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Peter Roth
Head of Patent Litigation ex-US Oncology Novartis

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BRAND NEW WORKSHOPS on 24th February:

A Trade Secret Working Group: Developing A Robust Trade Secret Framework Within Your Organisation

B U.S. Hatch-Waxman Act and Paragraph IV Litigation: Introduction to ANDA Litigation and Its Related Regulatory Schematic

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C5’s **Pharma and Biotech Patent Litigation** conference is the largest annual gathering of leading in-house IP counsel, patent prosecutors and litigators, judges, and IP policy experts from around the globe.

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- Developing best practice approaches for New Board of Appeal rules at the EPO: Hear how [Valneva](#) is adapting to the new rules and minimising costs
- Determining which research exemptions are available in Europe and U.S.: [Grunenthal](#) will explore how exemptions strengthen decision making at the pre-filing stage
- Formulating strategies relative to the latest Secondary Medical Use case trends: Find out how Sandoz is adapting to the latest infringement actions
- Leveraging the [Royalty Pharma](#) and Sandoz decisions to better understand Article 3(a) and (d): [Confo Therapeutics](#) will discuss how these decisions will affect future SPC litigation proceedings
- Challenging traditional preliminary injunctions and compulsory licencing frameworks: Hear from [Novartis](#) and [Merck](#) on how this will impact future patent enforcements
- Understanding the latest political and legal ramifications of the Unified Patent Court controversies: [Former Italian Supreme Court Judge](#), [Member of Italian Patent & Trademarks Board of Appeals](#) will discuss the latest on UPC procedures

Participate in our Patent Relief Think Tank: which features in-depth roundtable discussions on different patent relief mechanisms including, the [EU Enforcement Directive](#), [Arrow Declaration](#) and [Cross Border Relief Strategies](#).

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

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**Who Should Attend**

- In-House Counsel and Executives from Pharmaceutical and Biotech Companies, including:
  - Head of IP
  - Head of Patent Litigation
  - VP-Intellectual property
  - Scientific Director
  - Head of Legal / 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
  - Patent Counsel

- Law firm attorneys with practises in:
  - Intellectual Property and Patent Law
  - Life Sciences
  - European Patent Law
  - US Patent

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**Enhance your experience by attending the Pre-Conference Workshops on 24th February**

**A**

**Trade Secret Working Group:** Developing A Robust Trade Secret Framework Within Your Organisation

Attendees will learn how to build and enhance a trade secret protection framework to offer safeguards and protections against being compromised.

**B**

**U.S. Hatch-Waxman Act and Paragraph IV Litigation:** Introduction to ANDA Litigation and Its Related Regulatory Schematic

Join us for this primer on the “in and outs” of Paragraph IV/ANDA litigation and related regulatory components.

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Pre-Conference Workshops | Monday, 24th February 2020

A | Trade Secret Working Group: Developing A Robust Trade Secret Framework Within Your Organisation

Protecting trade secret information is a critical competency for today's life sciences industry. Companies need to establish sound practices, procedures, and policies to maintain confidentiality and reduce the prospect of misappropriation.

In this dedicated workshop, you will learn how to build and enhance a trade secret protection framework to offer safeguards and protections against being compromised.

**Part 1 – Trade Secret 101**
- Implementing the U.K Trade Secrets Regulation 2018 into the European directive on unlawful acquisition, use and disclosure of know-how, and business information
- Developing strategies for putting the changes in the EU directive into effect
- Finding evidence relating to the Trade Secret Directive

**Part 2 – Trade Secrets: Practical Considerations**
- Developing, implementing and enforcing a trade secret compliance program
- Enhancing database safety mechanisms to stop potential leaks
- Implementing available legal compliance measures to stop company personnel from leaking sensitive information
- Minimizing monetary impact resulting from trade secret leaks

**Part 3 – Trade Secret Litigation**
- Review of trade secret case law in Europe and the U.S.
- Identifying best practices in trade secret litigation

12:30 – 13:30 Lunch provided for participants of Workshop A and B

B | The U.S. Hatch-Waxman Act and Paragraph IV Litigation: Introduction to ANDA Litigation and Its Related Regulatory Schematic

Small molecule pharmaceutical patent litigation in the U.S. is a complicated process governed by the Hatch-Waxman Act. This type of litigation is known as ANDA or Paragraph IV litigation. This interactive workshop will provide a primer on the “in and outs” of this in this unique litigation and all its related regulatory components.

**Part 1 - IP Overview for Drugs and Biologics: Hatch-Waxman, BPCIA**

**IP Protection for Drugs and Biologics**
- Analyzing the patenting process for drugs and biologics
- Seeking patent protection during the pre-approval process
- IP and regulatory redress for time lost during the re-approval process
- Distinguishing the patenting process for drugs from that of biologics
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

**Drugs**
- Exploring the differences between an NDA (New Drug Application) and an ANDA (Abbreviated New Drug Application)
- ANDA: what does it require?
- Bioequivalence defined
- The Orange Book: what is it and why is it Orange?
  » Listings and de-listings
- The patent endgame (Hatch-Waxman Overview)
  » Overview of Hatch-Waxman and reforms under MMA (Medicare Modernization Act)
  » The role of Orange Book under Hatch-Waxman vis-à-vis the MMA
  » Exclusivity (180 day); 30-month stay
  » Patent extensions
  » The safe harbor

**Part 2 – Exploring the Link between the FDA Approval Process and the Patenting of Drugs and Biologics**
- Identifying the application process for the approval of a new drug, i.e., small molecule, new chemical entities, etc.
- NDA (New Drug Application): Definition, contents and regulatory overview
- IND (Investigational New Drug Application) aka "IND"
  » How does it differ from an NDA?
- Accelerated approvals
  » Defining eligibility criteria for accelerated approval and priority reviews
- What portions of approval submissions might FDA release and when?
  » Using advisory committees in the approval process

**Part 3 - Paragraph IV Disputes and Litigation**
- Paragraph IV Certifications and Notice Letters
- Pre-suit considerations
  » Initial pleadings
  » Multiple ANDA filers
  » Declaratory judgments
- Typical Paragraph IV litigation scenarios
- Hot button issues in Hatch-Waxman litigation
  » Settlements
  » Damages
  » Double-patenting

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Conference Day One  
Tuesday, 25th February 2020
08:00  
Registration & Networking Refreshments
09:00  
Co-Chairs’ Opening Remarks
Kristin Cooklin  
Head of Intellectual Property  
Zeniva (CZE)
Paul Imman  
Partner  
Gowling WLG (U.K)
09:10  
SPOTLIGHT
The Status of the Unified Patent Court in this Era of Political Uncertainty
Dr Massimo Scuffi  
Member  
Italian Patent & Trademarks Board of Appeals  
President Emeritus  
Intellectual Property Judges Association (IPJA) (ITA)
Former Supreme Court Judge, Rome
Daniel Thomas  
Former Director DG1  
European Patent Office
The legal implications of Brexit and German ratification continue to profoundly impact the existence of the Unified Patent Court and unitary patents. This spotlight presentation will provide an in-depth analysis of the on-going debate concerning the UPC and its status.

- Examining procedures before the EPO and the UPC: Comparing the respective advantages and drawbacks
- German ratification of the UPC: Is ratification necessary for the unitary patent system and the UPC to start functioning?
- Assessing consequential changes to naming and labelling for the U.K market: Predicting the scope of required changes for biopharmaceutical distribution in the U.K
10:00  
NEW PROCESS
Adrian Spillmann  
Head of Corporate IP  
Valneva (AUT)
Dr. Corinna Sundermann  
Senior Vice President, Intellectual Property Management  
Pharmaceuticals and Devices Division  
Fresenius Kabi Deutschland GmbH (DEU)
The amended rules of procedural at the EPO Board of Appeal will soon be upon us. Under the new rules, which go into effect on 1st January 2020, evidential requirements will become stricter for opposition cases at first instance. This session will enhance your knowledge of the amendments, help you adapt to the new rules and minimise risk.
Points of discussion will include:
- Analysing procedure changes at the EPO Board of Appeal for first and second instances
11:30  
Focus on Global Patent Disputes and Litigation
Developing Practical Strategies for Optimizing Patent Success in Europe – U.S – Asia
Nicola Dagg  
Partner  
Kirkland & Ellis International LLP (U.K)
Katherine A. Helm  
Partner  
Dechert (U.S)
Juan Lei  
Partner Attorney, Manager of Life Sciences and Chemistry  
Han Kun Law Offices (CHN)
This session will provide a detailed analysis of the most recent and significant pharmaceutical patent decisions from across the globe. Attorneys from Europe, the U.S. and Asia will help enhance your understanding of the enforceability of patents and provide practical advice for successfully devising global patent litigation strategies.
Europe
- Assessing the current plausibility test under Art. 83 and Art. 56 EPC in relation to different types of claims:
  » Compound claim with/without functional feature
  » Compound claim with functional feature
  » Secondary medical use claims
- Determining whether an applicant must conduct the necessary technical analysis to ensure the technical effect is plausible when plausibility is not self-evident
- Analysing whether prothetic examples in the specification are sufficient to satisfy enablement and/or sufficiency requirements
- Exploring whether post-filing data can be used to demonstrate that a patent filing is not purely speculative, and/or that the technical effect is plausible or achievable
U.S
- Assessing practical and strategic considerations for U.S. District Court litigation and PTAB proceedings:
  » Comparing U.S. and EPO Post Grant Proceedings and German/U.K and Chinese litigations and coordination across global tribunals
  » Examining the estoppel effects of PTAB proceedings on District Court litigation
  » Assessing the latest developments on U.S. disclosure requirements under 35 U.S.C. § 112
  » Exploring the latest developments on the enablement standard at the U.S. Court of Appeals for the Federal Circuit and the use of post-filing data compared with the plausibility standard in Europe

Asia
- Examining the China Patent Office’s data requirement rule for pharmaceutical inventions under the:
  » 2001 Amendment to Guidelines for Patent Examination: Part II, Chapter 10, Section 3.1(3)
  » 2017 Amendment to Guidelines for Patent Examination: Part II, Chapter 10, Section 3
- Understanding whether post-filing data can be considered in China
- Comparing and contrasting EPO, the U.S. and China patent office criteria for post-filing data for new effect
13:00  
Networking Lunch
14:00  
Biologics and Biosimilar Litigation: Enhance Success in Europe and The U.S
Martina Hufnal  
Principal  
Fish & Richardson (U.S)
Representative  
Pinsent Masons (U.K)
With an increasing number of biologic products set to lose patent protection by 2025, there is a huge opportunity for the entrance of biosimilar products across the globe. This practical session will focus on the ‘dos and don’ts’ of biosimilar litigation in Europe and the U.S. to enhance your patent strategies.
- Analysing patent linkage and patent litigation: Examining the differences between EU and the U.S.
- Leveraging the process and timeline of the patent dispute resolution process
- Evaluating the potential success of various strategies for conducting biosimilar litigation
- Cutting through reference product patent thickets
- Weighing the pros and cons of carving out patented indications
15:00  
Networking Break
15:30  
PATENT RELIEF THINK TANK
Part One – Examining Available Relief for Patent Infringement In Europe
In this interactive session, delegates will have the opportunities to break into roundtable think tanks for the unique opportunity to engage in an in-depth conversation to enhance their understanding of one of the following patent relief tools:
- Understanding how the proportionality test is applied in pharmaceutical and biotech infringement cases
- Comparing the differences in the national courts implementation of the EU enforcement directive to determine:
  » Whether there is a harmonisation of standard
  » What are the fundamental differences
  » What is the best practice strategy for utilizing EU enforcement directive for patent relief
B. Arrow Declaration
Paul Imman  
Partner  
Gowling WLG (U.K)
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**Conclusion of Day One**

**Cross Border Relief Strategy**
- Assessing the interplay between cross-border patent relief strategies and the corollary of interim injunction
- Understanding the benefit of using cross-border relief tools
- Examining the most recent judgments to discover emerging trends in cross-border relief

16:30  Refreshment Break

16:45  **PATENT RELIEF THINK TANK**
**Part Two – Patent Relief Think Tank Continued**

The conversation continues in part two as delegates switch tables and engage in a discussion of a different patent relief tool:

- EU Enforcement Directive
- Arrow Declaration
- Cross Border Relief Strategy

17:45  **Conclusion of Day One**

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**Conference Day Two**

**Wednesday, 26th February 2020**

**09:00  Co-Chairs’ Opening Remarks**

- **Kristin Cooklin**
  Head of Intellectual Property
  Zentiva (CZE)
- **Judith Krens**
  Partner
  Taylor Wessing (NED)

**09:10  Preliminary Injunctions and Compulsory Licences: Causes and Justifications**

- **Gemma Barrett**
  Partner
  Bristows LLP (U.K)
- **Willeke F.C. de Weerd**
  Director, Corporate Patent Counsel
  Patents Healthcare
  Merck (CHE)
- **Peter Roth**
  Head of Patent Litigation
  ex-US Oncology
  Novartis (CHE)
- **Dr Massimo Scuffi**
  Member, Italian Patent & Trademarks Board of Appeals
  President Emeritus
  Intellectual Property Judges
  Association (IPJ&A) (ITA)
  Former Supreme Court Judge, Rome

A successful preliminary injunction motion can stop infringement in weeks, not years, and often acts as a catalyst to end the dispute at a fraction of the cost of full-term litigation. Patent trial lawyers are understandably cautious about this procedure because it requires an alignment of special factors for success and can be costly and harmful if denied.

A compulsory license is a unique patent relief tool whereby a government allows someone other than the patent holder to make the patented product or patent-protected invention. Although they are a rare occurrence, the rulings and consequences of granting a compulsory license can have a profound impact on the IP community.

**Technical Analysis**
- Comparing the different decisions of the German and U.K. courts in Edwards Lifesciences v Boston Scientific as to what extent the courts have discretion over preliminary injunctions
  - Exploring the changing scope for injunction
- Assessing the German Federal Court of Justice’s reasoning for:
  - Granting a compulsory license in Merck vs Shionogi
  - Denying a compulsory license in Amgen vs. Sanofi
- Exploring compulsory licensing in Russia: Assessing how Nativa is utilizing a compulsory license strategy against innovators

**Philosophical Discussion**

- The granting of a compulsory licensing usually rests on a determination of the common good. The discussion will be examining both the moral and social conscience for granting a compulsory license.

**10:10 Secondary Medical Use: Understanding the Latest Judicial Decisions and Trends from German Courts**

- **Sara Burghart**
  Lead IP Litigation - Global Litigation & Launch - Global IP
  Sandoz International GmbH (DEU)
- **Daan de Lange**
  Partner
  Brinkhof (NL)
- **Peter Roth**
  Head of Patent Litigation
  ex-US Oncology
  Novartis (CHE)
- **Mathilde Rauline**
  Counsel, European Patent Attorney
  August Debouzy (FR)

- Analysing the Dusseldorf Court of Appeals review of the lower German court’s ruling on the scope of a secondary medical use patent
- Determining how to formulate a secondary medical use infringement actions
- Identifying how the courts distinguish between first and second medical use
- How are prayers for relief determined?
- Debating the practicality of the German court’s judgments on secondary medical use relative to the burden of proof

**11:10 Networking Break**

**11:30 Finding Safe Harbours Around the World: Comparing and Contrasting the Research Exemptions Available in Europe and U.S.**

- **Brian Coggio**
  Of Counsel
  Fish & Richardson (U.S)
- **Kathrin Koerner**
  SVP, Head of Global Patents and Trademarks
  Die Grünenhal Gruppe (DEU)
- **Dr Tobias Roeser**
  Head of Corporate Intellectual Property
  Bioteq AG (DE)
- **Representative**
  Pinsent Masons (U.K)

**Research Exemptions**

A research exemption is an affirmative defense to infringement when the alleged infringer is using a patented invention for research purposes. However, the interpretation and scope of research exemptions are varied among jurisdictions.

- Assessing the extent to which research is not considered part of patent infringement
- At what stage can the discovery of information during research be subject to litigation

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Bolar Exemptions
The Bolar exemption, named for the U.S. Supreme Court Case, Roche v. Bolar, is a research safe harbour which typically allows for the exemption of data necessary to the regulatory approval process. This exemption was adopted into the Hatch-Waxman Act in the U.S. and was subsequently adopted in various European countries and by EU Directive.

• Identifying jurisdictions in which:
  » The research exemption can be applied to avoid litigation
  » The research exemption is narrowly interpreted
• Determining when research is considered as scientific as opposed to commercial
• Developing best practices on how in-house counsel should advise scientists to avoid patent infringement in conducting research

SPC Manufacturing Exemption
The SPC Manufacturing and Stockpiling Exemption (“waiver”) based on EU Regulation 2019/933, went into effect on 01 July 2019 and exempts SPC protection for manufacture of protected API by third parties during the lifetime of an SPC if the purpose of exports is entering into “third countries.” The SPC Manufacturing Waiver also exempts stockpiling in the EU during the last 6 months of the SPC lifetime for the purpose of first-day launch after SPC expiration in the EU.

• Understanding which medical products are available for a Bolar exemption
• Determining whether a company is free to market and sell a generic version of a patented drug explicitly for use in testing under the Bolar exemption
• Analysing the German court and CJEU considerations in Astellas Pharma Inc v. Polpharma S.A. Pharmaceutical Works relative to a Bolar exemption

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B | U.S. Hatch-Waxman Act and Paragraph IV Litigation: Introduction to ANDA Litigation and Related Regulatory Schematic