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)
- Novartis Pharma AG (Switzerland)
- Merck & Co. Inc. (UK)
- Mylan (UK)
- Sandoz (Germany)
- Syngenta International AG (Switzerland)
- Emergent BioSolutions (UK)
- Winston & Strawn (UK)
- Atul Sharma, Consultant, Lakshmikumaran & Sridharan Attorneys (India)
- Fitzpatrick, Cella, Harper & Scinto (US)
- De Brauw Blackstone Westbroek (Netherlands)
- Crowell & Moring (Belgium)
- Allen & Overy (UK)
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- Killburn & Strode (UK)
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- Brtows (UK)
- Baker & McKenzie Krzyzowski i Wspólnicy (Poland)
- Gowlings (Russia)
- Danubia Patent & Trademark Attorneys (Hungary)
- Petr Kusý, Patent Attorney, ermáka spol.律 Law and Patent Offices (Czech Republic)
- Judge at the Federal Patent Court Munich (Germany)

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

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

To register call +44 (0) 20 7878 6888 or register online at www.C5-Online.com/patentlitigation
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 Bot, 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 Morgan, 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 Westbrook
Paul Inman, Partner, Wragge & Co.
Simon Dack, Partner, Hoyng Monegier
Brian Cordery, Partner, Bristows
Sean-Paul Brankin, Counsel, Crowell & Moring
Mark Ridgway, Senior Associate Allen & Overy LLP
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Dr. Leo Polz, Partner, Hoffmann-Eitle
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Peter-Ulrik Plesner, Partner, Plesner
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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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For more information about this program or our global portfolio, please contact: Jo Menzer on +44 (0)20 7878 6978 or email j.menzer@C5-Online.com
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?

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 / technical prejudice?
  - Contrast the decisions of UK national court against your own patenting

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  The Interplay Between Insufficiency of Disclosure and Future Embodiments in Biotech Inventions
- **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
    - 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

Moderator: Philip Carey, Associate, Winston & Strawn (UK)
Julia Pike, Head of Global IP Litigation, Sandoz (Germany)

• 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?

Mark Ridgway, Senior Associate, 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

Tbc

• 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. Leo Pola, 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 Pethő, Partner, Danubia Patent & Law Office LLC (Hungary)
Ewa Rutkowska, Partner, Baker & McKenzie (Poland)

Vladislav Ugyumov, 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)
- 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)

Brian Cordery, 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)

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

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Date: 31 January - 1 February 2012
Time: 8.30 - 17.15
Venue: Crowne Plaza Amsterdam City Centre Hotel
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Telephone: +31 (0)20 620 0500

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