C5’s 9th Conference on

PHARMA & BIOTECH PATENT LITIGATION

25th-26th April 2017 | Radisson Blu Hotel, Amsterdam

Join us to explore the complex and continually contentious legal landscape of patent litigation in the pharma and biotech sphere.

Key Topics Include

- The very latest updates on the Unitary Patent System and how Brexit will impact the Unified Patent Court.
- Regulatory considerations when assessing how to effectively manage the lifecycle of your patent and prepare for litigation.
- Understanding the latest trends in preliminary injunctions across Europe.
- Assessing Inter Partes Review 4 Years after its enactment.
- Litigating Biosimilars Across the Atlantic—Understanding the EPIClA patent litigation framework to avoid costly mistakes.
- A jurisdictional update on patent litigation in China, South Korea, India and Canada.
- An examination of second medical use patents looking at the key case of Lyrica and beyond.

Gain Practical Corporate Insight and Guidance From

Henrik Mathassen
Director and Head of IP Department
Zealand Pharma

Fiona Bor
Head of Intellectual Property
Mereo Biopharma

Stella Fletcher EPA
Head of IP
BIAL Portela & Ca SA

Dr. Jurgen Dressel
Head of Patent Litigation
Novartis International AG

Mads Damsgaard
Patent Specialist and European Patent Attorney
Lundbeck

Heli Pihlajamaa
Director, Directorate
Patent Law
European Patent Office

Dr. Sven Bostyn
Chair of the expert group on patent law, biotechnology and genetic engineering
European Commission

Pierre VÉRON
Member
UPC Drafting Committee

Bart van den Hazel
Director, Assistant General Counsel (Patents)
GSK Vaccines

Enhance your conference experience by attending our crucial and comprehensive Pre-Conference Workshop on Monday the 24th of April

Preparing for Patent Litigation under the UPC: Brexit and Beyond

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THE WORLD OF PHARMACEUTICAL AND BIOTECH PATENT LITIGATION IS MOVING INTO UNCHARTERED TERRITORY AND THERE IS MUCH TO CLARIFY

Dear Colleague,

With significant developments in the Pharma and Biotech industry in the past 12 months, in-house counsel and their litigation lawyers are being kept extremely busy across Europe. Patent infringement, interim injunctions, lifecycle extensions and global patent exploitation create a litigious industry where companies are using the courts to ensure they stay ahead of competition. Additionally, the Unitary Patent Court is set to go live in 2017 which will completely overhaul patent litigation throughout Europe.

Our conference focuses on litigation strategies for Pharma and Biotech companies in Europe, how they respond to patent challenges and conduct themselves in patent infringement actions. We feature all aspects of litigation, and how it is dealt with by in-house counsel and their private practice advisors.

C5’s 9th Pharma & Biotech Patent Litigation conference will provide an invaluable focus for analysis of all the fundamental changes affecting pharma and biotech patents across Europe and the US and consider the impact of judicial decisions in the national courts on your litigation strategies.

ATTEND THIS EVENT TO GAIN INSIGHT INTO:

The latest regulatory developments:
- The practicalities of the UPC and reconciling the UPC, Brexit and the European Patent Office
- What are the regulatory challenges when assessing patent enforcement?
- What are steps that need to be taken leading up to and preparing for litigation?
- What are the latest trends in preliminary injunctions across Europe?
- Interpreting the application of SPC legislation around Europe

Optimising your litigation strategy:
- Assess the impact of commercial restructuring of a business on its patent litigation strategy and how the brand vs. brand litigation trend feeds into this
- How to win the race for first filing while providing sufficient data

Benchmarking your strategies against other market leaders:
- Understand how to use the latest tools to protect and further your product
- Find clear legal pathways which will enable you to exploit your IP and maximise revenue
- Keep up to date with the fast paced world of Second Medical Use Patents, including but not limited to the key Lyrica case

Establishing best practices and approaches to patent litigation around the world:
- How to combat the practical issues that global pharma companies face when litigating disputes in China
- The Indian pharmaceutical patent regime and its effect on the innovator industry
- How can the types of filing in Korean patent litigation provide insight into the generics companies’ strategy?

Make sure you gain advantage by getting the latest thinking and strategic direction from the best in the business.

We look forward to welcoming you at the conference.

Danushka De Alwis
Legal Conference Producer
C5 Communications
+44 20 7878 6937 | d.dealwis@c5-online.com

A MUST-ATTEND EVENT FOR:

Pharmaceutical and Biotech Companies:
- In-House General Counsel
- Heads/Directors of IP, Patents and Legal Affairs
- Heads/Directors of IP, Patents and Legal Affairs
- VP/SCP of Patents
- IP Counsel and IP Managers
- Patent Counsel/Attorneys and Managers
- Patent Managers
- Head of R&D

Private Practice Lawyers and Patent Attorneys specialising in:
- IP and Patent Litigation
- Life Sciences/Pharma and Biotech

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Join the Conversation @C5Live #C5LifeSciences
It was announced on 16 January 2017 by the UPC Preparatory Committee that the UPC is expected to be operational by December 2017, with a sunrise period for opting out patents from its jurisdiction from September 2017. Yet many questions about how the court will operate in practice remain unanswered, chief of which is whether the UK can remain in the UPC/UP system in future even if it is no longer an EU member state.

Though the UK is seemingly moving towards participation in the system via its ratification of the UPC protocol it is still unclear as to how the UK could legally participate in the UPC if it is not an EU member state. Should there be no future for the UPC and the UK beyond Brexit, it will become one of the European jurisdictions where separate and additional patent protection will need to continue to be sought outside of the new UPC/UP system.

This workshop will keep you updated on all the latest jurisdictional developments and guide you on the practical issues at hand, including:

- Issues for co-owners and co-ownership agreements
- The law applicable to UPs
- Licensing opt-out and the impact on patent valuation as well as security of opting out or not and of obtaining unitary protection

**Conference Day One:**
Tuesday, 25th April 2017

8.30
Registration

9.00
Chair’s Opening Remarks

9.10
The Effect of Brexit on the Unitary Patent System and Court: Latest Updates

Pierre VÉRON
Member
UPC Drafting Committee

Heli Pihlajamaa
Director, Directorate Patent Law
European Patent Office

- The practicalities of the UPC and reconciling the UPC, Brexit and the European Patent Office
- The UK government announced its intent to ratify the UPS and UPC agreement but can the UK successfully negotiate with the European Union to remain in the UPS and UPC following Brexit?
- How to obtain a patent in the UK? Will the UK have a status similar to that of Switzerland, Norway, and Turkey?
- Would exit from the EU make the opt-out decision easier?
- Quick-fire Q&A with leading UPC experts

9.50
Effective lifecycle management and preparation for litigation

Manja Epping
Partner
Taylor Wessing

Judith Krens
Patent law partner in life sciences and chemicals
Taylor Wessing

- Pre-Action Preparation and the GENERIC challenge
- Regulatory considerations when assessing patent enforcement
- Assessing the lifecycle management of your patents and preparation for litigation

- What are the steps that need to be taken leading up to and preparing for litigation?
- What is the litigation timeline?
- Orphan drug case law and the issue of exclusivity

10.30
Refreshment Break

11.00
Latest trends in preliminary injunctions across Europe

Dr. Claudia Milbradt
Partner
Clifford Chance

Miquel Montanyá
Partner
Clifford Chance

Stephen Reese
IP Partner
Clifford Chance

- Brief introduction of preliminary injunctions in Germany, Spain, UK
  - The German Separation System
  - Preliminary Injunction (“PI”) vs Action on the Merits
  - Requirements (especially: level of evidence required, test of urgency, what does “imminence” mean, “legal validity of a patent”, bonds, cross-undertakings…)
  - Possible action of infringer in advance of a PI in Germany and Spain: Protective writ. Use of “Arrow” declarations in the UK
  - Possible reactions of defendant after grant of PI: objection, appeal, nullity action, damages claims
  - Timelines
  - Will the new Spanish Patent Law coming into force on 1 April 2017 change this landscape?
- Particularities in the pharmaceutical sector
  - Danger of first infringement/danger of recurrence in case of examinations in order to obtain a market authorization, application for a market authorization, advertisement before expiry of patent (Simvastatin)?
  - Particularities in case of an infringement by a generic company (lower requirements of legal validity of a patent)
  - Potential courses of action before the regulatory authorities
- Outlook: Preliminary Injunctions based on a Unitary Patent
11.40
How Does the Commercial Restructuring of a Pharma Business Impact on its Patent Litigation Strategy?
Mads Damsgaard
Patent Specialist and European Patent Attorney
Lundbeck
• Brand vs brand litigation trend
• Bayer v. Baxalta
• Has increased M&A activity played a role in the brand vs. brand trend

12.20
Lunch

1.30
Sufficiency Requirements- What requirements need to be satisfied to allow you to file a patent?
Dr. Sven Bostyn
Chair of the expert group on patent law, biotechnology and genetic engineering
European Commission
Bart van den Hazel
Director, Assistant General Counsel (Patents)
GSK Vaccines
• Striking the right balance between compiling sufficient data and the race for first filing
• How much information do you have to provide to meet the threshold of "plausibility" when filing for a patent?

2.10
Round Table Discussions
Round Table 1
Threat of infringement; What amounts to a threat of infringement?
Lucy Padget
Senior Patent Director
AstraZeneca

Round Table 2
What you must incorporate in your patent claims

Round Table 3
Possible problems with Biotech patent eligibility in the US

3.00
Refreshment Break

3.40
Inter Parties Review 4 Years on…
Henrik Mathassen
Director and Head of IP Department
Zealand Pharma
• What is happening- Facts and figures as to how it is being used
• How it works- How you use it/ How to defend against it
• Potential Advantages of IPR versus District Court Litigation
• Timing and how to approach Post Grant Proceedings and IPR
• What effect has the estoppel provisions had on concurrent or subsequent district court litigation?
• What lies ahead?- Practicalities about how it is going to be used

4.20
Litigating Biosimilars Across the Atlantic- Understanding the BPCIA patent litigation framework to avoid costly mistakes
Gavin Lawson
Director
Intellectual Property at Gilead Sciences
(Under Invitation)
• The Biologics Price Competition and Innovation Act ("BPCIA") procedures and the "Patent dance" between the biosimilar applicant and the innovator
• Caselaw updates and recent developments- There are seven ongoing biosimilar litigations in the U.S
• As a result of these disputes what is the basic framework for patent litigation that has taken shape?
• Trying to bypass the patent dance? - Pre-Application declaratory judgements have been rejected and seemingly abandoned.
• Is the patent dance optional for biosimilar applicants? - Amgen v. Sandoz, 794 F. 3d 1347 (Fed. Cir. 2015)
• The 180 Day Notice Period; when does it begin and is it mandatory?
11.40 Patent Litigation in South Korea
• What is the patent approval linkage system?
• What are the statistics on its usage and how can the types of filing provide insight into the generics companies’ strategy?
• The South Korean government’s commitment to enforce patent rights and protect Big Pharma
• Case law roundup

12.20 Lunch 🍽️

13.30 Second Medical Use Patents- Lyrica and beyond
Dr Jurgen Dressel
Head of Patent Litigation
Novartis International AG
• Lyrica Update: The Court of Appeal reaffirms the High Court decision
• How have intense budgetary constraints coupled with skinny labelling and the blue box concept impacted on originators’ clinical innovation/R&D?
• What are you entitled to in the event of an infringement, how can remedies or damages be assessed?
• How should parties respond to achieve clarity in cases where there are points of contention in the ruling?
• Prior to launching a product where a second medical use patent is still in force what must generic manufacturers do?
• Establish what steps second medical use patent owners should take when confronted with suspected infringement

14.10 Supplementary Protection Certificates – Are they still fit for purpose?
Fiona Bor
Head of Intellectual Property
Mereo Biopharma
• Understanding the need for reform
• What possible amendments to the SPC regulation can we expect?
• Analysing the likely outcome
• Interpreting the application of SPC legislation around Europe
• Outlining the difficulties with getting SPC extensions based on EU regulation
• What are the current complications within Europe?
• Understanding the likelihood of harmonisation across Europe

2.50 Refreshments ☕️

3.30 The Competition Authorities and the controversial issue of drug pricing
• Pharmaceutical firms face a battle with competition authorities around the world over allegations of excessive drug pricing
• Pfizer and Flynn fined by the CMA
• What will the CMA deem the suitable ‘profitable price’ to be?
• Will attacking “excessive pricing” and the abuse of a dominant position be a priority for competition authorities in the future?
• How do competition authorities deal with the issue of drug pricing in other jurisdictions?

4.10 Navigating the CRISPR patent landscape and its impact on business
Stella Fletcher EPA
Head of IP
BiAL Portela & Ca SA
• What is CRISPR?
• Recently issued CRISPR patents
• Claim types being granted in CRISPR patent
• Interference proceedings and other potential entanglement situations involving CRISPR patents
• Investing in biotech companies in the face of CRISPR disputes
• Viable applications and business opportunities, including licensing and collaboration

4.50 Chair’s Summation

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Attend the conference from the convenience of your home or office. Save money on travel and view the sessions according to your own schedule. This conference recording allows you to get all latest insights and will be available for you to view for 90 days after the event is over, so you can re-watch sessions, or view any sessions you may have missed.

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All Delegates will receive an online link to access the conference materials as part of their registration fee.
Conference materials are available 2 working days post event.

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Payment must be received in full by the conference date to ensure admittance. All discounts will be applied to the Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order.

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Fee Includes
The program, all program materials, refreshment breaks and lunches.

Venue Information
Date: 26th & 27th April 2017
Time: 8:45 – 17:10
Venue: Radisson Blu Hotel Amsterdam
Rusland 17, 1012 CK Amsterdam, Netherlands
Telephone: +31 20 623 1231