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Life Sciences IP Summit 2016

Best practice strategies in a post-Brexit Landscape

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- ✓ Ben Goldacre
- ✓ Brexit
- ✓ Clinical trial data
- ✓ Second medical use patents
- ✓ Patentability across jurisdictions
- ✓ Emerging Markets

Ben Goldacre

Dorian Immler
Chief Patent Counsel,
Bayer Intellectual Property GmbH

Stephen Inglis
Director
National Institute for Biological Standards & Control

Knut Mager
Head of Data Protection
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Life Sciences IP Summit 2016

C5's Life Sciences IP Summit returns for its third year offering a comprehensive programme that is bursting with variety, topical relevance and focussed discussion on the issues that really matter.

Our Summit takes place at a critical time for the industry and there is much to discuss. The UK referendum decision to leave the EU has thrown the UPC preparations into turmoil and has far reaching implications for life sciences from practical, regulatory and enforcement perspectives.

Key legislative changes around clinical trials, data privacy and trade secrets provide both increased opportunities yet simultaneously greater compliance obligations. Ongoing decisions around second medical use patents remain key to planning cross jurisdictional strategy.

Join with colleagues from across Europe to customise your learning and network in a prestigious and interactive environment.

Get up to speed with the latest legal & regulatory developments on:

- Publishing of Clinical Trial Data
- Second Medical Use Patents
- The Data Privacy Regulation
- The Trade Secrets Directive

Overcome international patentability challenges in:

- Europe
- United States
- Canada
- India
- China

Benchmark your approach to dealing with:

- Patent Protection
- Biosimilar Litigation in the US
- Patent trolls in Europe

Achieve competitive advantage in preparing for:

- Nagoya
- Unitary Patent Court
- TTIP

Understand the latest thinking on:

- Antitrust cases
- The BioPatent Directive
- The global challenges to patentees and the need for harmonization

4 specialised streams letting you set your own agenda:

Streams

1. **Patentability in a Global Context**
2. **Key Legislative Changes in Europe**
3. **Litigation and Patent Developments in the Emerging Markets**
4. **Can we Continue to Rely on the Conventional System of Patent Protection?**

Pre Conference Working Groups 19th October 2016:

WORKSHOP A | *9.00 – 12.00*

How to successfully draft antibody claims

Tom Leonard (United Kingdom)
Partner, **Kilburn & Strode**

- Effectively draft your antibody claims
  - Best practice in Europe
  - Different options for maximising scope of protection
- Antibody practice throughout the world
  - How different offices examine antibody claims
  - Srafting for protection in multiple countries
  - Case law
- FTOs for antibodies
  - Best practice freedom to operate for antibodies
  - Keyword and antibody searching
  - Common pitfalls
- Sharing recent experience
  - An opportunity to discuss individual experiences and recent developments
  - Bring a real world problem and discussion possible solutions

WORKSHOP B | *9.00 – 12.00*

Drafting claims for Algorithms

Philip Cupitt (United Kingdom)
Partner, **Finnegan**

WORKSHOP C | *14.00 – 17.00*

Focus on how the Data Privacy Regulation will impact on your business

The EU Data Protection Regulation will have a fundamental impact on the life sciences industry and all companies working within it. Our workshop will focus on all the key changes, how to prepare for them and what to expect if you don't.

- Focus on the Regulation
  - Impact on clinical trials
  - Data controllers and data processors
  - International transfers
  - of clinical data
- Health data and consent
- Medical research
- Enforcement of the Regulation
- Sanctions for non-compliance
- How to ensure you are prepared

WORKSHOP D | *14.00 – 17.00*

Prepare internally for Nagoya Protocol compliance

Philippe de Jong (Belgium)
Partner
Altius

Dominic Muyldermans (Belgium)
Senior Legal Advisor
ABS International

- General framework of the Nagoya Protocol and the EU ABS compliance legislation
- Detailed discussion of key elements
  - Genetic resources
  - PIC and MAT
  - Utilisation
  - Due diligence
- Practical guidance for the development of compliance policies
- Case studies

Join the Conversation C5_LifeSciences #C5LifeSciences Life Sciences & Healthcare Experts: Networking Group

Summit Day One
20th October 2016

8:00
Registration & Coffee

9:00
Opening Remarks from the Chair

Matthew Royle
Partner
Taylor Wessing (United Kingdom)

9:15
Early Publishing of Clinical Trial Data

Ben Goldacre (United Kingdom)

9.40
Early Publishing of Clinical Trial Data Striking the Balance between Patent Protection & the Wider Public Interest

Moderator:
Simon Bradbury
Head of Life Sciences
Appleyard Lees (United Kingdom)

Ben Goldacre (United Kingdom)

Oliver Werner
Head of SPC Working Group
German Patent and Trade mark Office (Germany)

Timo Minssen
Professor of Biotechnology Law, Jur. Dr., LL.M., M.I.C.L.
Centre for Information and Innovation Law (CIIR) (Denmark)

- Success of recent changes
- Is the industry complying in practise?
- Outcome switching
- Secondary filings
- Second Medical Use Patents
- Position of the key stakeholders
- Real consequences of publishing data earlier
- The perspective of innovators

10:40
Morning Refreshments

11:00
Second Medical Use Patents - How Much is the Patentee Now Required to Do?

Ian Hiscock
Head of IP Strategy and Policy
Novartis (United Kingdom)

Nicola Dagg
Partner
Allen & Overy (United Kingdom)

- Analysis of recent key cases
- Lyrica Appeal Decision
  - » Pricing & reimbursement
  - » Regulatory issues
  - » Stakeholder requirements
- Actavis v Lilly
  - » What are generics manufacturers *free* to do ?
  - » How much work is the patentee *required* to do?
- Approach of different jurisdictions (UK & Germany)

12:00
Is There Life (Sciences) After Brexit?

Moderator:
Bonella Ramsay
Partner
DLA Piper (United Kingdom)

Dr Peter Feldschreiber
Counsel
Four New Square (United Kingdom)

James Horgan
Assistant Managing Counsel
Merck Sharpe & Dohme (United Kingdom)

Paul Reeskamp
Partner
DLA Piper (Netherlands)

Following the surprising vote by the UK to leave the European Union, this session will look at the range of implications for the Life Sciences community:

- The practical consequences
  - » EMEA moving out of London
  - » Free flow of goods
- Extra layer of regulatory requirements in the pharma industry?
- Alignment of UK courts & other national patent courts within the EU
- Cross border injunctions
- The complications of enforcement
- Is Brexit a good thing for the UK & its relationship with SPC's?

12:45
Lunch

14:00
Europe & Plausibility - How Much Data do you Really Need to Support your Patent?

Matthew Royle
Partner
Taylor Wessing (United Kingdom)

Christoph de Costa
Partner
Taylor Wessing (Germany)

- Has plausibility been re-defined?
- What is driving the push to raise the expected standard of plausibility?
- Impact of Lyrica and other Second Medical Use Patents cases
- Priority filings as prior art?
  - » G1/15 case
  - » Impact on filing strategies
- "Poisonous priorities"
  - » Divergent interpretations of G2/98
  - » Referral to Enlarged Board of Appeal

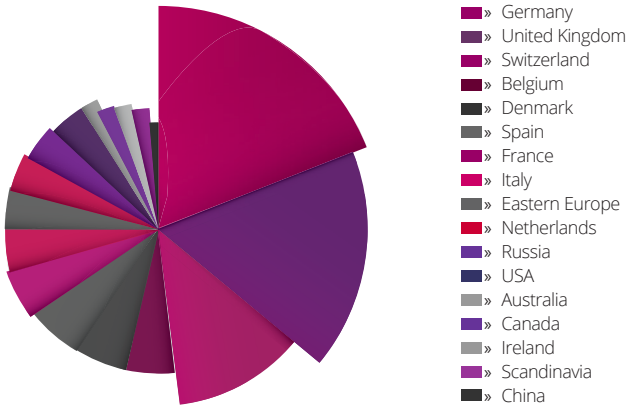
Tackling the Challenges of
Inventor Remuneration
19th October 2016 | London, UK

With the laws varying significantly across European jurisdictions and around the world, problems are arising with the increase of employees operating and collaborating across borders.

Companies are now facing divergent approaches on the substantive and procedural issues concerning inventor remuneration.

C5's conference will explore a range of topical issues and has been specifically designed to provide solutions and strategies to deal with the major challenges.

A Truly Pan-European Attendance



STREAM 1

Patentability In a Global Context: The Worrying Trend of Dis–Harmonisation

Why & how are different jurisdictions across the globe working against patentees?

15:00

Developments & Ongoing Patent Eligibility Challenges in the United States

Scott Reed
Partner
Fitzpatrick, Cella, Harper & Scinto (United States)

Ha Kung Wong
Partner
Fitzpatrick, Cella, Harper & Scinto (United States)

- Section 101 Patentability
  - » Case law update regarding the latest changes
  - » How can you prepare for patentability challenges?
  - » How might the law evolve in the future?
  - » How do the 2016 USPTO guidelines for examiners impact patentability?
- Inter Partes Reviews (IPRs)
  - » Brief Overview and Recent developments
  - » How have IPRs impacted biologics and pharmaceutical products?
  - » How can you prepare for an IPR challenge, either as a petitioner or patent owner?
  - » How do you deal with parallel US litigation?
- Post Grant Reviews
- Other unique challenges in the US system

15:45

Afternoon Refreshments

16:00

Canada: Is Case Law Moving Sideways? The Utility & the "Promise" issue

Gunars Gaikis
Partner
Smart & Biggar (Canada)

- Why is case law moving in the wrong direction?
- An increasingly higher utility requirement standard
- Analysis of key cases
  - » *Eli Lilly arbitration*
  - » *Astrazeneca v Apotex*
- Is the utility issue going to spread to other jurisdictions?

16:45

India: The Development of a More Pro-Patentee Attitude?

Hari Subramaniam
Partner
Subramaniam Partners (India)

Dorian Immler
Chief Patent Counsel,
Bayer Intellectual Property GmbH (Germany)

- Why the Indian regulatory & litigation environment was working against patentees
- Overview of the 2016 reforms
- How will the new enforcement system work?
- What impact have the new specialised courts had?
- Recent key patent case law

STREAM 2

Key 2016 Legislative changes in Europe

15:00

A long time coming - Practical Impact of the Data Privacy Regulation

Knut Mager
Head of Data Protection
Novartis (Germany)

Francesca Gaudino
Partner
Baker & McKenzie (Italy)

The European Commission has pushed for significant data protection reform. Now it is finally here, what can companies expect from the new regulation & how can you update your data compliance practices in anticipation of an increased compliance burden?

- Positive development or yet another challenge?
- Impact on the push for transparency of clinical trial data
- Repercussions for the future patentability of second medical use patents
- Cyber security threats & their increased potential for patent theft
- Transferring the data outside of the EU
- Penalties for non-compliance

15:45

Afternoon Refreshments

16:00

Will the Trade Secrets Directive Improve the Position of Patentees?

Elise Melon
Director of the Intellectual Property Policy
European Federation of Pharmaceutical Industries and Associations (Belgium)

Gabriel Cuonzo
Partner
Trevisan & Cuonzo (Italy)

- The patent strategy dilemma
- How will the legislation change the position of patentees?
- What will it add that we don't already have?
- What does it mean for biosimilars & biologics?
- Any additional enforceability rights?
- Can it be relied upon as part of a wider patent strategy?
- Sanctions for non-compliance
- The US – federal changes to Trade Secrets legislation
  - » Comparison with Europe
  - » How will this work?
  - » Size of damages

16:45

Patentability and Scope of Protection of Biotech Patents – The recent Evaluation of the Biotech Directive

Rob Aerts
Director IP
Tigenix SAU (Spain)

Jennifer Antcliffe
Senior Associate
Carpmaels & Ransford (United Kingdom)

- The issue of re-opening of the Biotech Directive: opening Pandora's Box?
- Which patentability issues were most controversial since the introduction of the Biotech Directive?
- How did patenting practice and case law develop since the introduction of the Biotech Directive?
- Analysis of the report of the European Commission Expert Group
- What are the outcomes for the key areas?
- Plant related inventions
- Patentability of human stem cells
- Scope of protection of nucleic acid inventions

17:30

Co-Chair's Closing Remarks - End of Day 1

17:45

Cocktail Reception for Delegates & Speakers

Summit Day Two
21 October 2016

8:30
Registration & Coffee

9:00
Biosimilar Litigation in the US – How to Prepare & Participate Effectively

Jonathan Singer
Partner
Fish & Richardson (United States)

Brian Coggio
Partner
Fish & Richardson (United States)

- Overview of the Biologics Price Completion & Innovation Act of 2009 ("BPCIA")
- Comparison to the Hatch-Waxman Act
- Key Definitions – "Biosimilarity"/ "Interchangeability"/"Extrapolation"
- Litigation Procedure – The First Wave
- The "Patent Dance"
- The 180-Day Notice Requirement
- Key Decisions
- Use of IPRs In Biosimilar Litigation
- Preparation for Biosimilar Filing & Litigation

10:00
The Unitary Patent and the Unified Patent Court – Brexit and Beyond

Moderator:
Gualtiero Dragotti
Partner
DLA Piper (Italy)

Sam Granata
Judge
Antwerp Court of Appeal (Belgium)

Christoph Rehfuess
Head of IP
Sotio (Germany)

Pierre Véron
Véron & Associés (Paris)
Honorary President
EPLAW (European Patent Lawyers Association) (France)
Member of the Expert Panel group of the Unified Patent Court
Member of the Drafting Committee of the Rules of Procedure

- What will be the impact of Brexit on the UPC?
- How are clients and advisors approaching the revised landscape?
- Analysis of some significant outstanding uncertainties before commencement
  - » Bolar Exemption
  - » SPC's
  - » Co-invention issues
- What kind of strategies have companies finally chosen to adopt?
- What are the next steps after choosing your initial patent strategy?
- How to prepare for litigation under the UPC
- The challenges of litigating in an untried system

11:00
Coffee Break

STREAM 3
Litigation & Patent Process Amendments in the Emerging Markets

11:30
Pharmaceutical Patents in China

Oliver Lutze
Partner
Spruson & Ferguson (China)

- Remuneration for Service inventions from local R&D centres
- Patents as support for a High & New Technology Enterprise Status
- Status of previously experienced issues in prosecution
- Patent Defence in invalidation proceedings
- Patent litigation strategies in a different environment
- New IP Courts

12:10
A Review of the Current and Changing Practises in Japan

Toshio Nakamura
Partner
Sakamoto & Partners (Japan)

- Development of "Patent Term Extension (PTE)" in Japan
  - » Review of the Japan Supreme Court judgment on **JPO vs Genentech**
  - » Recent confused decision on infringement based on PTE
- Current trend of "Doctrine of Equivalent" in Japan
  - » Review of the Grand Panel of the IP High Court on **DKSH Japan et al vs Chugai Pharmaceutical** concerning Vitamin D preparation method
- Outline of "Pharmaceutical Regulation" including "Drug Pricing System" in Japan

STREAM 4
Can we Continue to Rely on the Conventional System of Patent Protection?
What are the ongoing challenges we face & how can we surmount them?

11:30
Why We Need Global Harmonization of Patentability and Enforcement Standards

Juergen Dressel
Head of Global Patent Litigation Strategy
Novartis (Switzerland)

Elisabeth Greiner
Partner
df-mp (Germany)

- Why do we need global harmonization?
  - » Legal and business certainty
  - » Investment incentive for pharmaceutical innovation
- Why don't we have it?
  - » Anti-patent trends in many countries (e.g. patent eligibility in the US after Mayo/Myriad/Alice cases)
  - » Added matter at the EPO
  - » High revocation rates (Germany)
  - » Utility/sound prediction/false promise (Canada)
  - » Prohibition of supporting data post filing for inventive step
- Conflicting patentability criteria in different jurisdictions is putting patent applicants into Catch 22-situations
- Can we preserve the incentive for innovation by evolving the IP system of today from exclusion to inclusion?

STREAM 3 Continued...

12:45

Networking Lunch

14:00

Brazil – Where Are We Now?

Rana Gosain
Senior Partner
Daniel Advogados (Brazil)

- What are the existing challenges being faced by Brazil ?
- Doing business in Brazil-excessive bureaucracy, infrastructure –logistics after hosting two major events.
- The role of ANVISA
  - » Recent developments in the BPTO
  - » Examination Guidelines
- Is there an adequate legal framework to enforce IP Rights?
  - » Structure of Courts
- Specialised Courts
  - » What other forms of relief can be obtained for patent infringement?
  - » How is the IP environment?

14:45

Is the Life Sciences Industry taking the Nagoya Protocol seriously?

Philippe de Jong
Partner
Altius (Belgium)

***David Rosenberg**
VP IP Policy
GlaxoSmithKline (United Kingdom)

Stephen Inglis
Director
National Institute for Biological Standards & Control
(United Kingdom)

- Extent of preparations for Nagoya
- Expectations of the authorities
- Official guidance
  - » Reason for the delay
  - » Guidance sufficient?
- Key areas
- Sanctions for non-compliance
- How to prepare & establish internal processes

***To be confirmed**

STREAM 4 Continued...

12:10

Are Ambitious Patent Protection Strategies in Danger of Becoming Antitrust Problems?

John Schmidt
Partner
Shepherd and Wedderburn (United Kingdom)

- How to stay on the right side of the Competition authorities
- Consideration of recent cases
- *Fujifilm Kyowa Biologics v AbbVie Biotechnology*
  - » Divisional filing practise
  - » Analysis of the arguments
  - » When is declaratory relief appropriate?

12:45

Networking Lunch

14:00

New Challenges on the Horizon - Are the Patent Trolls Coming to Europe?

Gavin Lawson
Senior Counsel
Gilead (United Kingdom)

Louise Jonshammar
Attorney at Law
IAM Law (United Kingdom)

Benjamin May
Partner
Aramis (United Kingdom)

- Patent trolling as a new business strategy
- How worried should Europe be about US style troll threats?
- What lessons can Europe learn from the US?
- Could the new UPC framework clear the way for patent trolls increase activity in Europe?
- Can you "troll proof" your business?

15:30

Afternoon Coffee Break

15:40

What does TTIP hold for the Life Sciences community?

Doris Schernhammer
Senior Manager for Corporate Affairs
Eli Lilly (Belgium)

- What do we need to be aware of?
- What will be the impact on European healthcare provision
- Consequences for pharma & biotech companies
- IP Rights under TTIP
  - » Will court proceedings disappear?
  - » The impact on litigation strategies

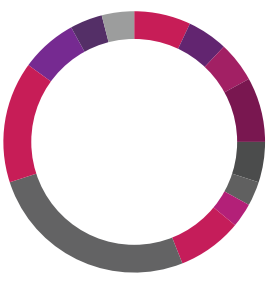
16.20

Closing Comments from the Chair

16.25

End of Summit

Titles in attendance



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