C5

In-depth and Practical Patent Litigation Strategies for the Life Sciences Industries

26th – 27th February 2019 | Radisson Blu Hotel, Amsterdam, Netherlands

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C5's 11th Annual Forum on

PHARMA & BIOTECH PATENT LITIGATION

The annual gathering exploring the inherently complex and continually contentious pharma and biotech patent litigation landscape

Key Themes for 2019

- The Impact of Brexit on the UPC
- The Trade Secret Directive's effect on patent rights
- The repercussions of recent Court of Justice SPC rulings
- Digital concerns for the quality of patents
- Functional patent claims and related burden of proof analyses
- Granting of Arrow Declaration from recent UK decision: GlaxoSmithKline v Vectura

International IP Focus Sessions on:

- U.S.: IP actions in the District Courts and the PTO's PTAB
- Asia: The impact of China IP on international IP

This Pan-European Pharma and Biotech Patent Litigation Forum will Feature Insights and Practical Guidance from:

Adrian Spillmann
Head of Corporate IP
Valneva

Dr. Stephan Kutik
European Patent Attorney
Chiesi Farmaceutici S.P.A

Francesco Macchetta
Director Intellectual Property
Bracco Group

Dr. Lorenz Kallenbach
Corporate Patent Counsel
Merck Group

Dean Thomas
Head of Intellectual Property
Glenmark Pharmaceuticals

Hubert Witte
Head of Patents
Roche

PRE-CONFERENCE WORKSHOP on 25th February:

READY, STEADY, BREXIT: Identifying and Mitigating the Immediate Patent Litigation Risks for Life Sciences Companies

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EXHIBITOR: Wolters Kluwer

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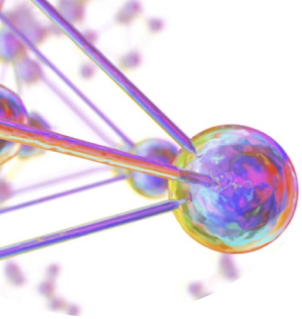

Life Science patent litigation filings are predicted to rise to new levels.

Be part of the only event where the "Who's Who" of the European Life Sciences Patent Bar gather each year to shape patent litigation policies and procedures throughout the continent.

The Pharmaceutical and Biotechnology industries are becoming increasingly competitive in the IP sphere. There will inevitably be areas where overlapping, interference, and marketing coming into play. However, the ability to secure and capitalize on the investment in patent rights and IP protections will mean a greater economic return for your products as well as IP portfolio.

C5's 11th Annual Pharma and Biotech Patent Litigation Forum comes at a significant time in Europe. With Brexit looming and the impending ratification of UPC from the German national courts, there are plenty of uncertainties for Pharmaceutical and Biotech companies conducting business in the European Market. This event is where you will find clarification on such matters and their consequential impact on patent litigation strategies.

This forum also introduces brand new topics which will help you prepare for impending challenges and allow you to:

- Understand how the digital age is impacting the quality of patents
- Appreciate the influence of The Trade Secret Directive (EU Directive (2016/43) on future patent strategies
- Realize the importance of patent litigation developments in Asia to European markets
- Contrast how current developments in the U.S. and their opposition from the EPO may impact new technologies through an examination of *CRISPR and Broad Institute vs. University of California*
- Maximise IP regulatory rights through developing a best practice strategy for patent protection and economic value

Considering the current state of IP as well as the present political uncertainty, you cannot miss this event. **Register today!**

Who Should Attend

- Representatives from corporate organisations including:
  - Patent Counsel
  - Head of IP
  - Head of Patent Litigation
  - VP-Intellectual property
  - Scientific Director
  - Head of Legal
  - Head Of Legal Affairs
  - Principal Patent Examiner
  - Head of Global Strategy
  - Director Innovation, IP and Portfolio Management
  - R&D Patent manager
  - Associate VP & Director of Technology Licensing & Commercialization
- Legal Practitioners with practises in:
  - Intellectual Property and Patent
  - Life Sciences
  - European Patent
  - US Patent

Enhance your experience by attending a workshop

READY, STEADY, BREXIT: Identifying and Mitigating the Immediate Patent Litigation Risks for Life Sciences Companies

Attendees will gain knowledge on how to mitigate litigation challenges associated with: Patent Protection, SPCs, Designs and Trademarks in view of the post-Brexit impact.

MEDIA PARTNERS:

CEE Legal Matters · glg global legal group · IPPro the internet · Life Sciences & recht · LSIPR Life Sciences Intellectual Property Review · pharmalicensing.com Global Technology Marketplace

Pre-Conference Working Group

Monday, 25th February 2019 | 13:00–16:00

READY, STEADY, BREXIT:
Identifying and Mitigating the Immediate Patent Litigation Risks for Life Sciences Companies

*Applicable to the Pharmaceutical, Biotechnology and Medical Device Industries

29th March 2019, marks the date for Brexit. This unprecedented event will have domino effects on all areas of IP protection. This workshop will provide practical insights into what strategies and protection mechanisms life sciences companies must take to enhance patent portfolio protection.

Attendees will gain knowledge of the Brexit impact and how to mitigate litigation challenges associated with: Patent Protection, SPCs, Designs and Trademarks.

12:30 Registration & Networking Morning Refreshments

13:00 – 14:00

Dissecting Brexit and its impact on IP protections

14:00 – 15:00

Practical solutions focusing on enhanced Patent and SPC protection

15:00 – 16:00

Practical solutions focusing on enhanced Designs and Trademarks

DAY 1 | Tuesday, 26th February – 13:00

FOCUS ON SPCs: Analysing Recent SPC Decisions Which Will Shape the Future of IP Protection

Adrian Spillmann
Head of Corporate IP
Valneva

Ricardo Dijkstra
Advocaat
Vondst

Marco Blei
Counsel
Portolano Cavallo

SPCs are a vital tool for innovator companies to extend the product lifecycle. Recently, there has been conflict between the legal and technical interpretation of SPC regulation and the application of decisions from European Court of Justice to ensure that the timeline of an SPC is fully satisfied by both innovators and generics. This panel will examine this conflict and its repercussions.

About us:

C5

The C5 Group, comprising C5 in Europe, The Canadian Institute, and American Conference Institute, is a leading global events and business intelligence company.

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.

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CONFERENCE DAY ONE

Tuesday, 26th February 2019

08:00

Registration & Networking Morning Refreshments

09:00

Chair's Opening Remarks

Judith Krens
Partner
Taylor Wessing

09:10 STAKEHOLDER THINK TANK

The Unitary Patent Court and Brexit – Devising Patent Strategies Which Adapt to the Variables of the Unknown

Francesco Macchetta
Director Intellectual Property
Bracco Group

Dean Thomas
Head of Intellectual Property
Glenmark Pharmaceuticals

Pierre Veron
Honorary President, **EPLAW**
Member, **Drafting Committee of the Rules of Procedure of the Unified Patent Court**
Member, **Expert Panel group**

Paul Inman – Moderator
Partner
Gowling WLG

The Unitary Patent Court (UPC) which will cover 25 countries is expected to come into full force in Spring 2019. This unified system will streamline the patent approval process through the use of both legal and technical experts and as such will likely provide cost savings in the long-term for Pharmaceutical and Biotech firms. The UK ratified the UPC system prior to its announcement that it would leave the EU, so it is anyone's guess as to what will happen to the UPC.

- Determining whether the UK can still participate in the UPC after its exit from EU
- What are the expected outcomes of Brexit to the UPC and how will this impact pharma and biotech organisations?
- Assessing the impact of Brexit on the European Court of Justice
- How will IP case law develop as a result of Brexit?

10:00 FOCUS GROUP

The Economics of Cross Boarder Patent Litigation Strategies: Effectively Utilizing Different Patent Systems to Protect IP and Ensure Product Value

Representative
Clifford Chance

Netherland

Arvid van Oorschot
Partner
Vondst

Germany

Dr. Claudia Milbradt
Partner
Clifford Chance

United Kingdom

Brian Cordery
Partner
Bristows

This session will provide a detailed analysis of landmark Pharmaceutical and Biotech patent cases that will help improve your understanding of the enforceability and value of of patent rights across significant jurisdictions.

- UK: How will Brexit affect cross boarder patent litigation strategies?
- Spain: Being outside of the UPC, how will this impact decisions and implementation of patent litigation?
- Germany: What are the current scenarios and developments for the future?

11:00 Networking Break

11:15

Arrow Declaration: Latest from the UK Courts

Paul Inman
Partner
Gowling WLG

- Understand the latest decision making for granting of arrow declaration in *GlaxoSmithKline v Vectura*
- Discover where potential infringement of patents can seek formal declaration from UK Courts against future infringement actions under patents not yet even granted at the time of the Judgment.
- Seek out When the relief is likely to be useful, how parties can utilise this litigation tool; and reviewing the relevant parts of the various judgments

12:00 Networking Lunch

FOCUS ON SPCs

13:00

Analysing Recent SPC Decisions Which Will Shape the Future of IP Protection

Adrian Spillmann
Head of Corporate IP
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SPCs are a vital tool for innovator companies to extend the product lifecycle. Recently, there has been conflict between the legal and technical interpretation of SPC regulation and the application of decisions from European Court of Justice to ensure that the timeline of an SPC is fully satisfied by both innovators and generics. This panel will examine this conflict and its repercussions.

- Examining the most recent SPC decisions and how they are applicable to innovators vs. generics
- Considering advances in technology in pharmaceutical and biotechnology: Which areas can the courts improve to ensure the pragmatic nature of SPC decisions
- What are the new proposals for SPC regulations?
- In light of Brexit, should SPC applications apply under existing EU laws or be held in abeyance until new UK laws are enforced?

14:00

Analysing the Influence of The Trade Secret Directive (EU Directive (2016/43) on Future Patent Strategies

Dr. Sven Bostyn
Associate Professor of Biomedical Innovation Law
University of Copenhagen

Benjamin May
Partner
ARAMIS Société d'Avocats

- Analysing the most recent implementation of UK Trade Secrets Regulation 2018 into the European directive on unlawful acquisition, use and disclosure of know-how, and business information
- How do pharmaceutical companies put the changes in the EU directive into effect?
- Will the trade secret directive amendments create a new and separate IP right?
- How to find evidence relating to the Trade Secret Directive?

15:00 Networking Break

15:30 DEBATE

Warner-Lambert vs. Generics: an Examination of the Proper Utilization of Secondary Medical Use Patents for Innovators and Generics

Judith Krens
Partner
Taylor Wessing

Dr. Lorenz Kallenbach
Corporate Patent Counsel
Merck Group

Hubert Witte
Head of Patents Basel
Roche

Professor Dr. Maximilian Haedicke, LL.M.
Professor of Intellectual Property Law
Freiburg University
(Former Judge at Higher Regional Court of Duesseldorf)

- Evaluating how the latest Secondary Medical Use cases are impacting innovators and generics
- What are the immediate and long-term effects of *Warner-Lambert vs. Generics* (UK) on Secondary Medical Use patents
- Discovering best timing strategy for Secondary Medical Use enforcement?
- Cost/benefit analysis for the originator's position to litigate weaker patents in the portfolio following expired product patents.
  - » Consideration for generics/biosimilars manufacturers who have already attempted to launch products with specific labelling strategies

16:30

Chair's Closing Remarks & Introduction to Day 2

CONFERENCE DAY TWO

Wednesday, 27th February 2019

08:00 Registration & Networking Morning Refreshments

09:00

Chair Opening Remarks

Paul Inman
Partner
Gowling WLG

09:10

Patent Legalities and Practicalities in the U.S.: Takeaways from the Latest U.S. District Court and Patent Trial and Appeals Board Decisions

Jon Singer
Principal
Fish & Richardson

- Understanding the different proceedings at the U.S. District Courts and PTAB
- Discovering the constantly evolving political and economic factors associated with filing for patents in the U.S.
- Developing the best practice strategy for filing patents in the U.S. and mitigating the cost of litigation

10:00

The Doctrine of Equivalence, where are we now?

Paul Reeskamp
Partner
DLA Piper

- A little history: what was the idea behind part 2 Protocol?
- Protection of equivalence and legal certainty
- Actavis v Lilly; Neuberger's Kirin-Amgen revenge?
- Recent developments in case law

11:00 Networking Break

11:30

Digital Concerns for the Quality of Patents

Dominic Adair
Partner
Bistows LLP

The digital era has brought a considerable amount of data to the field of patenting. This poses a real concern to innovators as how to best protect their products. Join us for a fireside chat with distinguished outside and in-house counsel as they discuss:

- How the digital age is affecting the quality of patent
- More data: can this create different types of claim?
- Whether an increase data can provide better claims?
- Creating insights for new ways in producing different results
- What are the consequences with access to more data.

12:30 Networking Lunch

13:30

European Patent Convention: Exploring Questions of Claim Construction and Burdens of Proof

Dr. Stephan Kutik
European Patent Attorney
Chiesi Farmaceutici S.P.A

Daan de Lange
Partner
Brinkhof

Through progressive technological advances in the areas of anti-bodies and therapeutics, function claims are being reexplored and questioned. This panel will explore these controversies

- How does the EPO assess patentability of broad claims?
- Exploration of recent EPO decision cases
- What legal provisions are infringed?
- Is there a lack of inventive step? (Art 56 EPC) or is there a lack of sufficiency disclosure? (Art 83 EPC)
- What can be considered as different standard of proof?
- What type of evidences are available and correct? What are the plausibility of national courts regarding establishing their own standard?

14:30

CRISPR and *Broad Institute vs. University of California*: Contrasting Current Developments in U.S. and Their Opposition from the EPO

Brian Coggio
Of Counsel
Fish & Richardson

Dean Thomas
Head of Intellectual Property
Glenmark Pharmaceuticals

- Discovering patentability requirements in the U.S. for natural sequencing to ensure a valid and correct patent application via *Broad Institute vs. University of California*
- What are the procedures and requirements to make a claim a priority?
- How does the recent decision from the EPO impact the future of CRISPR technology- influenced patents in Europe?

15:30 Networking Break

16:00

Maximising IP Regulatory Rights: Developing A Best Practice Strategy to Enhance Patent Protection and Economic Value

Jane Lambert
Barrister
4-5 Gray's Inn Square

Join us for an interactive session with IP authorities who will draw out a comprehensive timeline of pharmaceutical patent protections and the preservation of corollary economic worth throughout every stage of the product life cycle, inclusive of:

- Initial patent protection
- Supplementary Patent Certificate
- Orphan Exclusivity
- Paediatric Supplementary Protection Certificate

16:30 Chair's Closing Remarks & End of Conference

Venue:

Book your room now and SAVE!

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You may find all the legal updates for Life Sciences here:
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SESSION SPONSORS:

Aramis is a full service law firm specialising in French and EU law. Aramis provides advice in IP litigation, including pan-European patent cases, clearance strategies, anti-trust, regulatory, privacy, distribution and more generally all corporate and commercial matters. Clients include several major pharma companies and medical devices manufacturers as well as cosmetics and biotech companies. Key contact: Benjamin May, head of IP & Life sciences **www.aramis-law.com**

Brinkhof is a law firm with a strong focus on innovation, technology and market regulation. We cater to the needs of national and international clients in sectors such as electronics, IT, media, internet, telecommunications, pharma/ biotech and healthcare. On these markets, we advise and litigate in relation to patents, trademarks and designs, regulation, competition and IT/outsourcing.

Our breadth of knowledge and depth of specialist experience make Brinkhof a centre of legal expertise for modern markets. Our clients are driven, groundbreaking and innovative, and so are we. Nothing is self-evident to us, except the interests of our clients. **www.brinkhof.com**

Established in 1837, **Bristows** works with innovative clients in the Technology and Life Sciences sectors. We're an independent, international, full-service law firm bringing together a diverse collection of talent to deliver high-quality legal advice. We're well known for our lawyer's scientific and commercial background and a focus on Intellectual Property. **www.bristows.com**

Portolano Cavallo was founded in 2001 by partners Manuela Cavallo and Francesco Portolano.

Portolano Cavallo provides legal advice to companies operating in complex and evolving sectors: it is a leader in the Digital, Media and Technology sectors, in addition to being recognized in the Life Sciences and Fashion/Luxury fields.

The firm's practice areas range from litigation to M&A and venture capital, from emerging companies to the exploitation and protection of all forms of intellectual property, from employment to data protection, privacy and cyber-security issues, from technology transactions to antitrust and regulatory issues.

In all these areas, Portolano Cavallo is recognized by multiple legal Italian and international rankings and awards.

EXHIBITOR:

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You must notify us by email at least 48 hrs in advance of the conference if you wish to send a substitute participant. If you are unable to find a substitute, please notify us in writing no later than 10 days prior to the conference date and a credit voucher will be issued to you for the full amount paid, redeemable against any other C5 conference in the next 12 months. Delegates may not "share" a pass between multiple attendees without prior authorization.

All cancelled conference registrations will be subject to a cancellation fee of £250 and applicable VAT. If the conference currency is EUR or USD a €350 and applicable VAT or $350 cancellation fee will apply.

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C5's 11th

PHARMA & BIOTECH PATENT LITIGATION

26th – 27th February 2019
Radisson Blu Hotel, Amsterdam, Netherlands

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