, Fitzpatrick, Cella, Harper & Scinto (US)

8.50 **Instructing Scientific Experts in your Patent Litigation Proceedings in Light of Recent Case Law**

Paul Inman, Partner, Wragge & Co. (UK)

Dr. Jan-Hendrik Spilgies, Partner, Hoffmann-Eitle (Germany)

Peter-Ulrik Plesner, Partner, Plesner (Denmark)

- Recent judgment from the UK in *Medimmune v Novartis*
  - instructing experts: traps for the unwary
- Practical considerations for selecting experts
  - selecting a skilled team: *Schlumberger v EMGS*
  - what factors are taken into account?
  - determining the relevance of the person's expertise
- Litigation considerations
  - determining who was the skilled person at the time
  - conduct of experts: level of detail required on the patents
  - showing the expert prior art before showing the patent: what is the best approach?
- Instructing experts in Denmark
  - interlocutory proceedings
  - main proceedings
- Party and court experts in German nullity proceedings: recent developments
- The potential pitfalls of using the same experts in different jurisdictions
- Useful tips for obtaining objective opinion evidence in patent cases
- What the EPO considers the expert team should consist of

9.50 **Patent Litigation Strategies in Central and Eastern Europe**

This session will provide you with an overview of the patent litigation processes in Eastern European countries, including recent court decisions in pharma & biotech, which may impact

on the litigation strategies you employ and ultimately the decisions followed by courts throughout the rest of Europe. Other specific issues to be addressed include:

Moderator: Dr. Árpád Petho, Partner, Danubia Patent & Law Office LLC (Hungary)

Ewa Rutkowska, Partner, Baker & McKenzie Krzyzowski & Partners (Poland)

Vladislav Ugryumov, Partner, Gowlings (Russia)

Petr Kusý, Patent Attorney, Čermák a spol. Law and Patent Offices (Czech Republic)

Poland

- Approach to preliminary injunctions in patent litigation in Poland
- Evidence preclusion

Hungary

- Obtaining preliminary injunctions for crystalline form patents
- What constitutes an "immediate threat of infringement" in patent litigation?

Russia

- First injunction recently granted in the Supreme Court: what does this mean for future litigation in Europe?

Czech Republic

- Obtaining preliminary injunctions in the Czech Republic
- Declaratory proceedings before the Patent Office and their interaction with infringement proceedings in Court
- Patent nullity actions and their effect on other proceedings

11.00 **Refreshment Break**

11.15 Second Medical Use and Dosing Regimens Claims: Back in the Spotlight

Dr Fiona Bor, Director of IP, Mylan (UK)

Dr. Duncan Curley, Director, Innovate Legal (UK)

- The impact of recent developments in France: *Actavis v Merck*
  - medical use vs. therapeutic method
- Latest developments on second medical use claims in the UK
  - *Ranbaxy v AstraZeneca*
- What can be expected in the future for second medical use claims?

11.55 Developing a Successful Strategy for Pan-European Patent Enforcement Following Recent Case Law Developments on Cross-Border Injunctions

Simon Dack, Partner, Hoyng Monegier (Netherlands)

Alan Johnson, Partner, Bristows (UK)

Dr. Ewan Nettleton, Senior Patent Counsel, CVM, Novartis Pharma AG (Switzerland)

- The recent approach of the Dutch court
  - *Solvay v Honeywell*
  - *Yellow Page v Yell*
  - *Apple v Samsung*
- Implications of recent cross-border injunctions for pharma and biotech products
- Referral to the ECJ regarding provisional cross-border injunctions
- Comparing patents with other EU IP rights (CTMs Community designs)

12.55 **Lunch**

14.00 Disclosure of Prior Art and Forthcoming Antitrust Issues

Bernard McDonald, Global IP Manager, Legal Affairs Group, Emergent BioSolutions (UK)

Sean-Paul Brankin, Counsel, Crowell & Moring (Belgium)

- Lessons from the Losec appeal: what is the likelihood of a duty of full disclosure of prior art to European patent examining authorities?
  - to what extent could failure to disclose be considered fraud on the EPO?
  - clarifying what is meant by "abuse of a dominant position"
- Comparing the current US and European approaches to disclosure of prior art
- Consequences for pharma companies for failure to disclose prior art
- What can we learn from the *Boehringer/Amiral* settlement?
- Recent statement by the European Commission on antitrust issues
  - what is and what isn't permitted?
- Scope for compulsory licensing

14.50 The Stem Cell Patent Landscape: Overcoming the Legal and Regulatory Challenges

Dr. Jürgen Meier, Partner, Vossius & Partner (Germany)

- AG's opinion in Brüstle: are products derived from human embryonic stem cells patentable subject matter?
- Wider commercial implications: what will happen to biotech products originally based on human embryonic stem cells?
- Comparison of Brüstle opinion with the approach of the Enlarged Board in *WARF*
- A glance at hypothetical case studies
- Overcoming ethical problems through new technologies: Induced Pluripotent Stem Cells (IPS)

15.30 **Refreshment Break**

15.45 Avoiding Patent Infringements in Clinical Trials

James Horgan, Assistant Counsel, European Patents, Merck & Co. Inc. (UK)

- How much research can be undertaken without infringing?
- What does the EU Bolar provision safeguard in major territories?
- UK proposals to broaden the experimental use exemption
- The position on biosimilars
- Minimising patent infringement risks in clinical trials

16.25 Managing the Practical Implications of EU Border Enforcement of IP Rights

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

- The "Anti-Piracy Regulation" (Regulation 1383/2003)
- What is the scope of powers of the customs authorities?
- Divergent approaches: Netherlands vs. UK
  - how pharma & biotech companies can navigate the varying approaches
- Goods in transit: AG opinion in *Nokia* and *Philips*
  - what will be the practical implications for pharma & biotech companies?
- What can be expected in the proposed revised Regulation?
- Anti-Counterfeiting Trade Agreement (ACTA)

17.10 **Chairman's Closing Remarks and End of Conference**

C5's 4th Annual Conference on

Pharma & Biotech Patent Litigation

Practical and Commercial Litigation Strategies for Protecting Your Global Patent Portfolio and Maximising Revenues

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ADMINISTRATIVE DETAILS

Date: 31 January - 1 February 2012

Time: 8.30 - 17.15

Venue: Crowne Plaza Amsterdam City Centre Hotel

Address: 5 Nieuwe Zijds Voorburgwal, Amsterdam, 1012 RC, The Netherlands

Telephone: +31 (0)20 620 0500

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