This year marks 30 years since the inception of C5 Group. It is time to match our brand with the dynamic strides we have made. See inside for details…

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 BPICIA 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

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

Lise Abildgaard Ryberg
Head of Global Patents
Novozymes A/S

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

Preventing for Patent Litigation under the UPC: Brexit and Beyond

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Business Information in a Global Context
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 steps 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
- VP/SCP of Patents
- Heads/Directors of IP, Patents and Legal Affairs
- 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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For over 30 years, C5 Group has provided the opportunities that bring together business leaders, professionals and international experts from around the world to learn, meet, network and make the contacts that create the opportunities.
Our conferences and related products connect the power of people with the power of information, a powerful combination for business growth and success.

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 jurisdicational 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
11.40 How Does the Commercial Restructuring of a Pharma Business Impact on its Patent Litigation Strategy?
- Brand vs brand litigation trend
- Bayer v. Baxalta
- Has increased M&A activity played a role in the brand vs. brand trend

12.10 Lunch

1.20 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
- 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?

Stella Fletcher EPA
Head of IP
BIAL Portela & Ca SA
- What You Must Incorporate in Your Patent Claims’

Tobias Roese
Head Patents & Trademarks
Biotest AG.

2.40 The role of an in-house lawyer in coordinating multijurisdictional patent litigation

3.20 Refreshment Break

3.40 Litigating Biosimilars Across the Atlantic - Understanding the BPCIA patent litigation framework to avoid costly mistakes

Jonathan Singer
Principal
Fish & Richardson
- 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 judgments 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?

4.40 Inter Partes 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

2017 Conference Day Two:
Wednesday, 26th April 2017

8.30 Morning Refreshments

9.00 Chair’s Opening Remarks

9.10 Canada & CETA: The times they are a changin’

Yoon Kang
Partner
Smart & Biggar/Fetherstonhaugh
- What effect will the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union and Bill C-30 have on patents in the pharmaceutical industry?
- The right of appeal now afforded to brand-name manufacturers when relying on patent linkage mechanisms to provide market authorisation
- Certificate of Supplementary Protection (CSP) to mirror the European SPC system
- What conditions must be met to make a CSP application
- Analysing key cases
9.50  
The Enforcement of Pharmaceutical Patent Rights in China  
Ying Luo  
Partner  
Panawell & Partners LLC  
- Precedence established by case law China and its impact on pharmaceutical IP protection  
- Litigation strategies for pharma companies in view of the 2015 Pfizer and 2016 Eli Lilly cases  
- Is patent linkage promoting pharmaceutical innovation?  
- Plan for the future- Act now!

10.30  
Refreshment Break  

cup icon

11.00  
Patent litigation in India continues to throw up new challenges  
Hari Subramaniam  
Founding & Managing Partner  
Subramaniam & Associates  
- Overview of the reforms and the Patent (Amendment) Rules 2016  
- An examination of the Indian pharmaceutical patent regime and its effect on the innovator industry  
- Recent case law- Is this the dawn of a new era?  
- The issue of compulsory licensing and clashing with the US

11.40  
SPCs in the wings: prosecution strategies during patent litigation  
- 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  
Juergen Dressel  
Head Global Patent Litigation Strategy  
Novartis Pharma 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

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2.50  
Refreshments  

cup icon

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  
- 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
Taylor Wessing

Taylor Wessing is a leading international law firm. We think creatively about business issues and are constantly looking for new and better ways to add value with truly innovative solutions that help to grow our clients’ businesses. Our Patents group is one of the largest and best known in Europe. Highly experienced in both contentious and non-contentious patent matters, we help our clients, based in Europe and internationally, exploit, protect, manage and defend their IP rights. We serve knowledge-based and technology rich businesses operating across a variety of industry sectors including pharmaceuticals, technology and telecoms, biotechnology, chemicals, medical devices & equipment, electronics & software, automotive and the energy sector.

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Carpmaels & Ransford LLP is a leading firm of European patent and trademark attorneys. We have been at the vanguard of intellectual property for over 200 years and our pioneering roots in London now extend to Munich and around the globe.

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