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C5's 6th Forum on

Pharma & Biotech Patent Litigation

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Strengthening your Commercial Patent Litigation Strategies to Maximise Patent Protection and Enhance Profits

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28th & 29th January 2014 • Radisson Blu Hotel, Amsterdam, Netherlands

A First hand perspective on the Unified Patent Court Committees: A rare opportunity to have your questions answered from the Preparatory and Drafting Committees of the Unified Patent Court

Paul van Beukering, Chairman of the Preparatory Committee of the Unified Patent Court *(Netherlands)*

Kevin Mooney, Chairman of the UPC Drafting Committee *(UK)*

Willem Hoyng
Member of the UPC Drafting Committee *(Netherlands)*

Winfried Tilmann
Member of the UPC Drafting Committee *(Germany)*

Pierre Véron
Member of the UPC Drafting Committee *(France)*

Alice Pezard
Member of the UPC Drafting Committee *(France)*

Practical Tips on Planning Your Strategies From In House Counsel of Pharma and Biotech Corporations:

Juergen Dressel
Head of Patents Litigation ex USA
Novartis Pharma AG *(Switzerland)*

George Moore
Head, Transactions Patent Support & Senior Patent Litigation Counsel
Sandoz International GmbH *(Germany)*

Dr. Rob Aerts, Senior Patent Attorney
Keygene N.V *(Netherlands)*

Marcus J. Dalton
VP and Global Head Patents
GSK Vaccines
Glaxosmithkline *(UK)*

Paul Wiegel
Associate Director of Intellectual Property, Morphosys AG *(Germany)*

Dr Christian Drescher
Head of Patents
Midas Pharma GmbH *(Germany)*

Lars Conrad
Chief Patent Specialist
H. Lundbeck A/S *(Denmark)*

View from the Bench: Hear Leading Judges preside over a Mock Trial based on the draft UPC Rules of Procedure

His Honour Michael Fysh, QC, SC
8 New Square *(UK)*

Alice Pezard, Honorary Judge at the French Judiciary Supreme Court *(France)*

Samuel Granata
Judge, Commercial Court of Antwerp (Belgium)

An in-depth Look at Patent Settlement Agreements and Competition & Anti-Trust Law:

Blaz Visnar
European Commission
DG Commission

Add further value to your conference experience by attending our expert led workshop:

Interactive pre-conference workshop — Monday 27th January 2014

How to draft a Patent Settlement Agreement and How to Avoid Anti-Competitive Clauses

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The Unified Patent Court has become a significant development for every IP and Pharma expert in the world, regulatory bodies on both sides of the Atlantic are sanctioning Pharma companies for anti-competitive behaviour, EU national courts are increasing their referrals to the ECJ for answers and clarifications on a wide spectrum of topics, new European alternative IP courts are being created and Emerging Markets keep altering their IP laws and procedures.

C5's 6th Pharma & Biotech Patent Litigation forum will focus on the latest case law developments on Pharma and Biotech patents across Europe, the US and High Growth markets and will examine the impact of judicial decisions in the national courts on your litigation strategies. You will gain an in-depth understanding regarding the hottest and most important topics of the Pharma and Biotech industry in order to alter and strengthen your litigation strategies and tailor your techniques to the latest challenges and developments.

Top reasons to attend:

- Learn about the Unified Patent Court directly from the source. Members of the Preparatory and Drafting Committees will provide answers to all of your questions regarding the Unified Patent Court
- Gain insights into the Unified Patent Court procedures via our mock trial
- Develop an in-depth understanding of reverse payments and how to avoid the imposition of monetary fines
- Enhance your knowledge of the latest developments regarding stem cells and human patent cells post the landmark US case of Myriad and the recent referral of the International Stem Corporation case
- Expand your knowledge on how to tailor your legal strategy on preliminary injunctions and hear practical tips about the SPC's and the problems the SPC Regulation has caused to national courts across the EU
- Deal effectively with the ground breaking changes regarding second medical use patents and how patent filing strategies in this area need to urgently change to accommodate the newly decided criteria
- Network with judges, leading in house counsel and private practice lawyers in the field of Pharma and Biotech patent litigation

Don't miss this outstanding opportunity to learn from and network with those at the forefront of this field. Confirm your participation today and be rewarded with a significant discount.

C5's 6th Forum on Pharma & Biotech Patent Litigation will provide valuable insights for:

Pharma, Biotech and Chemical Companies:

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Pre-Conference Workshop: Monday, 27 January 2014

1:30 – 4:30

How to Draft a Patent Settlement Agreement and How to Avoid Anti-Competitive Clauses

This workshop will provide an in depth, practical guide to drafting a patent settlement agreement. Get commercial tips and hints on practical steps you need on how to draft the agreement avoiding the inclusion of clauses that can be anti-competitive which can lead to the imposition of high monetary fines. Our experts will share their best practices and critical insights and will highlight the most common errors and pitfalls. Case studies and real life practical examples will be used to highlight the litigation, drafting and anti-trust perspectives of this important topic.

James R.M. Killick, Partner, White & Case LLP (Belgium)

Dr Christine Kanz
Partner, Reimann Osterrieth Köhler Haft (Germany)

Hiroshi Sheraton, Partner, McDermott, Will and Emery (UK)

- Does a pay for delay settlement agreement always amount to a violation of competition law?
- Does the grant of such benefits to the generic pharma company per se equal to anticompetitive behaviour?
- If the agreement is found not to breach competition law when it comes to the originators payment to the generic company per se, when does the agreement become anti-competitive?
- Who bears the burden of providing evidence?
- Is the settlement justified under the exemptions of Article 101(3) TFEU?
- What should be the approach of the companies when considering whether to commence or defend litigation?
- What should be the approach of the companies when settling patent disputes?
- How to avoid the pitfalls and make use of safe harbours when structuring a patent settlement agreement?
- How to minimise, identify and mitigate risks when drafting a patent settlement agreement.

Main Conference Day One: Tuesday, 28 January 2014

8:00 **Coffee and Registration**

9:00 **Opening Remarks from the Chair**

Paul Inman, Partner, Wragge & Co (UK)

9:15 **The Unified Patent Court: How to Successfully Alter your Strategies and Prepare for the New Patent Litigation Era**

Preparatory and Drafting Committee Panel

You will be able to put questions to the panel on the day of the conference. Alternatively submit your questions beforehand anonymously to j.horner@c5-online.com

Paul van Beukering, Chairman of the Preparatory Committee of the Unified Patent Court (Netherlands)

Kevin Mooney, Chairman of the UPC Drafting Committee (UK)

Willem Hoyng, Member of the UPC Drafting Committee (Netherlands)

Winfried Tilmann, Member of the UPC Drafting Committee (Germany)

Pierre Véron, Member of the UPC Drafting Committee (France)

Alice Pezard, Member of the UPC Drafting Committee (France)

10:30 **Networking Break**

10:50 **Judges Panel and Mock Trial: A Practical Approach to the Trial Procedure of the Unified Patent Court**

Mock Trial

With the Unified Patent Court becoming an integral part of biotech and pharma patent litigators and experts, a lot of questions are being raised regarding the procedures of the UPC in practice. This session will bring together three judges from three different EU member states. Leading Counsel will argue a mock case before the panel. The panel of judges will give a verdict and their reasoning offering an insight into the Unified Patent Court three judge panel system.

Alice Pezard
Honorary Judge at the French Judiciary Suprene Court
Of Counsel, Heenan Blaikie, Paris (France)

His Honour Michael Fysh, QC, SC
8 New Square (UK)

Samuel Granata
Judge, Commercial Court of Antwerp (Belgium)

Mark van Gardingen
Partner, Brinkhof N.V (Netherlands)

Trevor Cook
Partner, Bird and Bird (UK)

12:45 **Networking Lunch**

2:00 **A Pan European Perspective on Preliminary Injunctions: What you Need to Know to Successfully Obtain a Preliminary Injunction**

George Moore
Head, Transactions Patent Support & Senior Patent Litigation Counsel, Sandoz International GmbH (Germany)

James Marshall
Partner, Taylor Wessing (UK)

Christoph de Coster
Partner, Taylor Wessing (Germany)

Benjamin May
Partner, Aramis (France)

- What criteria does the court apply when deciding whether to grant PIs and how common are they across Europe?
- What evidence is required? How long will it take and how much will it cost?
- If a preliminary injunction is refused, what happens next? What are the timescales for decision on the merits of the case? Is expedition available?
- What are the financial consequences if a preliminary injunction is awarded but the patentee is unsuccessful on the merits?
- What is the impact of patent weaknesses on the granting of preliminary injunctions? Can PIs be obtained and enforced even though the underlying patent was invalidated but the invalidation decision is under appeal?
- What pre-emptive strategies are deployed to avoid a preliminary injunction? When can a claim for a cross border declaration of non-infringement be made and what will its effect be on a PI application?
- Cross-border preliminary injunctions – what is the impact of Solvay now and how will it all work under the UPC?

3:30 **Networking Break**

3:45 **Supplementary Protection Certificates: Understanding the Implications of SPC Invalidity and Increasing ECJ referrals on Your Patent Litigation Strategy**

The SPC Regulation has been under severe scrutiny for the past three years. Judge Arnold characterised the Regulation as 'dysfunctional'. Is it time for the Regulation to be revised and will the UPC award pan European SPC's?

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

Marcus J. Dalton, **VP and Global Head Patents, GSK Vaccines,** GlaxoSmithKline **(UK)**

Lars Conrad
Chief Patent Specialist, H.Lundbeck A/S **(Denmark)**

- Will the UPC award pan European SPCs and if so what will be the effect for pharma companies?
- Update/Overview on the cases pending before the ECJ and the questions faced by the courts
- Is the SPC Regulation 1768/92 'fit for purpose' or is urgent reform and update needed?
- What are the problems faced by national courts with articles 3a, 3c and 3d of the SPC Regulation?
- Why have referrals to the ECJ escalated in recent years and how will decisions of the ECJ impact on the future of filing strategies of pharmaceutical strategies?
- If the court deems an SPC invalid, what are the most important commercial consequences for a pharma company?
- Update on SPC case law

5:00 **Stem Cell Patents: Strategy Considerations in Light of the *Brustle v Greenpeace* Case and the Recent Referral of *International Stem Corporation***

Dr Rob J. Aerts
Senior Patent Attorney, Keygene N.V. **(Netherlands)**

- Update on the case of *International Stem Corporation v Comptroller General of Patents* as referred to the ECJ by the UK High Court in 2013
- Are stem cells obtained by parthenogenically stimulated human ova excluded from patentability as 'human embryos' under Directive 98/44/ED?
- What are the current criteria for examination of human stem cell inventions at the EPO?
- To what extent do the referrals to the CJEU in the *Brüstle and International Stem Cell Corporation* cases influence the examination procedure at the EPO, and how to tackle the various issues of legal uncertainty?
- What are the commercial implications for biotech products originally based on human embryonic cells and their companies if the ECJ affirms *Brustle v Greenpeace?*

6:00 **Chairs Closing Remarks and End of Day 1**

From €645

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Main Conference Day Two: Wednesday, 29 January 2014

8:00 **Coffee and Registration**

8:30 **Opening Remarks from the Chair**

8:45 **Analysis of the Ground breaking Case of *Association for Molecular Pathology et. Al v Myriad Genetics Inc., et al.* and how it's Aftermath Might Affect Your Patent Strategies in the US**

Moderator:

Sheldon J. Hamilton
Partner, Smart & Biggar **(Canada)**

Panelists:

John D. Murnane
Partner, Fitzpatrick, Cella, Harper & Scinto **(USA)**

Luisa Beatrice Bartorelli
Partner, Dragotti & Associati **(Italy)**

- Is the decision of the US Supreme Court in *Myriad*, the rule or the exception for patenting genes?
- Is the Supreme Court's reasoning flawed?
- What considerations should be taken into account when drafting the patent application post *Myriad*?
- What strategic decisions must be made post *Myriad* by in house counsel and pharma companies?
- Will the decision in *Myriad* act as a deterrent for innovation?
- What is the Canadian approach to Myriad?
- Potential impact on Myriad on patentability on gene patents (and other fields)
- Does the Myriad decision affect patentability of gene sequences in Europe? Impact of the Biotech Directive
- Enforcement of gene sequence patents in Europe

10:00 **Morning Refreshments**

10:15 **Reverse payments: Why and When will Patent Settlement Agreements be Deemed Anti-Competitive and Put your Company at Risk of Fines and Costly Litigation?**

Blaž Višnar
DG Competition, European Commission

Paul Wiegel
Associate Director of Intellectual Property, Morphosys AG **(Germany)**

Dr. Bertold Bär-Bouyssière
Partner, DLA Piper UK LLP **(Belgium)**

- How should patent counsel and companies negotiate patent settlement agreements to comply with competition law?
- What should be the content of such an agreement and what to keep in mind when drafting it?
- Which forms of patent settlements may trigger antitrust sanctions by the European Commission or its national counterparts?
- Are "pay for delay" settlements inevitably in contravention of competition law and do they constitute an abuse of the dominant position of patent owners?
- How will national courts assess and enforce patent settlement agreements?
- Is the law in Europe stricter than in the US? What follows for companies operating globally? (cf. the US case of *FTC v Actavis* and the European decision regarding *Lundbeck A/S*)?

11:30 **How to Develop a Successful Strategy for Second Medical Use Patents**

Juergen Dressel
Head of Patent Litigation (ex USA)
Novartis Pharma AG **(Switzerland)**

Dr. Christian Drescher
Head of Patents, Midas Pharma **(Germany)**

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

- How difficult is it to get second medical use patents granted?
- What are the different attitudes of the national courts to second medical use claims?
- What kind of indications could be granted a second medical use patent by the EPO?
- How willing are the courts to grant injunctions in cases of carving out indications and skinny labelling?
- Would simply carving out the patented indications or dosage instructions be enough to defeat a claim of indirect infringement or is any additional action needed?
- Will companies who obtain second medical use patents adopt 'discontinued labelling' strategies to prevent carving out?
- Will generic pharma companies continue to put themselves at risk of indirect patent infringement?
- Is there adequate incentive for medical research to be encouraged into second and subsequent medical uses of already known compounds?
- What would be the appropriate compensation to patent owners if the generic company is found to be indirectly infringing the patent?
- Update on Second Medical Use Patent case law

12:30 **Networking Lunch**

1:45 **Forum Shopping: Where to Litigate to Increase the Chances of Success and What are the Relevant Cost Factors?**

Fiona Bor
Vice President and Director of IP
Mylan Europe **(UK)**

Dr. Leo Polz
Partner, Hoffmann Eitle **(Germany)**

- What are the criteria for a company when choosing where to bring litigation proceedings?
- Assessing the cost of patent litigation before the various national courts
- Is there real harmonisation between the different EU jurisdictions for biotech and pharma litigation proceedings?
- Would the UPC route be a solid and more affordable alternative for companies?
- What are the alternatives to litigation and how effective are they in practice in the various jurisdictions?
- Are there any indirect litigation costs in the procedure that companies need to be aware of?

2:30 **Managing the Practical Implications of Rapid IP Changes in the High Growth Markets of Brazil, India and China**

Brazil

Gustavo de Freitas Morais
Partner, Dannemann Siemsen Advogados **(Brazil)**

- What types of legal and administrative proceedings are available to a patent owner in Brazil?
- Do Brazilian courts grant cease and desist orders during the prosecution of an application and how easy is it for the patent owner to obtain such an order?
- What is the format of a patent infringement trial, what is the usual duration and cost of such a trial and to what extend are documents and experts permitted in the procedure?
- Does Brazil grant second medical use patents?
- What is the significance of the new updated rules for prior consent assessment of patent applications for medicine, issued by the National Health Surveillance Agency and what has been the reaction by the local courts?
- New mailbox patent lawsuits and constitutional challenges
- Update on Brazilian patent litigation case law

India

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

- Will the ruling on the Novartis case concerning Glivec, deter more western drug firms from entering the market and discourage expensive investment in new drug treatments?
- Has the interpretation of section 3(d) of the Indian Patent Act changed by national Indian courts? How to negotiate Section 3(d). Standard of evidence required.
- Why is India accused of flouting trade rules to bolster the Indian generic industry? Are the courts really balancing western companies IP rights against the need for cheap drugs for the Indian Healthcare system?
- Will the example of India inspire other emerging markets to challenge Western companies' patents?
- Why aren't second medical use or methods of treatment patents granted in India?
- Update on India patent litigation case law

China

Qinghong Xu
Lung Tin International Intellectual Property Agent Ltd

- What changes has the SIPO proposed to further amend the Chinese Patent Law and Examination Guidelines in 2013 and what would their likely impact be?
- What are the main criteria to take into account when you try to effectively enforce your patent in China?
- Update on Chinese patent litigation case law

3:45 **Afternoon Refreshments**

4:00 **Lifting the Lid on the Alternative European Courts: What are the Incentives for Companies to Litigate in the Russian Intellectual Property Court and the Swiss Federal Patent Court?**

Judge Dieter Braendle
President of the Swiss Federal Patent Court **(Switzerland)**

Andrey Zelenin
Partner, Lidings **(Russia)**

- What is the structure of the new courts?
- An account of the litigation and appeal procedures
- Description of litigation costs and court fees
- What are the remedies offered by the court?
- What are the incentives for a company to litigate in the Russian IP court and the Swiss Federal Patent Court?

5:00 **Chairs Closing Remarks and End of Conference**

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Pharma & Biotech Patent Litigation

Strengthening your Commercial Patent Litigation Strategies to Maximise Patent Protection and Enhance Profits

28th & 29th January 2014
Radisson Blu Hotel, Amsterdam, Netherlands

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Date: 28th – 29th January 2014

Time: 8:00am – 17:00pm

Venue: Radisson Blu Hotel, Amsterdam, The Netherlands

Address: 17 Rusland Street, 1012 CK, Amsterdam, The Netherlands

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