



Business Information  
In A Global Context

14th & 15th May 2014 | Hilton Munich City Hotel, Germany

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C5's 11th Forum on

# Freedom To Operate

Practical and Legal Strategies to Protect Your Patent Portfolio:  
Maximise the Benefits and Minimise the Risks of Your FTO Searches



## Hear From These Companies Leading In-House Counsel On Planning Your FTO Strategies:

- AarhusKarlshamn AB (Sweden)
- Bracco Group (Italy)
- Morphosys AG (Germany)
- Astex Pharmaceuticals (UK)
- H.Lundbeck A/S (Denmark)
- Novartis Pharma AG (Switzerland)
- GlaxoSmithKline Biologicals (Belgium)
- MagForce AG (Germany)
- Pfizer Pharmaceuticals (USA)

## Top Reasons to Attend:

- 1 Gain in-depth insights into the Unified Patent Court procedures via our Industry Panel. In-house experts will share their knowledge on some of the most talked-about issues of the new court and how FTO strategies will be affected
- 2 Develop a detailed understanding of the latest SPC developments and the implications these will have on your FTO strategies
- 3 Enhance your knowledge of the latest developments regarding Validity and Infringement Analysis, the impact of the amended EPO Rule 36 on FTO opinions and the Nagoya Protocol
- 4 Deal effectively with the fast paced FTO changes concerning the markets of USA, India and China

## Interactive Post-Conference Workshop:

Thursday 15th May 2014

From research to bedside:  
An activity-based approach  
to FTO and exclusivity in  
drug development

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FTO searches are critical for the patent-reliant pharma and biotechnology industry. Their enormous R&D costs, both in terms of money, time & human resource mean that they must be able to identify potential barriers to the commercialisation of products & technologies. Failure to conduct proper FTO is one of the major causes of patent litigation in this space.

FTO is in practice a strategic exercise. As well as trying to find out what else is 'on the market' so that you can launch your own technology and establish Freedom To Operate, it can impact your patent strategy by forcing you to design around or negotiate certain competitor patents. Depending on your portfolio, you may also conduct an FTO search to detect potential infringement action, enabling actions such as starting infringement, getting interim & final injunctions, seizing infringing products and getting damages or an account of profits. As such, it is both a tool that can be used to make sure you don't infringe – and to ensure no one is infringing your patents.

Our 2014 FTO Forum will focus on the practical solutions to the current challenges facing pharma and biotech companies, patent attorneys and legal practitioners. You will hear the specific strategies used by industry experts in dealing with FTO challenges which will impact your company in 2014 and you will gain valuable perspectives regarding the main considerations for a cost effective FTO assessment strategy and the SPC recent ECJ judgments.

Don't miss this outstanding opportunity to learn from and network with those at the forefront of this field.

#### Gain first hand insights from leading experts, including:

- 1 Practical tips about SPC's and how recent case law can impact your FTO strategy
- 2 Guidance on how to align the Unitary Patent with your FTO policy
- 3 An in-depth analysis of the US FTO-related law and the FTO challenges regarding the AIA and the Innovation Act
- 4 The FTO landscape in China and India and the main challenges

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For more information about this programme or our global portfolio, please contact: **Evi Kartsouni** on +44 (0)20 7878 6955 or email [E.Kartsouni@C5-Online.com](mailto:E.Kartsouni@C5-Online.com)

## WHO SHOULD ATTEND?

C5's 11th Forum on Freedom To Operate will provide valuable insights for:

### Pharma, Biotech and Chemical Companies:

- In-House Counsel and Legal Directors
- Patent Attorneys
- Heads/Directors of IP
- IP Counsel and IP Managers
- Heads/Directors of Patents,
- Patent Counsel
- Patent Managers
- Patent Specialists/Experts
- Private Practice Lawyers

### Private Practice Lawyers and Patent Attorneys specialising in:

- Life Sciences/Pharma and Biotech
- IP and Patent Litigation

# Main Conference Day One: Wednesday 14 May, 2014

## 8.00 Coffee and Registration

### 8.45 Chairs Opening Remarks

**Otto Swens**  
Partner, Vondst Law (Netherlands)

### 8.50 The Unified Patent Court and Freedom To Operate: How to Align the Unitary Patent with your FTO Policy

**Francesco Macchetta**  
Director of Intellectual Property  
Bracco Group (Italy)

**Bo Kalum**  
Senior Patent Specialist  
H.Lundbeck A/S (Denmark)

**Birgit Verberue**  
Patent Counsel, GlaxoSmithKline  
Biologicals (Belgium)

*With the new Unitary Patent and Unified Patent Court possibly coming into force in 2015, everyone involved in the pharma and biotech industry will need to re-assess the effect the new institution will have on their FTO policies. The session will be addressing the main changes the new institution will bring with its launch and how those will impact pharma and biotech companies FTO policies.*

## 10.10 Morning Refreshments

### 10.25 Practical Steps to Tailor your FTO Strategy in Response to the Latest SPC case law

**Elisabeth Greiner**  
Partner, dfmp (Germany)

- Effects of patent extensions on FTO
- Discuss the practical implications of the latest judgments on your FTO analysis (Eli Lilly, Georgetown, Actavis)
- Negative Term SPC
- Inventive Step
- Infringement of SPCs within the FTO framework
- Validity of SPCs within the FTO framework
- Comparative analysis of USPTO and EPO case law

### 11.20 The Main Considerations on How to Develop a Cost Effective and Efficient FTO Assessment Strategy

**Martin Lidén**  
Key Account Manager  
Swedish Patent and Registration  
Office (PRV) (Sweden)

**Tessa M. Malamud-Cohen**  
Senior Patent Counsel  
Ferring Pharmaceuticals  
(Switzerland)

**Katarina Dahlenborg**  
IPR Manager  
AarhusKarlshamn AB (Sweden)

- The factors of whether or not an FTO analysis should be carried out
- How to commission an FTO search
- The level of information needed by counsel for an FTO search
- The timing of conducting an FTO search
- The maintenance of search records
- The preparation of idelines for the FTO search
- Different types of FTO searches
- FTO search budget management
- Experience from FTO life examples
- Identifying and addressing any possible pitfalls

## 12.20 Networking Refreshments

### 12.30 Industry Roundtable: What FTO Information You Need to Know for Specialised Pharma and Biotech Fields

**Moderator: Stoyan Radkov**  
Senior Patent Attorney  
Urquhart-Dykes & Lord LLP (UK)

**Lachlan Campbell**  
European and Chartered Patent  
Attorney  
Novartis Pharma AG (Switzerland)

**Michelle Jones**  
Director  
Intellectual PropertyAstex  
Pharmaceuticals (UK)

*The industry panel will examine the FTO considerations for different fields of pharma/agro and biotech and what pharma/agro and biotech companies need to know about FTO in:*

- RNAi
- stem cells
- antibodies
- peptibodies
- small molecules
- combination treatments

## 1.30 Networking Lunch

### 2.30 What to Do When Your FTO Assessment Goes Wrong: Key Considerations, Remedies and Damages

**Chris Thornham**  
Partner, Taylor Wessing (UK)

**Anja Lonze**  
Partner, Taylor Wessing (Germany)

- Consequences of getting your FTO assessment wrong
- What contingency plans should you have in place?
- Remedies available to a patentee under the Enforcement Directive
- What damages are available?
- FTO opinions: what effect do they have on liability and damages?
- Practical steps to minimise the potential damage



### 3.30 How to Formulate Your FTO Tactics in China and India

- Effective FTO Strategies in China and India
- Is the lack of available data in relation to patent applications filed a problem for FTO searches in India?
- Is the patent document language a barrier for FTO searches in China?
- The issue of inaccurate patent document translations in China
- The Impact of the Schneider case on IP and FTO strategies

### 4.20 Afternoon Refreshments

### 4.40 The Amendment of Rule 36 and the Effect on Freedom To Operate Analysis

**Christoph Rehfuss**  
Director of Intellectual Property, MagForce AG (Germany)

*With the change of Rule 36 and the re-introduction of further divisional applications, the session will discuss the implications of the amended rule when an FTO opinion is drafted*

### 5.10 Freedom To Operate Tactics: Litigation or Settling out of Court?

**Lorna Brazell**  
Partner, Osborne Clarke (UK)

- If an infringement is found in the FTO search, what are the possible problems if you attempt to settle out of court?
- What would the best approach for an out of court settlement in such a case?
- In which cases would litigation be a better solution?

### 5.40 A Comparative European Perspective on Infringement and Validity Analysis on Freedom To Operate

**Simon Bradbury**  
Head of Life Sciences, Appleyard Lees (UK)

*A discussion of the differing approaches across Europe of:*

- Infringement
- Validity
- Injunctions
- Damages

### 6.10 Chairman's Closing Remarks

## Main Conference Day Two: Thursday 15 May 2014

### 8.30 Coffee and Registration

### 9.00 Chair's Opening Remarks

### 9.05 FTO Analysis in Light of the Latest Case Law in the US: How Will this Affect Your Global FTO Strategy?

**Stephanie Monaco**  
Assistant General Counsel, Pfizer Pharmaceuticals (USA)

- Joint Induced Infringement – *Limelight v Akami*
- Burden of proof – *Medtronic v Boston Scientific*
- Is de novo review appropriate in a fact based determination of whether a case is exceptional under 35 US 285? – *High Mark v Allcare*
- Standard for determining if a case is exceptional under 35 US 285 – *Octane Fitness*
- Is the Federal Circuits standard of insolubly ambiguous as a predicate for finding a claim indefinite proper? – *Nautilus v Biosig*
- Is patent exhaustion doctrine a defense to the use or sale of a self-replicating product? – *Bowman v Monsanto*
- The objective indicia of non-obviousness in the obviousness analysis - *Apple Inc. v. ITC; Leo Pharmaceutical Products Ltd. v. Rea; Rambus Inc. v. Rea*
- Post-Therasense, what conduct is necessary for the courts to find a patent unenforceable due to inequitable conduct? - *Intellect Wireless Inc. v. HTC Corp*
- When do statements made by a patent applicant during prosecution limit the scope of the patent? - *SkinMedica Inc. v. Histogen Inc.; 3M Innovative Prop. Co. v. Tredegar Corp*
- When can a biosimilar manufacturer seek declaratory judgment against the patents covering a reference biological product? - *Sandoz Inc. v. Amgen Inc*

### 10:00 Morning Break

10:15 **Overcoming FTO Challenges Relating to the America Invents Act, the Inter Partes Review provision and the Innovation Act**

**Raymond Mantra**  
Partner, Fitzpatrick, Cella, Harper and Scinto (US)

*Post AIA changes, the session will examine the practical impact of the US Patent Reform on litigation, the success of the Inter Partes Review provision under the AIA and whether there were any practical implications on your EU FTO processes. The session will also discuss the Innovation Act (HR 3309), which was recently passed by the House of Representatives and how the changes to the patent litigation system will impact your FTO strategies.*

11:20 **Freedom To Operate and the Nagoya Protocol: What You Need to Know About the New EU Legislation**

**Gertjan Kuipers**  
Partner, De Brauw Blackstone Westbroek N.V. (Netherlands)

*The Nagoya Protocol is set to become part of the EU Legislation in 2014. Even though the European Commission amendment proposals were clear, it seems that the European Parliament amendments injected a sense of uneasiness within the pharma and biotech community. Anyone dealing with Freedom To Operate must surely be familiar with this new piece of legislation, which will definitely have a significant impact on FTO strategies.*

11:50 **Chairman's Closing End of Conference**

12:10 **Networking Lunch**

## Post-Conference Workshop: 1.30 – 5.30

### From Research to Bedside: An Activity-Based Approach to FTO and Exclusivity in Drug Development

**Bernd Hutter**  
Head of Intellectual Property, Morphosys AG (Germany)

**Hakan Yildirim**  
Patent Attorney, Groth & Co (Sweden)

Put into practice everything you've learned in the conference in this highly interactive session. Participants will go through all stages of a conventional drug development program. Participants will form virtual companies and protect their product during the drug development process. Based on certain information provided, the teams will develop their own patent filing strategy with the goal to increase value and extend exclusivities. At the end of the IP activity, participants will discuss reasons and outcomes of their decisions.

The session will be accompanied by breakout sessions on various FTO-related topics, including FTO clearance and searching & interpretation of Third Party patents.

#### Connect with us!



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#### WEBCAST

Can't take time out of the office? Attend the conference from the convenience of your home or office. Save money on travel and view the conference according to your own schedule. This interactive live webcast allows you to participate in the sessions as they occur, download handouts, and ask speakers questions.

If you can't watch the live feed, the recorded archives of the presentations will also be available for you to view for 45 days after the conference is over, so you can re-watch sessions, or view any sessions you may have missed.





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\*ELITEPASS is recommended for maximum learning and networking value.

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## ADMINISTRATIVE DETAILS

Date: 14 & 15 May 2014

Time: 8.00 am - 6.10 pm

Venue: Hilton Munich City Hotel

Address: Rosenheimer Strasse 15, 81667 Munich, Germany

Telephone: +49 (0)89 4804 0

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8.5 hours (conference only) plus 4.0 hours per workshop towards Continuing Professional Developments hours (Solicitors Regulation Authority). Please contact C5 for further information on claiming your CPD points.

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Payment is due in full upon your registration. Full payment must be received prior to the event otherwise entry will be denied. All discounts will be applied to the Main Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organisation.

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