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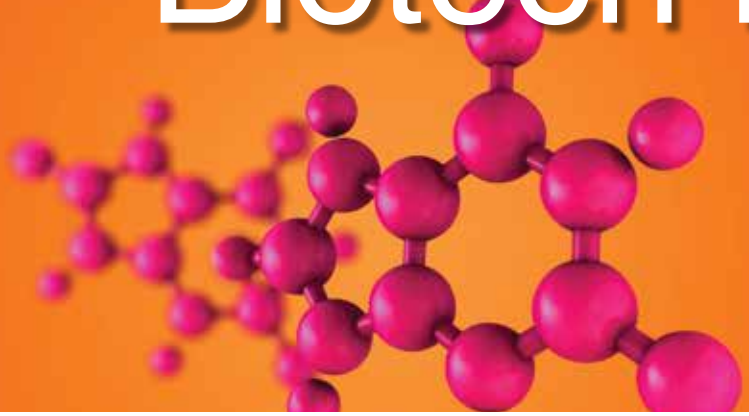
26th Forum on Biotech Patenting



Practical and Legal Strategies to Protect Your Biotech Patent Portfolio

Top Reasons to Attend:

1. Learn about the Unified Patent Court from two European Judges with extensive experience of the subject. Honorary Judge Alice Pezard is a member of the UPC Drafting Committee and Judge Sam Granata wrote the authoritative book 'Introduction to the Unitary Patent and the UPC: The (Draft) Rules of Procedures of the UPC'
2. Gain in-depth insights into 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 including the 'opt-in/opt out option', the composition of the judges panels, the issue of Pan-European PI's and annual renewal fees.
3. Develop an in-depth understanding of the latest EPO developments and the implications these will have on your legal strategies.
4. Enhance your knowledge of the latest developments regarding Antibody Patents and Confidentiality in Clinical Trials.
5. Deal effectively with the fast paced changes concerning Biosimilars and Second Medical Use patents.

Add further value to your conference experience by attending our expert led workshop:

Interactive pre-conference workshop - Tuesday, 25th March 2014
Strategies in International Biotech Litigation from a Business and a Legal Point of View

Johan Renes, Partner, JP Wave (Netherlands)

Paul Reeskamp, Partner, Klos Morel Vos & Schaap (Netherlands)

A View from the Bench: Perspectives on the Unified Patent Court

Alice Pezard, Honorary Judge at the French Judiciary Supreme Court (France)

Judge Sam Granata, Commercial Court of Antwerp (Belgium)

Practical Tips on Planning your Strategies from Leading In House Counsel:


Emil Pot, General Counsel, Actogenix (Belgium)

Kathrin Körner, Principal Counsel & Head of Biologics Patents, Sanofi-Aventis Deutschland GmbH (Germany)


Harry Kraft, Senior Patent Attorney, Ablynx (Belgium)


Dr. Christoph Volpers, Director IP Biologics, Teva Pharmaceutical Industries (Germany)


Mads Damsgaard, European Patent Attorney, H.Lundbeck A/S (Denmark)


Arturo Lucas, Senior Legal Counsel, Chemo Group (Spain)


Stephen Ingham, Assistant General Patent Counsel, Lilly UK (UK)

Dr. Volker Mahlbacher, VP, Global Dept. Patents Biotechnology, Boehringer Ingelheim Pharma GmbH (Germany)


Nicolas Vincent Ruiz, Intellectual Property Director, Esteve (Spain)


Rob Aerts, Senior Patent Attorney, Keygene A.V. (Netherlands)


James Horgan, Assistant Managing Counsel, European Patents, Merck Sharpe & Dohme (UK)

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Biotech drugs account for nearly 15% of the current pharmaceutical market and is recognised as a major growth area for the pharma industry. Pharma companies spend billions on biotech R&D but resulting inventions are only as valuable as the patents they can obtain. In order to exploit such inventions commercially and exclude any possible competitors, it is necessary to have a forward looking patent portfolio.

Our 2014 Biotech Patenting Forum will focus on the practical solutions to the current challenges facing pharma and biotech companies, patent attorneys, legal practitioners and regulatory officers. You will hear the specific strategies used by industry experts in dealing with biotech patenting challenges which will impact your company in 2014 and beyond.

By attending this leading industry event, you will gain valuable perspectives on the new Unified Patent Court from two European judges who are very closely associated with the new institution and our Industry Panel will offer valuable insights into the different considerations and dilemmas faced by in-house counsel and biotech companies regarding this new European system.

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, ECJ referrals and the problems SPC regulation has caused to national courts across the EU
2. Guidance on the representation of Patent Attorneys before the UPC
3. An in-depth analysis of the standards of personalised medicines in the EPO and the enforcement and litigation procedure of infringed personalised medicine patent claims
4. The development of high growth markets in Colombia, Mexico and South Korea and ensuring patent protection and enforcement in these jurisdictions

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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.

WHO SHOULD ATTEND

C5's 6th Forum on Biotech & Pharmaceutical Patent Litigation 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

TaylorWessing 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.

df-mp has a recognized biotechnology and pharmaceutical patent practice. The firm offers an international focus and a multinational team, with attorneys having qualifications and experience in intellectual property law in the European and U.S. legal systems. df-mp was noted as a top firm in Germany in "IAM 1000: The World's Leading Patent Practitioners 2013" since df-mp "operates at the cutting edge of…biotechnology, pharmaceutical and chemistry areas" and "multinationals flock here for the group's cross-border experience". df-mp attorneys are involved in patent litigation (infringement, nullity and opposition), patent prosecution, client counselling (FTO and validity opinions) and advising on patent extension strategies, including SPCs.

Carpmaels & Ransford LLP is a leading firm of European patent and trade mark 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.

Licks Attorneys is a Brazilian-based intellectual property law firm with the background, experience and technological capabilities to provide comprehensive legal counsel, prosecution and litigation services to companies of all sizes.

Licks Attorneys includes a legal team that spans generations, fully accredited by the Brazilian Bar Association and licensed to practice law before all Brazilian courts.

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

MEDIA PARTNERS:

Pre-Conference Workshop: Tuesday 25 March, 2014

1:30 – 4:30

Strategies in International Biotech Litigation from a Business and a Legal Point of View

Johan Renes
Partner, **JP Wave** (Netherlands)

Paul Reeskamp
Partner, **Klos Morel Vos & Schaap** (Netherlands)

- The strategic and communication issues between 'legal' and management that may arise when preparing a law suit
- Demonstration of a software tool that enables an estimate of the financial impact of litigating (or settling) a patent portfolio in the relevant jurisdictions. This tool can be implemented in e.g. a pre suit investigation, so that the financial impact of different scenarios can be presented to management. This will be achieved by discussing a business case
- The attitude of various European jurisdictions on reach through claims and breadth of claim issues regarding biotech patents, and chain of title issues regarding priority documents

Main Conference Day One: Wednesday 26 March, 2014

8:00 **Coffee and Registration**

8:45 **Chairs Opening Remarks**

Marjan Noor
Partner, **Simmons & Simmons** (UK)

9:00 **A View from the Bench: Evaluating the Implications of the New UPC System on Your Biotech Patent Strategies**

Alice Pezard
Honorary Judge at the French Judiciary Supreme Court, Of Counsel Heenan Blaikie, Paris (France)

Samuel Granata
Judge, **Commercial Court of Antwerp** (Belgium)

With UPC preparations in full swing, every biotech company in the world is trying to adjust its patent strategy to accommodate the new UPC system. As the Rules of Procedure are still in development and with no official launch date, the patenting world is eagerly awaiting the new system to be unveiled. Judge Sam Granata and Hon. Judge Alice Pezard will be discussing various aspects of the new system with the delegates in an attempt to shed light on this important new institution in the patent world.

10:00 **Morning Refreshments**

10:15 **Industry Roundtable: How to Manage and Exploit Your Patents in the UPC**

Moderator:

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

Panellists:

Dr. Volker Mahlbacher
VP, Global Dept. Patents Biotechnology
Boehringer Ingelheim Pharma GmbH (Germany)

Rob Aerts
Senior Patent Attorney
Keygene A.V. (Netherlands)

James Horgan
Assistant Managing Counsel, European Patents,
Merck Sharpe & Dohme (UK)

- What are the advantages for opting in and for opting out of the UPC system?
- What are the objective benefits of having a biotech case decided by a national court instead of the UPC?
- If a patent holder chooses to opt out, can he decide to opt in at a later stage?
- The effect of subsequently opting in, if a patent holder has already initiated national litigation
- Should individual proprietors have the right to opt out on a country-by country basis?
- Would the new UPC system attract patent trolls and what are the safeguards for biotech companies?
- Significance of the composition of the UPC judges panels
- Would the UPC issue pan-European preliminary injunctions?
- Whether proposed high annual renewal fees will constitute a problem for biotech companies
- Legal challenges to the Unitary Patent system: What is the actual use of the Unified Patent Court if the Unitary Patent Regulation will be annulled?

11:45 **How Can Biotech Companies Keep the Bolar Rolling: Key Developments in the European Biotech Landscape**

Dr.Mike Snodin
Senior Attorney & Head of Pharma and Nutrition Group, **Avidity IP** (UK)

Richard Schlotter
Partner, **Wragge & Co** (Germany)

As the UK is getting ready to amend the UK Patents Act, the Bolar-type exceptions have been the centre of attention in continental Europe. This session will offer a comparative view on the Bolar exemption situation in Germany, France, Poland, UK and the proposed Bolar-type exemption of the UPC. Furthermore, the session will examine up-to-date European case law, in an attempt to shed light on the lack of EU harmonisation on this important legal matter.

12:30 **Networking Lunch**

1:30 **Breadth of Claims: Practical Claim Tips to Avoid Subsequent Invalidity of Your Patents**

Rainer Friedrich
Partner, **df-mp** (Germany)

Kathrin Körner
Principal Counsel & Head of Biologics Patents,
Sanofi-Aventis Deutschland GmbH (Germany)

This practical session examines how drafting of patent claims has gradually evolved and how the courts and national patent offices have altered their criteria for the validity of patents. The questions of how broad a patent claim should be drafted, if a biotech company would risk having a broad claim subsequently being invalidated and when a claim is speculative or not will be discussed in detail.

2:30 **Representation of Patent Attorneys Before the Unified Patent Court: Considerations, Dilemmas, Suggestions and the Best Routes Examined**

Axel Casalonga
Chairman of the EPI Litigation Committee
European Patent Institute

This session examines the on-going discussion of the representation rights of patent attorneys before the UPC. The highly anticipated European Patent Litigation Certificate is still without solid criteria and it is still debated how the different levels of legal qualification of national patent attorneys would be balanced in the new system. Is the latest draft of Art.48 (1) and 48(2) clearer on this subject and what are the fears and concerns of patent attorneys which will ultimately impact their businesses, jobs and clients?

3:10 **Understanding the Importance of Personalised Medicine Patents in Biotechnology**

Daniel Wise
Partner, **Carpmaels and Ransford LLP** (UK)

Mads Damsgaard
European Patent Attorney, **H.Lundbeck A/S** (Denmark)

- What are the current standards of the EPO for personalised medicines?
- Enforcement and Litigation Procedure of infringed personalised medicine patent claims
- What is the connection of personalised medicine and life cycle extension?
- Can you patent different patient groups and dosage regimes and how do you provide novelty?
- Patient Population type patents
- The different approaches of the Examining Division at the EPO and Technical Board of Appeal

4:10 **Networking Break**

4:25 **How to Develop a Successful Strategy for Antibody Patents**

Emil Pot
General Counsel, **Actogenix** (Belgium)

Harry Kraft
Senior Patent Attorney, **Ablynx** (Belgium)

- When is the right time to file your patent and what are the risks if the patent application is filed too early?
- The necessary level of disclosure at the point of application
- Drafting of antibody claims and the red flags to be avoided
- Strategies on antibody patent filings and prosecution in major markets
- Optimising patent protection and applying life cycle management

5:05 **Regulatory Insight and Industry Perspectives on your Biosimilars Strategies**

Dr Christoph Volpers
Director IP Biologics
Teva Pharmaceutical Industries (Germany)

- Commercial potential of biosimilars for biopharma companies
- Current and up-to-date regulatory and legal requirements and developments
- Strategic aspects of IP work from a Biosimilars perspective
- Update on relevant Biosimilars case law

5:30 **Evaluating the Significance of Transparency and Confidentiality in Clinical Trials**

Arturo Lucas
Senior Legal Counsel, **Chemo Group** (Spain)

Following recent case law, the issue of disclosure of clinical trial data has been widely debated. If the pharmaceutical companies win the aforementioned cases that would mean that transparency would be greatly reduced but it would also impact upon commercial confidentiality. Critical issues such as the definition of confidentiality and who should decide what is truly confidential will be discussed in this session.

6:00 **Chairman's Closing Remarks**

Main Conference Day Two: Thursday 27 March, 2014

8:00 **Coffee and Registration**

8:45 **Chairs Opening Remarks**

Mark van Gardingen
Partner, **Brinkhof N.V.** (Netherlands)

9:00 **A Pan European Perspective on SPCs: What you Need to Know to Successfully Obtain a SPC**

Sandra Pohlman
Partner, **df-mp** (Germany)

Stephen Ingham
Assistant General Patent Counsel, **Lilly UK** (UK)

Nicolas Vincent Ruiz
Intellectual Property Director, **Esteve** (Spain)

- What level of information needs to be included in the claims of a biotech patent in order for an SPC to be granted?
- The need for reform of the EU SPC Regulation
- Can you get more than one SPC per patent?
- Impact of ECJ referrals decisions on biotech patent companies strategies
- Will the UPC issue Pan-European SPCs?
- What are the commercial implications on a biotech company if an SPC is deemed invalid?
- Update on the cases pending before the ECJ

10:25 **Inside the European Patent Office: Understanding the Implications of EPO developments on Your Patents**

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

Divisional Applications: Rule 36 and what changes should occur after the abolition of the two year rule

As of 1 April, 2014 the EPO will abolish the 2 year deadline for filing a divisional application and will revert back to the old regulation which allows divisional applications to be filed at any time so long as an EPA is pending. The session will discuss what are the advantages and disadvantages of this development and whether the newly introduced additional fee for second-generation divisional applications will manage to keep them under control

EPO Appeals and the issue of New Requests

Recent case law from the EPO Boards of Appeal have concluded that applicants cannot postpone the filing of new requests which could have been presented during the first instance proceedings as this allows a sort of forum shopping which would disable the proper distribution of functions between first instance and the European Board of Appeals. What would be the consequences of this significantly stricter approach of the EPO Board of Appeal?

Grace Period

Despite, recent changes in the patents landscape around the world, the introduction of a grace period in the EU remains a long-standing and controversial debate. Would a harmonised grace period, in both scope and duration, be of real and practical substantial benefit?

11:20 **Morning Coffee and Networking**

11:35 **Strategy and Drafting Considerations for Human Genes post Myriad**

- Drafting of patent applications post Myriad
- What should companies include in their PCT application to ensure validity of their patents?
- Impact of Myriad on Biotech patent strategies
- Are antibodies and other classes of naturally occurring isolated biomolecules patentable post Myriad?
- Ariosa Diagnostics Inc. v Sequenom Inc. and update on US Case Law
- Will the case act as a deterrent for biotech innovation?
- Would the Myriad case set a trend for the EU?
- What would be the impact on the EU Biotech Directive?

12:00 **Lifting the Lid on Second Medical Use Patents: Understanding the Implications of Infringement of Second Medical Use Patents**

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

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

- A review of the protection available for second medical uses
- Direct and indirect infringement by different parties
- Gathering evidence and proving infringement
- Specific issues regarding off-label use
- Remedies: the scope of damages and injunctions available

1:00 **Networking Lunch**

Global Biotech Patent Strategies Afternoon: High Growth Markets

2:00 **Patent Protection and Enforcement in Brazil**

Otto Licks
Partner, **Licks Advogados** (Brazil)

- Brazilian Patent Law: Actual scenario and the new implications of Bill #5,402/2013
- New guidelines for examination of Biotech applications
- Different interpretation and views of Brazilian IP legislation over Biotech and Pharm applications among the country´s agencies: INPI (PTO), ANVISA and CEGEN
- Enforcement of Biotech Patents in Brazil
- An overview on Partnership for Productive Development (PDP) and patent licensing

2:40 **Opportunities to Expand Your Patents Portfolio in Canada**

David Schwartz
Partner, **Smart & Biggar/Fetherstonhaugh** (Canada)

- The promise of the patent, the utility doctrine and sound prediction in Canada
- Eli Lilly v Canada
- Update on the proposed introduction for SPCs in Canada
- Impact of the EU Comprehensive Economic and Trade Agreement
- Update on Canadian biotech patent case law

3:10 **Afternoon Refreshments**

3:25 **Global Biotech Patent Strategies Afternoon: Up-and-Coming Markets**



With many biotech companies launching their products globally, the companies have to adhere to various and different legal jurisdictions and their often stringent requirements. The second half of the Global Biotech Strategies session will examine four up-and-coming markets and explore their unique patent criteria.

Colombia, South Korea and Mexico

Juan Pablo Cadena
Partner, **Brigard & Castro** (Colombia)

Susanne Høiberg
CEO and Partner, **Hoiberg A/S** (Denmark)

Alejandro Luna
Partner & Co-Chair Life Sciences Industry Group
Olivares (Mexico)

- What kind of patent protection can be obtained?
- What are the main problems which affect the patent rights of biotech companies in these countries?
- Enforcement of patent holder rights in these jurisdictions
- Update on biotech patent case law

4:25 **Manage the Practical Implications of the *Lundbeck* and *Actavis* Reverse Payments Cases**

George Peretz
Barrister, **Monckton Chambers** (UK)

- The competition regulators wage war on 'reverse payments': Actavis, Lundbeck
- Analysis of the antitrust case against patent settlements
- Compare and contrast the approach in the EU and US
- Practical implications for pharmaceutical companies
- Avoiding the pitfalls in entering into patent settlements

4:50 **How to formulate your Stem Cell Strategies in light of the Brüstle v Greenpeace and International Stem Cells Corporation Cases**

Nick Bassil
Partner, **Kilburn & Strode** (UK)

- Criteria for examination on human stem cell inventions at the EPO
- Potential impact for biotech companies if *ISCC* affirms the *Brustle* decision.
- Will the EPO and national patent offices delay prosecution of applications involving hESCs deriving from parthenotes pending the CJEU decision?
- Would PGD cells and iPS cells be the technologies available that do not involve the destruction of a human embryo and fall outside Brüstle?
- Update on the Brüstle v Greenpeace and ISCC cases

5:15 **Chairman Remarks and End of Conference**

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ADMINISTRATIVE DETAILS

Date: 26th & 27th March 2014

Time: 8:00 - 5:15

Venue: Hotel Vier Jahreszeiten Kempinski

Address: Maximilianstrasse 17, 80539, Munich, Germany

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