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In A Global Context

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Life Sciences IP Summit 2014

Powering Business Growth through Practical and Innovative Patent Monetisation and Protection Strategies

12 – 14 November 2014 • Hotel Novotel Amsterdam City, Netherlands

- A Team Pass for Industry
- Dedicated Streams, Keynote Addresses and a Mock Trial
- Patent Office Roundtable Breakfast Briefing
- Over **70%** Industry Attendees
- **40+** Industry and Regulatory Speakers
- Comprehensive Industry Driven Programme

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Life Sciences IP Summit 2014

C5 has been a trusted provider of leading edge technical conferences to the life sciences industry for over 15 years. Relied upon by the world's leading life sciences companies for the latest legal and regulatory insights and analysis; thousands of IP professionals globally have attended a **C5** event.

An innovative new solution written in response to market demand, **The Life Sciences IP Summit** is part of **C5's** industry-leading portfolio of intellectual property events for the life sciences industries. In what will be a premier must-attend annual industry gathering, the Summit presents a new and exciting event experience for the life sciences industries, offering enhanced and unparalleled social networking opportunities and industry exposure.

Benefit from a one-stop-shop approach and gain access to a diverse and broad range of expert IP practitioners and patent attorneys from Europe's leading and up-and-coming life sciences companies at the one time in the one place.

Based on over 200 hours of dedicated market research, the summit programme and exceptional speaker faculty builds on the high standards delegates already expect from C5, providing industry with the practical solutions they need to exploit and defend their inventions commercially.

The **Life Sciences IP Summit** experience provides exclusive learning, benchmarking and networking opportunities, offering unparalleled access to the leading companies in Europe. **Designed for your entire in-house team**, each attendee is able to create a personalised professional development agenda tailored to their and their company's needs, through **dedicated streams, workshops and training sessions** taking place throughout the Summit.

Designed for Your Entire In-House Team:

- One great value price for up to 5 delegates from the same company, bringing together colleagues from across Europe
- Teams individual professional development needs are met through a choice of dedicated technical streams
- Extended networking, and one to one meetings provide platforms for benchmarking, cross-pollination and exchange of ideas

Dedicated Streams, Workshops and Training Sessions

- The critical patenting challenges facing industry as they look to monetise and defend their patent portfolio, including: cross-border litigation, second medical use patents, personalised medicines & biomarkers, and supplementary protection certificates
- Take action now to incorporate the Unitary Patent Court into current patenting strategies: mock trial featuring leading European judges
- Invaluable insights from key authorities and the European Patent Office
- Advanced technical guidance on a range of valuable niche areas including: freedom to operate, licensing, competition, and executing robust collaboration agreements

Extended Networking Opportunities

With a large audience generating an engaged and spirited atmosphere, a focus of the Summit will fall on creating unique and meaningful networking opportunities. Join colleagues from across Europe and make the most of your time spent out of the office by customising your learning and networking schedule in a prestigious and interactive environment.

Speaker Faculty

Keynote Addresses

Henri Piffaut
DG Competition
European Commission

Speaker TBC
European Patent Office

Paolo Balboni
Scientific Director
EU Privacy Association

Mock Trial Judges

Sir Robin Jacob (Presiding Judge)
Hugh Laddie Professor of Intellectual Property Law, UCL

Judge Dr. Matthias Zigann
Munich Regional Court

Judge Karin Friehe
Federal Patent Court, Munich

Judge Edger Brinkman
Court of Appeal, The Hague

Patent Offices

Martin de Lange
Patent Examiner, Netherlands Patent Office

Per Foss
Director General
Norwegian Industrial Property Office

Thomas Xavier Duholm
Deputy Director, Policy and Legal Affairs
Danish Patent and Trademark Office

Katalin Miklo
Head of Chemistry and Agriculture Unit
Hungarian Intellectual Property Office

Oliver Werner
Senior Examiner
German Patent and Trademark Office

Maria Inês Silva
Head of Patents & Utility Models Department
Portugal Institute of Industrial Property

Susanne Ås Sivborg
Director General and President
Swedish Patent and Registration Office

Industry Insight

Arturo Lucas
Senior Counsel, Chemo Group

Christina Takke
Partner, Forbion Capital Partners

Christoph Rehfuess
Director of Intellectual Property
MagForce AG

Debbie Allen
Vice President Business Development
arGEN-X

Emil Pot
General Counsel, Actogenix

Fiona Bor
Vice President and IP Director
Mylan Europe

Francesco Macchetta
Director Intellectual Property
Bracco Group

Frank Burkert
Senior Patent Counsel
Bayer Intellectual Property GmbH

Frank Landolt
V.P. Intellectual Property and Legal
Ablynx N.V.

Gavin Lawson
Senior Manager, Intellectual Property
Gilead Sciences Europe Ltd

Henrik Mathiassen
Head of Patent Department
Zealand Pharma

Juergen Dressel
Head Global Patent Litigation Strategy
Novartis

Lise Abildgaard
Vice-President, H.Lundbeck

Marc Markus
European Biology Patent Lead, Pfizer

Nicolas Vincent Ruiz
Intellectual Property Director, Esteve

Pascal Touchon
Vice-President, Scientific Cooperation and Business Development, Servier

Peter Picht
Senior Research Fellow, Max-Planck-Institute for Innovation and Competition

Reginald Seeto
Vice President, Head Of Partnering & Strategy, MedImmune

Richard Vary
Head of Litigation, Nokia

Sally Curran
Senior Patent Director, RIA & Emerging Innovations Unit, AstraZeneca

Vanessa Currat
Director, Legal Affairs
Debiopharm International S.A

Expert External Counsel

András Kupecz
European Patent Attorney, Kupecz IP

Bryan Diner
Partner, Finnegan, Henderson, Farabow, Garrett & Dunner LLP

Christoph de Coster
Partner, Taylor Wessing

Erik Vollebregt
Partner, Axon

Hugh Goodfellow
Partner, Carpmaels and Ransford LLP

James Marshall
Partner, Taylor Wessing

Jonathan Singer
Partner, Fish & Richardson

Kristina Cornish
Partner, Kilburn & Strode LLP

Liz Cohen
Partner, Bristows LLP

Penny Gilbert
Partner, Powell Gilbert

Pierre Veron
Partner, Veron and Associes

Uli Foerstl
Partner, Olswang

Vladimir Belkov
Patent Attorney
Baker & McKenzie – CIS, Limited

Willem Hoyng
Partner, Hoyng Monegier

Wouter Pors
Partner, Bird & Bird

And many more to be announced...

Agenda-at-a-Glance

Main Summit Day One: 13 November 2014

8:30 Registration and Coffee

8:45 **Opening Remarks from the Chair**

9:00 **Keynote Address: European Patent Office**

10:00 Morning Refreshments

STREAM A: IP Portfolio Management – Partnering, Licenses & Business Development

10:30 **Commercial Overview: Identifying the Current Drivers and Trends in Deal-Making**

11:30 **Successfully Implementing Open Innovation as Part of Your Innovation Strategy**

12:00 **Maximising Your Patent Portfolio ROI Through Win-Win Licensing Agreements**

STREAM B: Litigation

10:30 **Preliminary Injunctions: What You Need to Know to Safeguard Your Legal Rights and Protect Your Patent Portfolio**

11:30 **Practical Tips to Develop a Successful Cross Border Litigation Strategy**

12:30 Networking Lunch

STREAM A: Competition

1:45 **Pay for Delay and Anti-Trust Law: Protect Your Patent Portfolio from the Practical Implications of the Latest Competition Law Cases**

2:30 **Keynote Address: European Commission**

STREAM B: Unitary Patent and Unified Patent Court

1:45 **The Unified Patent Court: How to Successfully Alter Your Strategies and Prepare for the New Patent Litigation Era**

Part A: Drafting Committee of the UPC

Part B: Industry Perspective – Are We In or Out?

3:15 Afternoon Refreshments

3:45 **Mock Trial: Obtaining a Preliminary Injunction Under the Rules of the Unified Patent Court**

6:00 **Chairs' Closing Remarks followed by Networking Drinks Reception**

Main Summit Day Two: 14 November 2014

8:00 – 9:30 **Closed Door Breakfast Briefing: Patent Office Roundtable**

9:00 Registration and Coffee

STREAM A: Biotech & Pharma Patenting

10:00 **Second and Subsequent Medical Use Patents Under the Spotlight: Assessing their Commercial Value and Overcoming Possible Challenges**

10:45 **How to Expand Your Patent Portfolio Via the Commercialisation and Patent Eligibility of Personalised Medicines and Biomarkers**

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STREAM B: Global Focus

10:00 **Analysing the Impact of the USPTO Post-Myriad Guidance on Human Gene and Other Natural Product Developments**

10:45 **Protecting Your IP in the World's Most Lucrative Life Sciences Market: An Update on the Practical Operation of the America Invents Act and the Patent Trial & Appeal Board**

11:15 **Protection of Biotech and Pharma Inventions in Russia**

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1:30 **In-House Roundtable: How In-House Counsel are Selecting & Evaluating their Outside Counsel, Containing Costs, and Formulating their Patenting and Litigation Strategies**

2.30 Afternoon Refreshments

STREAM A: Regulatory Compliance

3:00 **Ensuring Transparency in Accordance With Recent Legislative Changes and Case Law Developments**

3:40 **Data Collection & Usage: What EU Data Protection Reform Means for the Life Sciences Industries**

4:20 **Aligning Your Regulatory and Compliance Practice with the Upcoming Changes in Clinical Data Requirements for EU Medical Devices**

STREAM B: Biotech & Pharma Patenting

3:00 **Timing Is Everything: The Main Considerations on How to Develop Successful Patent Filing Strategies for Antibodies**

3:40 **Assessing the Implications of Broad Patent Claims on Your Patenting Strategies**

4:20 **How to Optimise Your Patent Portfolio by Taking Advantage of the Latest Patent Expiry Strategies**

5:00 **End of Summit**

Elite Pass

Enhance your conference experience with an *Elite Pass* and benefit from unrestricted access to all additional features of the Summit, including Pre-Summit Workshops, Pre-Summit Welcome Dinner, and the Exclusive Breakfast Briefings.

Pre-Summit Workshops: 12 November 2014 (3:00 – 6:00 PM)

WORKSHOP A: Step-by-Step Guide to Developing and Maintaining an Effective Freedom to Operate Strategy

Kristina Cornish, Partner, Kilburn & Strode LLP

In this highly interactive and practical session, our workshop leader will walk you through the latest trends, pitfalls and techniques for developing the most time efficient and cost effective FTO strategy possible.

- Benchmarking your FTO strategy against industry-best practices
- Interpreting FTO search results and patent validity to reduce the risk of litigation and secure future revenue
- Balancing concerns of privilege and confidentiality when reporting your FTO strategy
- What impact are recent developments in case law and the introduction of the America Invents Act in the US having on FTO analysis?
- Interaction of FTO and supplementary protection certificates

WORKSHOP B: Executing Well-Crafted Agreements that Develop Fruitful Collaborations and Limit the Potential for Future Disputes and Litigation

Koos Rasser, Partner, Rasser De Haan BV

András Kupecz, European Patent Attorney, Kupecz IP

- What are the common ambiguities and pitfalls that can lead to conflict in life sciences collaborations?
- Negotiating, drafting and executing robust agreements: best practice contractual safeguards to incorporate in all contracts and agreements
  - Recommended clauses for agreements with academia, CROs, small biotech, etc.
- Developing sound agreement governance mechanisms
  - Prioritizing activities and avoiding internal competition
- Addressing differences between partners in product development strategies
- Exploring creative deal structures
  - Option-based agreements
  - Using milestones frequently
- Factoring in third party lawsuits, patient complaints and clinical trial/ regulatory hurdles: should you plan for a joint defence – and how can you establish an agreed litigation process

Pre-Summit Welcome Dinner: 12 November 2014 (7:00 PM)

Maximise your opportunities to network with some of the most influential people in the industry at our pre-summit welcome dinner for all speakers and delegates.

Breakfast Briefing – Patent Office Roundtable: 14 November 2014

Benefit from invaluable patent office insight and exceptional networking opportunities in this intimate closed-door breakfast briefing

Martin de Lange
Patent Examiner
Netherlands Patent Office

Per Foss
Director General
Norwegian Industrial Property Office

Katalin Miklo
Head of Chemistry and Agriculture Unit
Hungarian Intellectual Property Office

Thomas Xavier Duholm
Deputy Director, Policy and Legal Affairs,
Danish Patent and Trademark Office

Oliver Werner
Senior Examiner
German Patent and Trademark Office

Maria Inês Silva
Head of Patents & Utility Models Department
Portugal Institute of Industrial Property

Susanne Ås Sivborg
Director General and President
Swedish Patent and Registration Office

Who Should Attend?

Life Sciences IP Summit 2014 will provide valuable insights for: Pharma, Generic 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 and Patent Managers
- Patent Specialists/Experts

Private Practice Lawyers and Patent Attorneys specialising in:

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

Summit Day One: 13 November 2014

8:30 Registration and Coffee

8:45 **Opening Remarks from the Chair**

Penny Gilbert, Partner, Powell Gilbert

9:00 **Keynote Address: European Patent Office**

TBC, European Patent Office

10:00 Morning Refreshments

MORNING STREAMS (please choose A or B)

STREAM A: IP Portfolio Management – Partnering, Licenses & Business Development

10:30 **Commercial Overview: Identifying the Current Drivers and Trends in Deal-Making**

Moderator:

Christina Takke, Partner, Forbion Capital Partners

Pascal Touchon, Vice-President, Scientific Cooperation and Business Development, Servier

Reginald Seeto, Vice President, Head Of Partnering & Strategy, MedImmune

Debbie Allen, Vice President Business Development, arGEN-X

- What are the current drivers for pharma/biotech collaborations and what is the impact of current economic trends on future deals?
  - Statistics on recent deal activity: who's ahead of the competition in the race for deals?
  - How is the pipeline gap being filled, who is collaborating and why?
- Developing a strategy in light of decreased appetite for risk
- Reflecting on changing development time horizons and what they mean for investment in new ventures
- Analysing the impact of spreading investment risk across a larger portfolio of product candidates and wider spectrum of development phases
- The suitor still bears the risk: but do biotechs still hold the best cards?
- Choosing the right partner and deal structure
- Ensuring an equitable share of risk and reward
- Selecting the right deal structure and what might influence its success

11:30 **Successfully Implementing Open Innovation as Part of Your Innovation Strategy**

Henrik Mathiassen, Head of Patent Department, Zealand Pharma

- Advantages of Open Innovation:
  - Access to knowledge, innovation and talented individuals residing internally and externally through the development of high quality, reliable and extensive networks of strategic partners
  - Delivery of projects rapidly by combining the best internal and external expertise
  - Creation of businesses that are agile and responsive to change
  - Maximisation of return on R&D investment
- Barriers to overcome:
  - Undertaking significant cultural change: creating partnerships to access external innovation and talent whilst avoiding the 'Not Invented Here' syndrome
  - Recognizing and rewarding staff for value adding behaviours: reaching out and connecting beyond the traditional organisational boundaries
  - Aligning open innovation to the organisational strategy and put processes in place to measure the value created

12:00 **Maximising Your Patent Portfolio ROI Through Win-Win Licensing Agreements**

Emil Pot, General Counsel, Actogenix

- Establishing and developing effective licensing strategies
- Examining recent deal trends and structures: range of agreements, value splits and deal drivers
- How to identify and select licensing partners
- How to structure a win-win licensing deal: key considerations and pitfalls to avoid
- Negotiating, drafting and executing robust licensing agreements: critical terms to include
- Managing the clinical evaluation and post-deal alliance stages of the agreement
- Considering both sides of the coin: licensing to and from big pharma
- SMEs in the licensing space: who are they and what are they looking for?
- Licensing implications of the new Technology Transfer Block Exemption Regulation (TTBER)
- Dispute resolution: what happens when the licensing agreement goes wrong?

STREAM B: Biotech & Pharma Litigation

Moderator: James Marshall, Partner, Taylor Wessing

10:30 **Preliminary Injunctions: What You Need to Know to Safeguard Your Legal Rights and Protect Your Patent Portfolio**

Gavin Lawson, Senior Manager, Intellectual Property, Gilead Sciences Europe Ltd

Uli Foerstl, Partner, Olswang

- When is the right time to bring proceedings for a PI?
- The criteria applied by various national courts across Europe when granting Preliminary Injunctions:
  - Case merits
  - Degree of urgency
  - Commercial balance vs. possible PI effect
- What is the procedure for securing a PI, what are the costs of the procedure and the level of evidence needed?
- Does the court take into account the balance of convenience or commercial factors?
- What are the commercial consequences if a PI is granted but the patentee fails on the merits?
- Enforcement of PIs across Europe
- What are the remedies for PIs granted erroneously by the courts and how is the level of compensation assessed by the court?

11:30 **Practical Tips to Develop a Successful Cross Border Litigation Strategy**

Christoph de Coster, Partner, Taylor Wessing

James Marshall, Partner, Taylor Wessing

Fiona Bor, VP and Director of IP, Mylan Europe

- What are the main procedural differences between civil and common law systems?
- Assessing the advantages and disadvantages of each jurisdiction, in terms of:
  - Timing
  - Availability of preliminary/permanent injunctions
  - Remedies available
  - Defences/counterclaims that can be raised by the defendants
- Gathering evidence:
  - How to gather evidence?
  - How to use evidence gathered abroad?
  - How to protect the evidence until it reaches the court room?
- Strategic time management of the actions:
  - How to cross-fertilize proceedings?
  - Impact of decisions on the other jurisdictions

12:30 Networking Lunch

AFTERNOON STREAMS (please choose A or B)

STREAM A: Competition

1:45 **Pay for Delay and Anti-Trust Law: Protect Your Patent Portfolio from the Practical Implications of the Latest Competition Law Cases**

Laetitia Szaller, Legal Director, Emerging Markets EuAfMe and Central European Region, Zoetis

Dr. Peter Picht, Senior Research Fellow, Max-Planck-Institute for Innovation and Competition

- Applying for patents, SPCs, and divisional patents without abusing a dominant position
- Guidelines on different types of "no-challenge" clauses in settlement agreements
- Understanding the practical implications of the Lundbeck and Actavis reverse payments cases: a comparison between the EU and US approaches
- How to settle a patent dispute without infringing competition law:
  - How should patent counsel draft patent settlement agreements to comply with competition law?: content of the agreement
  - Why and when will a patent settlement agreement be deemed anti-competitive by the European Commission?
  - Do "pay for delay" settlements constitute an abuse of the dominant position of patent owners?
- How do national courts assess and enforce patent settlement agreements?
- Ensuring your IP department understands competition law interference with the patent life cycle: how to spot the red flag competition issues for patent attorneys

2:30 **Keynote Address: European Commission**

Henri Piffaut, DG Competition, European Commission

STREAM B: Unitary Patent and Unified Patent Court

1:45 **The Unified Patent Court: How to Successfully Alter Your Strategies and Prepare for the New Patent Litigation Era**

Part A: Drafting Committee of the UPC

Moderator: Speaker TBC, WIPR

Willem Hoyng, Member of the UPC Drafting Committee (Netherlands) (Partner, Hoyng Monegier)

Pierre Veron, Member of the UPC Drafting Committee (France) (Partner, Veron and Associes)

The Unified Patent Court (UPC) will soon go live. To help businesses and practitioners, we have put together a panel of experts from the Drafting and Preparatory Committees of the UPC to answer your questions about the structure of the UPC, fees and litigation costs, the role of the national courts, the procedures in the UPC, the appeals system, the possibility of pan-European injunctions, the competency and judges of the Court, the opt in and opt out option, the role of experts in the UPC, the role of the ECJ and the much debated issue of bifurcation.

Part B: Industry Perspective – Are We In or Out?

Moderator: Wouter Pors, Partner, Bird & Bird

Lise Abildgaard, Vice-President, H.Lundbeck

Francesco Macchetta, Director Intellectual Property, Bracco Group

Richard Vary, Head of Litigation, Nokia

Christoph Rehfuess, Director of Intellectual Property, MagForce AG

Having heard from the Drafting Committee on the letter of the law, industry take their turn, with an informal roundtable discussion designed to share insights on what the UPC means for them practically in their day to day roles.

3:15 Afternoon Refreshments

3:45 **Mock Trial: Obtaining a Preliminary Injunction Under the Rules of the Unified Patent Court**

Judging Panel:

Sir Robin Jacob, Hugh Laddie Professor of Intellectual Property Law, UCL (Presiding Judge)

Judge Dr. Matthias Zigann, Munich Regional Court

Judge Karin Friehe, Federal Patent Court, Munich

Judge Edger Brinkman, Court of Appeal, The Hague

Counsel:

Final counsel to be announced

With the UPC becoming an integral part of patent procurement and litigation strategy, a lot of questions arise regarding the procedures of the UPC in practice. This session will bring together three judges from different EU member states. Two leading counsel will argue a mock case, seeking a preliminary injunction in a dispute before the panel. The panel of judges will give a verdict and their reasoning will offer an insight to the UPC judge panel system.

6:00 **Chairs' Closing Remarks followed by Networking Drinks Reception**

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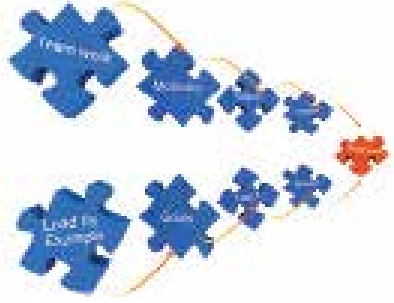
WEBCAST

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 all 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 from both streams will be available for you to view for 45 days after the conference, so you can re-watch sessions, or view any sessions you may have missed.



IN-HOUSE TRAINING

C5 is focused on providing the most relevant training experience for companies across the world. Our world class executive learning & development programmes cover the latest regulatory and finance related challenges being faced in business today.

However, we recognise that your needs may require a bespoke programme written just for you that is the best fit for your organisation.

With this in mind **C5** introduces In-house training to our portfolio of events which will allow you and your organisation to tailor your training needs.

Contact **Nathan Denham** with your training needs **N.Denham@C5-Online.com**

Summit Day Two: 14 November 2014

Closed Door Breakfast Briefing: Patent Office Roundtable (8:00 – 9:30)

Benefit from invaluable patent office insight and exceptional networking opportunities in this intimate closed-door breakfast briefing

Martin de Lange
Patent Examiner, Netherlands Patent Office

Per Foss
Director General, Norwegian Industrial Property Office

Katalin Miklo
Head of Chemistry and Agriculture Unit
Hungarian Intellectual Property Office

Thomas Xavier Duholm
Deputy Director, Policy and Legal Affairs
Danish Patent and Trademark Office

Oliver Werner
Senior Examiner
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Maria Inês Silva
Head of Patents & Utility Models Department
Portugal Institute of Industrial Property

Susanne Ås Sivborg
Director General and President
Swedish Patent and Registration Office

9:00 Registration and Coffee

MORNING STREAMS (please choose A or B)

STREAM A: Biotech & Pharma Patenting

10:00 Second and Subsequent Medical Use Patents Under the Spotlight: Assessing their Commercial Value and Overcoming Possible Challenges

Juergen Dressel, Head Global Patent Litigation Strategy, Novartis

Hugh Goodfellow, Partner, Carpmaels and Ransford LLP

- Overcoming the difficulties of getting second medical use patent claims granted:
  - Risk exposure and pitfalls to avoid
  - Drafting the claim: scope, timing and how much needs to be disclosed?
  - Considering the indications to be granted
- Analysis and implications of current case law on second medical use patents
- The national courts attitudes towards skinny labelling, carve outs and off label use: weighing the advantages and limitations of each
- Methods to prove indirect and contributory infringement and the willingness of national courts granting injunctions or other remedies
- Developing a successful enforcement strategy:
- Distinguishing between the attitude and approach of the national courts and the EPO towards the use of second medical use claims

10:45 How to Expand Your Patent Portfolio Via the Commercialisation and Patent Eligibility of Personalised Medicines and Biomarkers

Marc Markus, European Biology Patent Lead, Pfizer

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.

- Patenting various patient groups, sub-populations and dosage regimes and the standard of novelty
- To what extent do personalised medicines fit within the existing European patenting framework?
- Positioning your claim to meet the current standards of the EPO
- Is the European Patent System keeping up with the developments in the personalised medicine area?
- Infringement of Personalised Medicines claims – how to ensure effective enforcement and how to formulate your relevant litigation strategy
- What is the potential for, and issues with, the use of '-omics' technologies in personalised medicine?
- How different are the approaches of the Examining Division and the Technical Board of Appeal?

11:30 Does it Take Three to Bolar?: Understanding the Application of the Bolar Exemption Across Europe

- Recent referral of the Dusseldorf Court to the ECJ: Whether and under what conditions is the supply of patent protected substances by a 3rd party to a generic company, which intends to use the substance for obtaining a marketing authorization, covered by the Bolar exemption
- The forthcoming Bolar amendments in the UK; who will benefit from the widening of the Bolar exemption?
- Is there European harmonization or has Directive 2001/83 failed to achieve its purposes?
- How will the Bolar Exemption fit within the UPC framework and Article 27(d)?
- A detailed examination of recent national case law across the EU Member States
- An overview of the Bolar Exemption outside the European Union

STREAM B: Global Focus

10:00 Analysing the Impact of the USPTO Post-Myriad Guidance on Human Gene and Other Natural Product Developments

Jonathan Singer, Partner, Fish & Richardson

- In-depth and practical analysis of the Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance), and its impact on the future of biotech patenting:
  - What class of genes does the Guidance cover?
  - What is now patentable in light of the new guidelines?
  - How will genetic testing and diagnostic patents now be treated?
  - What is the impact on therapeutic patents based on gene technology?
  - What is the impact on patents to transgenic or transformed organisms?
- What considerations should be taken into account when drafting the patent application in light of the Guidance?
- What are the potential ramifications for European companies?

10:45 Protecting Your IP in the World's Most Lucrative Life Sciences Market: An Update on the Practical Operation of the America Invents Act and the Patent Trial & Appeal Board

Bryan Diner, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner LLP

As the practical impact of the America Invents Act (AIA) and the Patent Trial and Appeal Board (PTAB) is fully felt, it is absolutely critical that in-house counsel are entirely up to speed with the new law, in order to ensure that their patent strategies take full advantage of the new legislation and processes. This session will decipher the key provisions of the Act, with a step-by-step guide to adapting your patent strategies in response to the AIA and PTAB.

- Practical steps to ensure compliance with the strict time limits observed under the "first-to-file" system
- Challenging the validity of patents under the AIA: Inter Partes Review (IPR) and Covered Business Method Review (CBM)
- How is the Patent Trial and Appeal Board working in practice?
  - Recent statistics on the success of patent challenges
  - Interaction between parallel proceedings at the board and district courts

11:15 Protection of Biotech and Pharma Inventions in Russia

Vladimir Belkov, Patent Attorney, Baker & McKenzie – CIS, Limited

Russia is one of the rapidly growing markets for pharmaceutical and biotechnology products. This session will give an overview of the legislation effective on the territory of Russia, patent and court systems, and regulatory issues including:

- Two patent systems: Russian & Eurasian
  - Overview and comparison
  - Recommendations for choosing patent system
- Specifics of Russian legislation
  - Patent Term Extension; Bolar Exemption
- Enforcement of patent rights in Russia
  - Characteristics of court system. Practical aspects
  - Court for intellectual property rights
- Some aspects of regulation of circulation of medications in Russia
  - Biosimilars; Data exclusivity
- Comparison of Russian and European patent systems. Major differences

12:00 Networking Lunch

1:30 **In-House Roundtable: How In-House Counsel are Selecting & Evaluating their Outside Counsel, Containing Costs, and Formulating their Patenting and Litigation Strategies**

Dr. Frank Burkert, Senior Patent Counsel, **Bayer Intellectual Property GmbH**

Vanessa Currat, Director, Legal Affairs, **Debiopharm International S.A**

Frank Landolt, V.P. Intellectual Property and Legal, **Ablynx N.V.**

- What clients really want to know before engaging outside counsel
- How outside and inside counsel can interact: best practices
- Factoring how legal fees are being structured into law firm selection and evaluation
- Containing costs and managing the rising amount of litigation
- Discussion on how in-house counsel approach litigation:
  - Do they see themselves as the driver of the litigation or do they instruct external counsel and allow them to deal with it?
  - How they deal with conflicts between settling the litigation and ensuring that they do not affect the company's other goals
- What innovative measures do counsel want their external advisers to take in respect of billing and case management practices? How much progress are law firms making in this regard?

2:30 Afternoon Refreshments

AFTERNOON STREAMS (please choose A or B)

STREAM A: European Regulatory Compliance

3:00 **Ensuring Transparency in Accordance With Recent Legislative Changes and Case Law Developments**

Arturo Lucas, Senior Counsel, **Chemo Group**

- How to Ensure Transparency under the new Clinical Trial Regulation
  - Discussing the new elements introduced by the New Authorisation Procedure
- Reconciling the transparency implications of the ECJ decision in AstraZeneca v Commission (C-457/10 P) on IP procurement and enforcement procedures with existing case law and regulations
- Transparency vs. commercially confidential information
- Will the new legislation achieve EU harmonisation and avoid the problems of the 2001 Clinical Trials Directive?
- Risks to clinical trial subjects: regulatory requirements and transparency
- Best Practices for a smooth transition from the directive to the new regulation

3:40 **Data Collection & Usage: What EU Data Protection Reform Means for the Life Sciences Industries**

Paolo Balboni, Scientific Director, **EU Privacy Association**

The European Commission is currently pushing significant data protection reform, raising a variety of problems for companies in the data rich life sciences industries. What can companies expect if the draft regulation is adopted, and how can you update your data compliance practices now in anticipation of an increased compliance burden?

- Implications for research clinical trials
- How can patient information be collected, used and disclosed?
  - What constitutes consent from a data subject?
  - Scope of personal data
  - The rights of individuals to be forgotten
  - What constitutes a legitimate reason to keep data in a database?
- What are the restrictions for transferring the data outside of the EU?
- Pharmacovigilance issues: complying with Directive 2010/84/EU and Regulation 1235/2010.
- Penalties for non-compliance

4:20 **Aligning Your Regulatory and Compliance Practice with the Upcoming Changes in Clinical Data Requirements for EU Medical Devices**

Erik Vollebregt, Partner, **Axon**

The proposed Clinical Data for Medical Devices requirements will require increased effort from pharma companies where clinical data is concerned. The panel will discuss why and in what ways the EU wants manufacturers to assume responsibility for their products and medical device companies to pursue a clear understanding of the clinical framework in which they operate. This includes a thorough understanding of device performance and safety as demonstrated by objective clinical data.

- Overview of the medical device and in-vitro diagnostics legislative systems and classification rules
- The requirements for clinical investigations and the role of competent authorities and notified bodies at the development stage and for the conformity assessment
- Discussing the current regulations concentrating on the differences with the forthcoming new regulations on medical devices and in vitro diagnostics under review by the EU Parliament
  - The Commission's proposed "scrutiny procedure"
  - The restriction of "hazardous substances"
  - The re-use of single-use medical devices
- Potential challenges of the co-development of drug/medical device and drug/companion diagnostic products

STREAM B: Biotech & Pharma Patenting

3:00 **Timing Is Everything: The Main Considerations on How to Develop Successful Patent Filing Strategies for Antibodies**

Liz Cohen, Partner, **Bristows LLP**

As patent attorneys face a delicate balancing act between applying for patents too early or too late, the challenge is to determine which side of the line you are on, and how you can satisfy the requirements of inventive step and industrial applicability through complex patents where "the devil is the detail".

- At what point do you have the invention in your hands in order to obtain the patent?
  - What risks do you run if you apply for a patent too early?
- How specific does your initial application need to be?
  - Deciphering nuances of sufficiency to identify the level of disclosure required at the point of application
- How to draft your claims to meet the heightened patentability requirements of antibodies as compared to small molecules:
  - Overcoming the higher standard of proving sufficiency and inventive step
  - Establishing novelty
  - Obviousness: to what extent can a new antibody to a known antigen still be inventive?
  - Deciphering the test of industrial applicability under articles 52 and 57 of the EPC
- Monoclonal Antibody patents and SPCs: Eli Lilly v HGS (C- 493/12)
- Update on antibodies case law including Lilly v JAI and Hospira v Genetech
- Strategies on antibody patent filings and prosecution in Europe, US and Asia

3:40 **Assessing the Implications of Broad Patent Claims on Your Patenting Strategies**

Sally Curran, Senior Patent Director, RIA & Emerging Innovations Unit **AstraZeneca**

In the past decade, national patent offices and courts have changed their approach to validity of pharmaceutical patents. The criteria applied have become more stringent and the scope of the claim has been questioned on many occasions. The panel session will attempt to explain in detail how broad a pharma patent claim should be drafted and what would be the consequences if a patent is invalidated or a claim is found to be speculative.

4:20 **How to Optimise Your Patent Portfolio by Taking Advantage of the Latest Patent Expiry Strategies**

Dr Nicolas Vincent Ruiz, Intellectual Property Director, **Esteve**

With the patent cliff fast approaching, patent attorneys face the challenge of maximizing the value of their patent portfolio through the use of innovative patent expiry strategies. This session will examine the strategies that major companies are utilising in the face of patent expiries, and consider what you can and can't do to extend the value of your products. Topics to be covered include:

- Weighing the strengths and weaknesses of patent expiry strategies, including:
  - Early data mining to explore potential new indications and delivery methods
  - New formulations, uses and routes of administration
  - Stereoselectivity
  - Combinations
  - Polymorphism
  - Salts
- Paediatric use extensions and data exclusivity protection
- Injunctive relief: how early can you claim and on what grounds?
- Customs enforcement and changes to the EU Customs – do they help?
- Supplementary Protection Certificates: analysis of recent case law – addressing the ambiguities, inconsistencies, and implications

5:00 End of Summit

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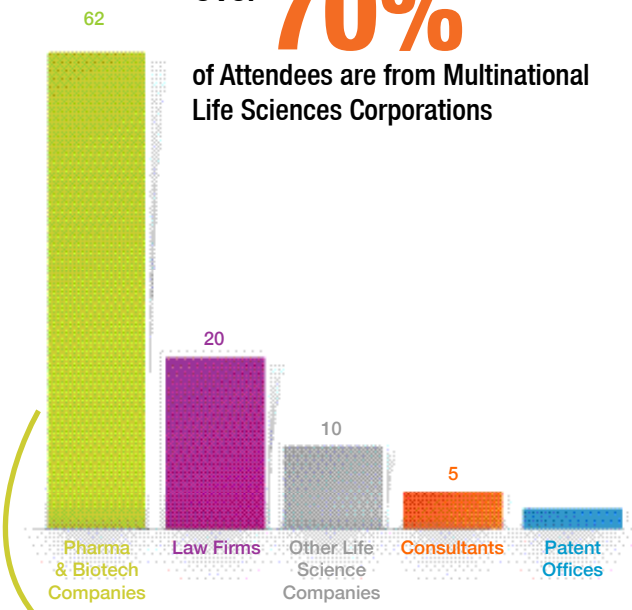

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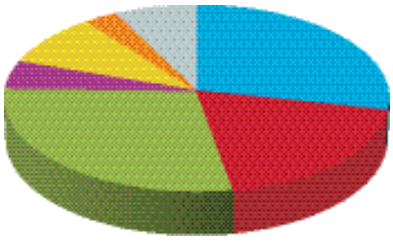

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