C5's industry-leading event allows you to benchmark against the best practice strategies employed by the market leaders. Our first-class speaking faculty will provide up-to-the-minute clarity on the latest regulatory developments, case law, challenges and opportunities in biotech patenting, including:

- Maximising your available data to establish the strongest patent position possible in light of the VEGF cases
- Successfully filing your patents at the earliest allowable stage in accordance with *HGS v Eli Lilly*
- The red flags every patent attorney needs to recognise in the new biosimilar regulations
- The latest developments on the patentability of stem cells and plant & seed biotechnology
- Securing patents for personalised medicines and biomarkers
- Extending your market dominance by utilising SPCs to extend the life of your patents
- Complying with the America Invents Act to protect your IP in the world’s most lucrative biotech market
- Overcoming the challenges of managing and protecting your patents in Asia

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The Market Leading Conference Update on Biotech Patenting Strategies

More so than ever, patent attorneys are indispensable contributors to the commercial success of biotech products.

In tough economic times, companies look to maximise their return on investment through more efficient use of their existing resources. For pharmaceutical companies, this creates an incredibly important role for patent attorneys, who are tasked with maximising the company’s available data to establish the strongest patent position possible.

Through the utilisation of patent extensions, supplementary protection certificates and innovative patenting strategies, a pro-actively managed patent portfolio can yield lucrative rewards.

These opportunities to drive the commercial success of a product via patenting do exist, however the constantly shifting IP landscape and rapidly evolving case law make this a difficult task. Patent attorneys need to find answers to the myriad of strategic, regulatory and litigation questions which face them before their competitors find them first.

Be sure to also attend the pre-conference Masterclass on the 14th of March to build on your knowledge gained with practical in-depth discussion during our Step-by-Step Guide to Developing and Maintaining an Effective Freedom to Operate Strategy for Biotech Products

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Through the utilisation of patent extensions, supplementary protection certificates and innovative patenting strategies, a pro-actively managed patent portfolio can yield lucrative rewards.

With over six decades of experience in the Brazilian and International markets, Daniel Advogados offers an extensive team of professionals specialized in Intellectual Property matters to address all the needs of its clients in this area. Trademarks, Patents for Inventions and Utility Models, Industrial Designs, Trade Dress Protection, Combating of Piracy, Transfer of Technology, Licensing and Litigation are some of our main IP practices.
10.30 Coffee and Registration

9:00 Opening Remarks from the Chair

Marjan Noor
Partner, Simmons & Simmons

9:15 How to Establish the Strongest Patent Position Possible With Limited Available Data

Bart van den Hazel
Director — Patent Counsel, GlaxoSmithKline Biologicals

Jens Viktor Nørgaard
Partner, Hoiberg A/S

The pressure remains on patent attorneys to secure the broadest patent coverage for their company’s products as possible. This is often done on the back of limited amounts of data, creating the risk that the patent is too wide to be valid. In light of the recent VEGF cases (Regeneron v Genentech and Bayer v Genentech), what are the practical steps you can take to maximise the data available to you in the framework of a patent specification in order to obtain the broadest coverage possible?

• How broadly can you support inventive steps across the full scope of your patent application?
• At what point is a wide patent claim no longer valid on the grounds of lack of novelty or inventive step?
• To what extent can the scientific community’s reaction to an invention be considered in an assessment of obviousness to the “person skilled in the art”? To what extent can potential therapeutic applications be directly and unambiguously disclosed?
• To what extent are the German courts hearing parallel proceedings in the VEGF cases likely to differ from the approach in the UK?

10:00 Morning Refreshments

10:30 Keynote Address: European Patent Office

Heli Pihlajamaa
Director Patent Law, European Patent Office

This keynote address from the European Patent Office will be followed by an extended Q&A session.

11:30 Extending the Exclusivity of Patent Protection Through the Utilisation of Supplementary Protection Certificates

Part A: SPC Fundamentals

Steven Cattoor
Partner, Hoyng Monegier

• Under what circumstances can you extend a patent with a SPC?
  – New indications under the scope of the patent
• Utilising paediatric trials to obtain an extension on their SPC
  – What are the requirements and how are they practically applied?
  – Merck’s Januvia case (C125/10): Obtaining negative term SPCs

Part B: Case Law Application

Hugh Goodfellow
Partner, Carpmaels & Ransford

• What practical impact has the European Court of Justice’s “Big 6” decisions on SPCs for combination vaccines had on patent attorneys?
  – How to adapt your strategies in response to these decisions
  – Factors to consider when drafting patents
  – Interpretation issues raised in the Actavis v Sanofi referral
  – How are the cases being interpreted at a national level?
• In-depth analysis of Medimmune v Novartis, and what it means for interpreting the “Big 6” cases in relation to SPCs on biologics

12:30 Networking Lunch

1:30 Strategies for Converting the Stem Cell Challenges Posed by Brüstle v Greenpeace Into Opportunities

George Schlich
European Patent Attorney, Schlich LLP

Clara Sattler de Sousa e Brito
European Patent Attorney, Liermann-Castell

In effectively taking away the most readily available source of cell lines, the EJ has thrown the entire biotech industry into turmoil with their decision in Brüstle v Greenpeace. As the EPO firms up what was already an adverse position towards stem cells by incorporating the decision into their guidelines, it is left for patent attorneys to make sense of the situation and develop strategies to work within and around these new constraints.

• Deciphering the impact of Brüstle v Greenpeace:
  – How wide will the exclusion against using cell lines derived from human embryonic stem cells be applied?
  – What room is there for patents on stem cells?
  – What is the scope for patenting inventions utilising early human development stages?
  – What falls within the definition of an “embryo”? To what extent will cells generated through the process of parthenogenesis be treated as coming from an embryo?
• What are the alternative techniques for generating stem cells and are they commercially and scientifically viable?
• To what extent will the EPO allow moral and ethical considerations to influence their interpretation and application of the Brüstle decision?
• To what extent does the decision point towards the creation of pan-European regulations forbidding funding of stem cell research?

Opportunities to Expand Your Patent Portfolio Via the Patent Eligibility of Personalised Medicines and Biomarkers

James Horgan
Assistant Counsel, Merck Sharp & Dohme

Lars Högland
European Patent Attorney, Zacco

Prometheus v Mayo is leading the intellectual property landscape into a new era of patentable biomarkers and personalised medicines, and there is a race on to discover what patent protection can be secured over and above what is already established. With the majority of big pharma in the final stages of developing and releasing their first personalised medicines for particular patient subsets, this shapes to be one of the hottest topics over the coming year.

• To what extent do personalised medicines fit within the existing European patenting framework?
• How can you position your claim to meet the current standards of the EPO?
• How would personalised medicine patent claims be infringed from an enforcement and litigation perspective?
• How do dosage regimes fit within the context of personalised medicines and biomarkers?

3:00 Afternoon Refreshments

3:15 Managing Your Patent Portfolio to Maintain Competitive Advantage and Maximise Return On Investment

Harry Kraft
Senior Patent Attorney, Ablynx

Stephen Yoder
CEO, Pieris AG

• Defining the scope of your patent portfolio to enable the successful defence of your products

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• Identifying how to time and position your patents and IP strategies
• Working around third party patents
• Developing IP commercialisation strategies: enhancing product development through the licensing and acquisition of third-party IP
• Ensuring full integration with your R&D team to ensure research is focused on outcomes that may be patentable
• What are the pros and cons of filing patent applications in individual member states as opposed to filing with the EPO?

4:00 How to Enforce Your Biotech Products: Key Developments and Trends in Biotech Litigation Strategies

Gisbert Hohagen
Partner, Taylor Wessing

Simon Cohen
Partner, Taylor Wessing

• Recent case law developments in biotech patent litigation and what it means for your litigation strategies
• Practical considerations for selecting and instructing scientific experts
• What are the available forms of disclosure?
• Developing a successful strategy for pan-European patent enforcement following recent case law developments on cross-border injunctions
• Overview of procedures in key European jurisdictions: where to litigate?
• What are the pitfalls of pursuing parallel proceedings at the EPO and national level?

4:45 Getting Your Product to Market Through Non-Injunctive Patent Infringement Remedies

Dr. Christopher Stothers
Partner, Arnold & Porter (UK) LLP

As biotech innovators increasingly claim early patents over the widest scope possible, we see an increase in innovator/innovator disputes involving distinct and often superior products being blocked from going to market. Raising public health interests and competition concerns, alongside standard patent issues, the courts have to consider whether to provide injunctive remedies for patent infringement. How can you ensure your company's product gains market access?

• Are compulsory licenses ever a suitable alternative to injunctions?
• What are the ethical and public health arguments to be made against a court-issued injunction?
• What are the competition issues to be raised where one company has a dominant position?
• What are the top tactics at your disposal to overcome a competitor's blocking patent?

5:30 Chairs' Closing Remarks

WEBCAST

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To register call +44 (0) 20 7878 6888 or register online at www.c5-online.com/biotech
11:30 The Red Flags Every Patent Attorney Needs to Know to Successfully Navigate the Regulatory Landscape for Biosimilars

Part A: Europe
Manja Epping
Partner, Taylor Wessing

Breaking down the 2012 amendments to the European Medicines Agency (EMA) guidelines on biosimilar and monoclonal antibody approval.

• Definition of and distinction between a biologic and a biosimilar
• What level of clinical trials data is required to prove safety and efficacy?
• To what extent can data be extrapolated between indications?
• What degree of pharmacovigilance and immunogenicity testing will be required of biosimilars?
• Utilising comparative in vitro pharmacodynamic studies to assess the difference in biological activity between the biosimilar and the reference product

Part B: America
Carol Pitzel Cruz
Partner, Knobbe Martens Intellectual Property Law

Analysing the key features of the new Food and Drug Administration guidelines for American biosimilar approval under the Biologics Price Competition and Innovation Act.

12:30 Networking Lunch

1:30 Surmounting the Problems Arising from Inconsistent Provisions in Brazil’s Paradoxical Patent Law to Successfully Protect Your IP Assets

Rana Gosain
Partner, Daniel Avogados (Brazil)

As an emerging economy, Brazil is becoming one of the most important economies in the world. It has brought its IP legislation into sync with international standards, however, inconsistencies in its patent provisions are causing concerns.

• What type of patent protection can be obtained?
  – what are the patentability requirements?
  – how does ANVISA apply the requirements?
• To what extent is the current IP law TRIPS compliant?
• Enforceability of patent rights:
  – what do you need to do to get an injunction?
  – how easy is it to enforce your IP rights? what conditions need to be satisfied?
• How often are compulsory licences issued?
• Guidelines regarding manufacturing: what must you do to manufacture there?
• What are the particular problems which affect the patent rights of biotech companies doing business in Brazil?
• How much action do the competent authorities take to protect data against disclosure and unfair commercial use during the established periods of exclusivity?
• Understanding the provisions within the Bolar exemption and the implications of the mandatory review of pharmaceutical patent applications by ANVISA
• Evaluating the recent decision undertaken by Brazilian Courts to re-evaluate the status of data protection for human drugs

2:15 Wrinkled Tomatoes, Broccoli & Melon Disputes: The Latest Developments in Plant & Seed Breeding Patents

Liesbet Paemen
European Patent Attorney, De Clercq & Partners

Ulf Schaberg
Global IP Lead Vegetables, Syngenta

• What insight do the “amicus curia” briefs submitted to the court in the second “Wrinkled Tomato” appeal (G2/12) provide into the biotech industry’s position on breeded plants derived from biological processes patents?
• What is the current scope of the patent exclusion of biological processes in light of the initial appeal?
• To what extent can the inclusion of other technical processes in addition to the biological process take you outside the exclusion?
• To what extent can a “product” be patentable separate from the excluded biological process that led to its creation?
• How does the EPO approach to plant and seed patenting differ to that taken at a national level?

3:00 Afternoon Refreshments

3:15 Overcoming the Regulatory and Strategic Challenges of Managing and Protecting Your Patents in Asian Markets

Peter Dolan
Head of China, India, Japan & Asia-Pacific Patents, Sanofi-Aventis

• What are the regulatory and patenting challenges opportunities unique to the IP landscape in Asia?
• What elements of European patentability criteria are similarly observed in the region?
• Best practice strategies to successfully protect and enforce your patents
• Practical analysis of the latest IP case law developments

4:00 Utilising the America Invents Act to Protect Your IP in the World’s Most Lucrative Biotechnology Market

Li Westerlund
VP of Global IP, Bavarian Nordic Group

As the full and final implementation of the America Invents Act (AIA) takes place, this session will provide in-depth and practical analysis of the key provisions you need to know in order to update your patent strategies in the US.

• Step-by-step guide to adapting your patent strategies in response to the AIA
• Ensuring compliance with the strict time limits observed under the “first-to-file” system
• How will the patent Trial and Appeal Board work in practice?
  – Interaction between parallel proceedings at the board and district courts: to stay or not to stay?
• What are the key differences between the American and European systems?
  – What challenges does this present for European patent attorneys?
  – To what extent can you harmonise your global patent filing strategies in light of the new system?

4:45 The Unitary Patent and Unified Patent Court: Opportunities for New Patenting Strategies and Practical Challenges to be Overcome

Dr. Rob J. Aerts
Patent Attorney, Keygene N.V.

“The new rules, once in place, will increase the potential for inventions and innovation within the European Single Market and reassert Europe’s competitiveness... We urgently need to adopt unitary patent protection in Europe”: Michel Barnier, EU Internal Market Commissioner (2012)

• The ‘Patent Package’: what would the Unitary Patent and Unified Patent Court look like?
• Are there still difficulties to be solved before the Package can be introduced?
• What are the possible next developments?
• What advantages could we expect from the Package?

5:15 Chairs’ Closing Remarks and End of Forum

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# Biotech Patenting 2013

## Business Information

### 24th C5 Forum on Biotech Patenting 2013

Proven strategies to extend, expand and maximise the scope of your existing patent portfolio

### 13th & 14th March 2013 | Innsbruck Parkstadt Schwabing Hotel, Munich, Germany

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**Time:** 8:30 - 17:15  
**Venue:** Innsbruck Parkstadt Schwabing Hotel  
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