

22nd Annual IBC Legal Conference

Biotech & Pharmaceutical Patenting 2014

Protecting and exploiting medical innovation around the globe

Sheraton Munich Westpark, Munich, Germany – Tuesday 25th & Wednesday 26th February 2014

Chair:



Paul Wiegel
Associate Director of IP
MORPHOSYS AG

Keynote:



Henri Piffaut
DG Competition
EUROPEAN COMMISSION

Special Address:



Heli Pihlajamaa
Director Patent Law
EUROPEAN PATENT OFFICE

In just two days you will:

- Examine **competition law** and the **sectoral investigation** in the pharmaceutical industry
- Debate patent filing – **litigation strategies and timing issues**
- Analyse the latest position of the **UPC** and where it is going
- Discuss second **medical use claims** and **dosage requirements**
- Receive a **regulatory** update
- Explore the key issues of **managing patent expiry** including data-mining, injunctions and commercial solutions
- Examine **biosimilar guidelines** on non-clinical and clinical issues for authorising biosimilars
- **Personalised medicines and biomarkers** – exploring the limits of patent eligibility – *Prometheus v Mayo*
- An industry and a practitioner perspective on filing in **developing countries** with a special focus on Brazil, India and China
- **Preliminary injunction** masterclass – safeguard your legal rights against your rivals
- The **'red flag' competition law** issues in pharmaceutical and biotech patenting
- Patent eligibility of **human genes** – industry responses and implications
- Biotechnical and pharmaceutical patenting in the **US market** including *FTC v. Actavis* & reverse settlements
- Assessing **Bolar** and research/experimental use exemptions
- **SPCs** – maximising commercial value and successful litigation tactics in SPCs

Don't miss the opportunity to hear from our exceptional panel including:

Industry Speakers

- Bernd Hutter, Senior Director, Head of IP, MORPHOSYS AG
- David O'Connor, European Patent Counsel, ELI LILLY
- Marcus Dalton, VP, Global Head Patents, GSK VACCINES
- Marianne Freisleben, European Patent Attorney, Patent Manager, NOVOZYMES A/S
- Geovana Rosales, Patent Manager, Corporate Patent Europe, DUPONT NUTRITION BIOSCIENCES APS
- David Ricol, Senior Patent Attorney, EPA, PFIZER
- Dr. Michael Kompter, Senior Patent Counsel – IP Awareness & Enforcement, BOEHRINGER INGELHEIM GMBH
- Ian James Hiscock, Head IP Strategy and Policy, NOVARTIS INTERNATIONAL AG
- Rebekah Martin, Senior Counsel, ASTRAZENECA UK LIMITED
- Dr. Frank Burkert, European Patent Attorney, Senior Patent Counsel, BAYER INTELLECTUAL PROPERTY GMBH
- Dr. Christian Drescher, Head of Patent Affairs, MIDAS PHARMA
- Dr. Christof Bull, Associate General Patent Counsel, UCB PHARMA SA

Other Experts

- Liz Cohen, Partner, BRISTOWS
- Morten Garberg, Partner, HOFFMANN EITLE
- Dr. Sebastian Höpfner, Partner, BIRD & BIRD
- Chris Mercer, Consultant, CARPMAELS & RANSFORD LLP
- Bert Oosting, Partner, HOGAN LOVELLS LLP
- Gustavo de Freitas Morais, Partner, DANNEMANN SIEMSEN ADVOGADOS
- Dr. Henrik Holzapfel, Associate Partner, GLEISS LUTZ RECHTSANWÄLTE
- Dr. Anna Wolters, Partner, BIRD & BIRD LLP
- Dr. Penny Gilbert, Partner, POWELL GILBERT LLP
- Prof. Dr. Christian Dierks, Rechtsanwalt, DIERKS + BOHLE ATTORNEYS
- Dr. Robert Burrows, Partner, BRISTOWS
- Dr. Christopher Stothers, Partner, ARNOLD & PORTER (UK) LLP
- Kevin Mooney, Partner, SIMMONS & SIMMONS LLP
- Christine Kanz, Partner, REIMANN OSTERRIETH KOHLER HAFT
- Dr. Arwed Burrichter, Partner, COHAUSZ & FLORACK PATENTANWÄLTE
- Dr. Bernard McDonald, Patent Counsel, GILL JENNINGS & EVERY LLP
- Pierre Véron, Avocat, VÉRON & ASSOCIÉS

Judges' Panel

- His Honour Michael Fysh, QC, SC, 8 NEW SQUARE CHAMBERS
- The Hon. Mrs Justice Fidelma Macken, SC Judge, BRICK COURT CHAMBERS

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Gain the essential patenting update and maximise the scope and benefit you derive from your patent portfolio!

DAY 1, TUESDAY 25th FEBRUARY 2014

8.30 Registration and coffee

9.00 Chair's Introduction

Recent Developments and Case Law

9.10 **Developments in European Patent Law in the Last 12 Months**

An essential round up of the key case law and regulatory developments in biotech and pharmaceutical patenting and their impact on your portfolio from the last 12 months

Liz Cohen, Partner, **BRISTOWS**

Dr. Robert Burrows, Partner, **BRISTOWS**

9.55 **KEYNOTE – European Patent Office**

Heli Pihlajamaa, *Director Patent Law*,
European Patent Office

Put questions in advance and on the day to Heli Pihlajamaa of the EPO

10.30 Refreshments

10.50 **SPECIAL ADDRESS – Henri Piffaut**, DG Competition, **European Commission**

Tactical Biotech and Pharmaceutical Patenting

11.20 **Second Medical Use & Dosing Regimens**

Claims in the UK & at the EPO Infringement by Off-label Use

- What are the risks?
- Where is the exposure?
- The challenges of getting second medical use granted
- 'Discontinued' labelling risk

Christine Kanz, Partner,

REIMANN OSTERRIETH KOHLER HAFT

12.00 **Successful Patent Filing Strategies**

- Timing is everything
- Risk management
- Specifics – the devil in the detail
- Drafting tips and traps
- Proof in the pudding – sufficiency and inventive step
- Specific issues to consider
- Practical points for successful filing

Moderator: **Bernd Hutter**, Senior Director, Head of IP,

MORPHOSYS AG

Marianne Freisleben, European Patent Attorney, Patent manager, **NOVOZYMES A/S**

Morten Garberg, European and British Patent Attorney, Partner, **HOFFMANN EITL**

Dr. Sebastian Höpfner, Partner, **BIRD & BIRD**

13.10 Lunch

14.10 **JUDGES' PANEL: Biotechnical & Pharmaceutical Patenting – Some Judicial Perspectives**

Moderator: **Kevin Mooney**, Partner,

SIMMONS & SIMMONS LLP

His Honour **Michael Fysh**, QC, SC,

8 NEW SQUARE CHAMBERS

The Hon. Mrs Justice **Fidelma Macken**, SC Judge,
BRICK COURT CHAMBERS

14.55

Managing Patent Expiry

- Forms of protection: SPCs, paediatric extensions, data exclusivity
- Early warning systems for generic entry
- Responding to generic marketing authorisations
- Pan-European litigation: managing revocation/declaratory actions and preliminary injunctions
- Commercial resolution

Dr. Christopher Stothers, Partner, **ARNOLD & PORTER (UK) LLP**

Rebekah Martin, Senior Counsel, **ASTRAZENECA UK LIMITED**

15.30

Biosimilars

- The market opportunity
- Biosimilars players and strategic partnerships
- Biosimilars approval pathways in key markets
- Data exclusivity – a barrier to market entry?
- Indication expansion
- Navigating the patent landscape

Dr. Christof Bull, Associate General Patent Counsel,

UCB PHARMA SA

16.20

Refreshments

16.40

Personalised Medicines – Exploring the Limits of Patent Eligibility

- The key case law – *Prometheus v Mayo*
- Marketing authorisation
- Practical guidance on constructing a protection strategy for personalised medicines
- Material features – tips and traps
- Tackling validity issues
- Strategies for successful claims

David O'Connor, European Patent Counsel, **ELI LILLY**

David Ricol, Senior Patent Attorney, EPA, **PFIZER**

Prof. Dr. Christian Dierks, Rechtsanwalt, **DIERKS + BOHLE ATTORNEYS**



Transporting and Enforcing Patents to Developing Countries

17.30 **An Industry and a Practitioner Perspective on Filing in Developing Countries**

This session will explore the practicalities of patenting pharma (including HGS v Eli Lilly) in these rapidly growing areas.

Insights into patenting pharma in these three massive growth areas

o INDIA

- The impact of *Glivec*
- Indian Patent Act
- The pressure of the vast healthcare needs of India on the legal system
- Protecting your patent in India
- Caselaw update

o BRAZIL

- The pitfalls of patent filing in Brazil
- New rules issued by Anvisa (Brazilian regulatory agency) regarding biosimilars
- Examination criteria adopted by the Brazilian PTO
- Protection strategies in Brazil
- Practical tips in enforcement: how strong are pharmaceutical patents
- Brazilian patent law reform
- mailbox lawsuits
- constitutional challenge re: patent term

Ian James Hiscock, Head IP Strategy and Policy,

NOVARTIS INTERNATIONAL AG

Gustavo de Freitas Morais, Partner,

DANNEMANN SIEMSEN ADVOGADOS

Geovana Rosales, Patent Manager, Corporate Patent Europe,

DUPONT NUTRITION BIOSCIENCES APS

18.30

Close of Day 1 and **Drinks Reception**



To register or for the latest programme please visit: www.ibclegal.com/biopharma

- 8.30 Registration and coffee
- 9.00 Chair's Introduction
Paul Wiegel, Associate Director of IP, **MORPHOSYS AG**

Minimising Legal Risk in Pharmaceuticals

- 9.15 **Preliminary Injunction Masterclass: Safeguard Your Legal Rights Against Your Rivals**
Dr. Henrik Holzapfel, Associated Partner, **GLEISS LUTZ RECHTSANWÄLTE**
Dr. Arwed Burrichter, Partner, **COHAUSZ & FLORACK PATENTANWÄLTE**
- 10.10 **The 'Red Flag' Competition Law Issues in Pharmaceutical and Biotech Patenting**
- 'Pay for delay' anti-competitive sanctions in settlement agreements
 - Abusive exclusionary conduct by a dominant company – the benchmarks for abuse and practical tips for avoiding the issue
 - License refusal – tips and traps
 - Avoiding the pitfall of charging 'excessive' prices
 - Vertical arrangements – when are they anti-competitive?
 - US vs. Europe approach

11.10 Refreshments

Interplay and Regulatory Framework

Case Law Spotlight

Association for Molecular Pathology v Myriad Genetics

- 11.30 **Patent Eligibility of Human Genes**
- Why has the US Supreme Court singled out human gene sequences in this way when other naturally occurring chemical compounds remain patentable?
 - What is the impact on the pharmaceutical industry?
 - What are the parameters of the decision, will it extend to antibodies and vaccines?
 - What are the possible industry responses?
 - What are the implications for European companies?
- Dr. Frank Burkert**, European Patent Attorney Senior Patent Counsel, **BAYER INTELLECTUAL PROPERTY GMBH**

- 12.20 **Biotechnical and Pharmaceutical Patenting in the US Market**
- An analysis and evaluation of differences in procedure and strategy
 - *Mayo v Prometheus*
 - *FTC v Actavis* – reverse settlements – is the agreement illegal
 - *Bowman v Monsanto Co* – patent protection for seeds
 - Anti-competitive conflicts
 - Divided infringement – claim steps by more than one party
 - FTC & DoJ

13.10 Lunch

COMMERCIAL FOCUS

The Unified Patent Court – The Real Deal

A real world, business focussed examination using a case study followed by a panel discussion

- In a nutshell – what does it really change?
 - The true impact on patent litigation
 - Practical steps your organisation can take to prepare
 - Opting out – is it a sensible option?
 - Advantages – differing perspectives across Europe
- Moderator: **Dr. Penny Gilbert**, Partner, **POWELL GILBERT LLP**
Dr. Bernard McDonald, Patent Counsel, **GILL JENNINGS & EVERY LLP**

Chris Mercer, Consultant, **CARPMAELS & RANSFORD LLP**
Christine Kanz, Partner, **REIMANN OSTERRIETH KOHLER HAFT**
Pierre Véron, Avocat, **VÉRON & ASSOCIÉS**

15.10 Refreshments

- 15.30 **Bolar and Research/Experimental Use Exemptions**
The Current status of the Legislation and the Latest Case Law
- The UK Patents Act amendments
 - What changes to expect
 - The global impact on pharma and biotech companies
- Dr. Christian Drescher**, Head of Patent Affairs, **MIDAS PHARMA**
Dr. Michael Kompter, Senior Patent Counsel – IP Awareness & Enforcement, **BOEHRINGER INGELHEIM GMBH**

- 16.20 **Patentability and the Biochem Directive – and the Recent Cases**
His Honour Michael Fysh, QC, SC, **8 NEW SQUARE CHAMBERS**

- 16.50 **Strategies for Maximising Patent Life Cycles – Exploring the Application of SPCs to extend patent**
- Regulatory exclusivities, Paediatric Extensions and SPCs
 - Recent case law and varying requirements around Europe
 - Recent commentary for SPC applications and parameters
 - *Lilly v. HGS, Georgetown, Sanofi v. Actavis* and *Boehringer Ingelheim* – Where are we now?
 - What if the worst happens and your SPC is invalidated
- Bert Oosting**, Partner, **HOGAN LOVELLS**
Marcus Dalton, VP, Global Head, **GSK VACCINES**

17.30 Close of Conference

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O Swens

"Excellent mix of discussion, panels and presentations. Very interesting topics"

Past Delegate, PMPS

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Biotech & Pharmaceutical Patenting 2014

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