



Business Information
In A Global Context

Register before 18 April and SAVE £300

C5's 13th International Forum on

Pharma Patent Extensions

Capitalise on the Latest Patent Extension and Protection Strategies.
Build your Patent Portfolio to Maximise your Capital Investment.

25th & 26th June 2014 | Kingsway Hall Hotel
London, United Kingdom



Meet Industry Leaders from:

H. Lundbeck A/S (Denmark)
Novartis Pharma AG (Switzerland)
Abylrx N.V. (Belgium)
Eli Lilly (UK)
Bayer (Germany)
Merck Sharp & Dohme (UK)

Gain Direct Insights from Regulatory Experts:

European Commission
German Patent and Trademark Office
(Germany)
Unified Patent Court (Sweden)
European Patent Office (Netherlands)
Intellectual Property Office (UK)

Portfolio Sponsor:

TaylorWessing

Executive Sponsors:

ALLEN & OVERY

SNA Subramaniam
& Associates
Attorneys-at-Law • Patent and Trademark Agents

Unparalleled industry expert speaker faculty, comprising key regulators and leading practitioners, sharing optimal strategies to maximise your patent portfolio, including:

- **The radical SPC decisions** in Georgetown University, Actavis and Eli Lilly
- **Capitalise on second medical use patents** by implementing proven strategies and utilising tactical enforcement and remedial methods
- **Fundamental update on the imminent Unitary Patent and Unified Patent Court** and how to adapt your business strategies effectively
- **The 'Right' to Priority** case law developments and their implications for patents
- **Expand your patent portfolio** by taking advantage of the latest patent expiry strategies
- **A cross jurisdiction analysis of the Bolar exemption** and how to operate the recent developments advantageously
- **Essential insight into personalised medicines** and the consequences of recent case law
- **Recent developments in US patent reform** and impact on global patent management strategies
- **Hear key insights into biosimilars** and the opportunities to obtain market and commercial opportunities

Up to
13.5 CPD

Plus add further practical value to your experience when you attend the:

Early Riser Workshop on:

How to Improve your Patent Portfolio with the Latest Successful Patent Filing Strategies

Held on 26th June 2014, this workshop will equip you with key strategic tools and practical insights to utilise at the filing stage to ensure maximum opportunity to expand your patent portfolio.

To register call +44 (0) 20 7878 6888 or register online at www.C5-Online.com/PPE

C5's 13th International Forum on Pharma Patent Extensions

Strategies to maximise patent extensions are at an acute stage with recent landmark cases and procedural developments. It is imperative to understand the impact on the industry and how your organisation should adapt its policies to properly capitalise your opportunities.

The landscape of the patent portfolio is constantly shifting with important rulings on SPC's in Georgetown, Actavis and Eli Lilly, the forthcoming amendments to the UK Patent Act, in line with the Bolar exemption, the imminent launch of the Unitary Patent and legislative developments in India.

C5's International Forum on Pharma Patent Extensions will analyse and expose how case law developments and legislative changes will impact the patent strategy of pharma innovators, pharma originators and generic manufacturers. Maintaining and expanding your organisation's patent portfolio is imperative to capitalising on your return on investment. It is thus essential that you understand the optimal strategies to utilise in order to maximise profits and keep abreast with the ever changing intellectual property landscape.

Bringing you an outstanding speaker faculty with leading in-house counsel from the world's largest pharma companies and their expert advisors, this event will provide you with an essential update on the constantly evolving case law and important legislative amendments and their implications on your organisation's patent strategies.

Leading experts will share proven tactics to optimise your patent portfolio at the filing and expiry stage and provide clarity on the complex regulatory and procedural requirements.

You will also hear from key regulators including, the European Commission, Unified Patent Court, European Patent Office and the Intellectual Property Office as they deliver an insightful outlook on Pharma Patents and the multifaceted environment.

Plus add further practical value to your experience when you attend the:

Early Riser Workshop on How to Improve Your Patent Portfolio with the Latest Successful Patent Filing Strategies on 26th June 2014. Presented by Stephen Smith, you will learn:

- How and where to file your applications
- Essential timing considerations
- Successful drafting techniques and common pitfalls
- How to assess and minimise your risks
- Practical and tactical points for successful filing

Participants will receive a comprehensive set of valuable materials prepared by the speakers specifically for this event. These are materials that you will be able to use again and again.

Reserve your place today by calling **+44 (0) 20 7878 6888**, faxing your registration form to **+44 (0) 20 878 6885**, sending an email to **registrations@C5-Online.com** or registering at **www.C5-Online.com/PPE**

WHO SHOULD ATTEND?

C5's 13th International Forum on Pharma Patent Extensions 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

PORTFOLIO SPONSOR:

TaylorWessing

Taylor Wessing 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.

EXECUTIVE SPONSOR:

ALLEN & OVERY

Allen & Overy is one of the largest international legal practices with approximately 5,000 staff and some 512 partners worldwide. Since opening our first office in London in 1930, we have grown into a global organisation with 43 offices in 30 countries across Europe, Asia Pacific, the US, South America and the Middle East.

GLOBAL SPONSORSHIP OPPORTUNITIES

C5 works closely with sponsors to create the perfect business development solution catered exclusively to the needs of any practice group, business line or corporation. With over 500 conferences held in Europe, Russia and the CIS, China, India, the US and Canada, **C5**, **ACI** and **CI** provide a diverse portfolio of first-class events tailored to the senior level executive.

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:



PHARMANEWS.EU

8.15 **Registration and Coffee**

9.00 **Opening Remarks from the Chair**

Simon Cohen
Partner
Taylor Wessing (UK)

9.10 **How the Latest Landmark SPC Decisions Will Impact Your Patents Life Cycle**

Martijn de Lange
Patent Examiner Chemistry
Dutch Patent Office (Netherlands)

Stephen Ingham
Assistant General Patent Counsel
Eli Lilly & Company Limited (UK)

Dr. Oliver Werner
Senior Examiner
German Patent and Trademark Office (Germany)

Dr Lawrence Cullen
Deputy Director
Intellectual Property Office (UK)

On the 12th December the CJEU delivered three important rulings on SPC's. The rulings follow the outcome of the CJEU's important Medeva decision of 2011. However, only Georgetown and Actavis can be thought to clarify matters. Whilst Georgetown provides considerable relief to SPC owners on the issue of the number of SPCs potentially permissible per patent, the third, Eli Lilly, sends an important issue – the degree to which a patent must identify a product in order for it to be capable of SPC protection – back to the national courts, where different interpretations now seem inevitable. A number of other questions remain unanswered which is further intensified following the CJEU ruling in GSK Biologicals and the AG's Opinion in Bayer CropScience. This session analyses the important decisions, addresses the ambiguities and considers what the future might hold for SPC's after these decisions

- A crucial analysis of the recent decisions and the implications:
 - Georgetown University
 - Actavis v Sanofi
 - Eli Lilly v HGS
 - GSK Biologicals
 - Bayer CropScience (AG Opinion)
 - Merck Canada Inc v Accord Healthcare Limited
- The ongoing saga: at the time of printing further referrals have been made to the CJEU on SPC-related matters including the "Forsgren" (case C-631/13) and *Actavis Group* (Case C-577/13). Hear a crucial update about how the issues will unravel and apply to your organisation, and the need for reform of the EU SPC Regulation
- How you can maximise on potential opportunities to obtain more than one SPC per patent
- Understand how the UPC may provide clarity on matters and how it is likely to evolve

10.30 **Networking Break**

11.00 **A Critical Time for the Bolar Exemption – How, When and Where Does it Apply?**

Christoph de Coster
Partner
Taylor Wessing (Germany)

Nigel Stoate
Partner
Taylor Wessing (UK)

Lindsey Kent
European Patent Counsel, European Patent Operations
Eli Lilly & Company Limited (UK)

The Bolar Exemption is being scrutinised in a number of European countries. Will this bring harmonisation and certainty?

- An in-depth analysis of the implementation of the Bolar provision in Germany, Poland, UK and France
- Scope of the Bolar provision and its consequences for originators and generic companies
- The recent referral to the CJEU regarding "third party supply"
 - A review of the referral by the Dusseldorf Court of Appeal
 - Poland's Supreme Court decision in the Polpharma case
 - Consequences and practical considerations for Continental Europe
- The forthcoming amendment to the UK Patent Act
 - The relationship with the experimental use exemption and gaps
 - What and who benefits from the widening of the exemption?
 - A look at the practical implications for your organisation
- What is the impact of Article 27(d) of the UPC agreement?

12.00 **Understand the Value of Second Medical Use Patents: An Analysis of Strategies and Enforcement**

James Horgan
Assistant Managing Counsel,
Merck Sharp & Dohme (UK)

Laetitia Benard
Partner
Allen & Overy (France)

- Second medical use patent claims:
 - Claim drafting and its effect
 - Timing and how much needs to be disclosed?
- Issues raised in the market – advantages, disadvantages and limitations of the following:
 - Skinny labelling
 - Carve-outs
 - Off-label use
- Enforcement and Remedies – vital insights to ensure you make the right decision:
 - Proving infringement – can it be done?
 - Contributory infringement – a look at the cross jurisdictional approach
 - Obtaining an injunction and other remedies
 - Overcoming the critical challenges faced by the enforcement of second medical use patents
- An overview of the national courts attitude towards the use of second medical use claims

13.15 **Networking Lunch**

14.30 **The 'Right' To Priority – Pitfalls Vs. Benefits**

Andrew Waugh QC
3 New Square (UK)

Dr Liesbet Paemen
Partner, European Patent Attorney,
De Clerq & Partners (Belgium)
European Patent Office Speaker

- An acute examination of the current issues:
- The title problem – the *Edwards v Cook* Issue
- Cutting back in prosecution and the intermediate generalisation problem – *Hospira v Novartis*
- Poisonous Priority – the *Samsung* and *Nespresso* cases
- Partial Priority in the EPO – conflicting cases ripe for a references to the Enlarged Board – T 1127/00, T 1443/05, T 1877/08, and T 476/09 on the one hand and T 665/00 and T 1222/11 on the other?
- Do the benefits still outweigh the risks?

15.45 **Networking Break**16.00 **Patently Dangerous: Strategic Patent Use and Competition Law Enforcement**

Paul Fehlner
Global Head, Pharma IP
Novartis Pharma AG (Switzerland)

Dr. Bertold Bar-Bouyssièr
Partner
DLA Piper UK LLP (Belgium)

The application process to the settlement of patent disputes in competition law and policy affects all stages of the patent lifecycle. This session provides guidance on how to avoid running foul of competition law.

- Non abusive conduct in patent and SPC application procedures
- Where can you safely refuse a licence?
- Anti-trust limits to infringement proceedings
- How to settle patent disputes safely
- Does strategic patent use equal abuse?

17.00 **A Crucial Update on Patent Term Adjustments and Extensions in the United States**

Scott K. Reed
Partner
Fitzpatrick, Cella, Harper & Scinto (US)

- Patent Term Adjustment (PTA) under 35 U.S.C. §154 and 37 C.F.R. §1.701 et seq. for delays at the patent office
 - General Overview
 - America Invents Act (“AIA”) – changes to PTA time periods for PCT applications
 - Recent cases
 - *Novartis v. Lee and Exelixis v. Lee*, United States Court of Appeal for the Federal Circuit, January 2014
- Patent Term Extension (PTE) under 35 U.S.C. §156 and 37 C.F.R. §1.710 et seq. for patent covering approved drug products
 - General Overview
 - Relevant Cases
 - *Ortho-McNeil v. Lupin* – Federal Circuit May 2010
 - *PhotoCure v. Kappos* – Federal Circuit June 2010
 - USPTO, November 2013, “reverse-PhotoCure” case
- The PTO’s reasoning appears to directly challenge the Federal Circuit’s holding in *PhotoCure*, but the applicant did not request rehearing of the decision within the required two-month time period, so there will apparently be no Federal Circuit appeal. This decision leaves the law unclear

17.45 **Chair’s Closing Remarks and Conference Adjourns**7.30 **Registration and Coffee**8.00 **How to Improve Your Patent Portfolio with the Latest Successful Patent Filing Strategies**

Stephen Smith
Partner
Potter Clarkson (UK)

Dr. Morten Rosted
European Patent Attorney & CDPA
Senior Director, Global Patents, H.
Lundbeck A/S (Denmark)

Don't miss this engaging, interactive practical session. The leading industry expert will lead you through the key points and practicalities.

Your will learn about:

- Patent Co-operation Treaty v the First Priority Application
- At what point should you file your patent and what are the associated risks?
- Successful drafting techniques and common pitfalls to avoid at the application stage
- A closer look at the disclosure regimes
- Practical and tactical points considered for successful filing
- Risk management- how to assess and minimise your risk

10.00 **Workshop Ends with Networking Break****MAIN CONFERENCE DAY TWO****26TH JUNE 2014**10.15 **Opening remarks from the Chair**10.30 **The Final Countdown – The Unitary Patent and Unified Patent Court (UPC): Ensuring You are Ready**

Alexander Ramsay
Vice Chairman of the UPC Preparatory Committee
(Sweden) (Deputy Director, Ministry of Justice)

Bernie McDonald
Patent Counsel
Gill Jennings & Every LLP (UK)

Lise Abildgaard Ryberg
VP, Corporate Patents & Trademarks
H. Lundbeck A/S (Denmark)

Pierre Veron
Member of the UPC Drafting Committee (France)
(Partner, Veron & Associates)

- Practical steps in formulating procedures and policy to prepare for the UPC and the Unitary Patent
- Understand what the transitional provisions mean for your European patents
 - how to opt out and how to withdraw an opt out:
 - The effect of opting out – litigating in the UPC versus the National Courts – *advantages and disadvantages explored*
- The effect of opt out on SPCs?
- Understanding the potential risks of a single EU-wide action
- Jurisdictional issues raised by transitional period and opt out
- The practical effect of incomplete ratification of the UPC

- A Pan-European view of the UPC delivered by cross jurisdiction experts
- Which substantive patent laws apply to European Patents which have opted-out?
- An update on the pending action by Spain for the annulment of the Unitary Patent Regulation

11.30 **Networking Break**

11.45 **Expanding Your Patent Profile for Personalised Medicines**

Dr. Wolfgang Bublak Patentanwalt
European Patent Attorney
Bardehle Pagenberg Partnerschaft mbB (Germany)

Steven Davis
Partner
McCarter & English, LLP (US)

Personalised medicines are at the forefront of the debate with landmark cases shaping the intellectual landscape into patentable personalised medicines. Hear an essential insight into the authorities and consequential affects on your organisation as well as strategies to maximise your patent portfolio.

- A review of the leading US case *Prometheus v Mayo*, and its implications
- An analysis of the *Duke University and Cognosci* case:
 - The '601 patent assigned to Duke University and Cognosci for methods of diagnosing cancer
 - Is a diagnostic patentable?
 - An in-depth analysis of the decision and implications
 - Can it be entered into the orange book?
 - Will the personalised medicine to a diagnostic protect your organisation once the core patent expires?
 - What the decision means going forward
- Top tips to create an effective patenting strategy
- How would personalised medicine patent claims be infringed from an enforcement and litigation perspective?
- What are the exposures and risks?

12.45 **How the Latest Developments in India are Affecting the Pharma Patent Landscape**

Hari Subramaniam
Partner
Subramaniam & Associates (India)

- An important analysis of the Indian Patents (Amendment) Rules 2014 published on the 28th of February 2014
 - An overview of the amendments
 - The implications for your company going forward
 - The practical and procedural requirements
- An essential update on India's complex compulsory licensing system
 - A review of the requests for change
 - The implications of the Nexavar compulsory licence
 - An update on the outstanding applications including the Bristol-Myers Squibb drug
 - The commercial realities of patent grants, enforcement and licenses in India - what's really going on?

13.30 **Networking Lunch**

14.45 **Assessing the Market Opportunities and Commercial Practicalities of Biosimilars for Pharma Companies**

Frank Landolt
V.P. Intellectual Property and Legal
Ablynx N.V. (Belgium)

Maarten Meulenbelt
Partner
Sidley Austin LLP (Belgium)

- Top tips biosimilars should invoke in order to obtain approval of their products
- The issues raised by expanding the indications of a biosimilar
- Strategies being employed to limit biosimilar competition
- An update on the biosimilar cases and legal developments
- To what extent do biosimilars fall within the Bolar exemption and which jurisdictions are most advantageous in this regard?
- Regulatory considerations when bring a biosimilar to market
- The practical differences between biosimilars and 'bio-betters'

15.45 **Capitalise on the Latest Patent Expiry Tactics**

Genevieve Michaux
Counsel
Hunton & Williams (Belgium)

Dr. Alexander Nowak
Assistant Chief Patent Counsel
Head of IP Operations Pharma Monheim
Bayer Intellectual Property GmbH (Germany)

Curtail the effects of the patent cliff by ensuring you capitalise on the most effective patent expiry strategies. This session will provide an insight into the key strategies your organisation should employ.

- Patent portfolio expiry strategies and strength of protection:
 - Second generation patents:
 - Salts
 - Polymorphs
 - Dosage regimens
 - Formulations
 - New indications
- Paediatric use extensions and data exclusivity protection
- How applicable is SPC protection to second generation patents?
- Keeping an on eye on generic entry and marketing authorisations
- How early can preliminary injunctive relief be obtained and on what grounds?
- Customs enforcement and changes to the EU customs regime – do they help?

17.00 **Chair's Closing Remarks and End of Conference**

Connect with us!



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 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 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.

Pharma Patent Extensions

Business Information
In A Global Context

25th & 26th June 2014 | Kingsway Hall Hotel | London, United Kingdom

Priority Service Code

508L14.S

5 EASY WAYS TO REGISTER

WEBSITE: www.C5-Online.com/PPEREGISTRATIONS & ENQUIRIES
+44 20 7878 6888EMAIL: registrations@C5-Online.com

FAX: +44 20 7878 6885

PLEASE RETURN TO
C5, Customer Service
11th Floor, The Tower Building, 11 York Road
London, UK SE1 7NX

FEE PER DELEGATE	Register & Pay by 18 April, 2014	Register & Pay before 23 May, 2014	Register & Pay after 23 May, 2014
<input type="checkbox"/> ELITEPASS* : Conference plus early riser workshop	£1995	£2145	£2295
<input type="checkbox"/> Conference Only	£1495	£1645	£1795
<input type="checkbox"/> Webcast	£545	£545	£745

PLEASE ADD VAT TO ALL ORDERS

TEAM DISCOUNTS: Booking 2 or more delegates? Call +44 (0) 20 7878 6888 for details.

**ELITEPASS is recommended for maximum learning and networking value.*

DELEGATE DETAILS

NAME _____ POSITION _____

APPROVING MANAGER _____ POSITION _____

ORGANISATION _____

ADDRESS _____

CITY _____

POSTCODE _____ COUNTRY _____

PHONE _____ FAX _____

EMAIL _____

TYPE OF BUSINESS _____

FOR MULTIPLE DELEGATE BOOKINGS PLEASE COPY THIS FORM

PAYMENT DETAILS

Event Code: 508L14-LON

BY CREDIT CARD

Please charge my AMEX VISA MasterCard Discover Card

NUMBER _____ EXP. DATE _____

CARDHOLDER _____

BY CHEQUE

I have enclosed a cheque for £ _____ made payable to C5

BY BANK TRANSFER

C5 Communications Limited

Account Name: C5 Communications Limited

Bank Name: HSBC BANK Plc

Bank Address: 31 Chequer Street, St Albans Herts AL1 3YN, UK

Bank Branch: St Albans Branch

BIC (Bank Identifier Code): MIDLGB22

GBP Account (VAT num: 913 0992 30)

IBAN: GB41 MID L 4040 0182 1816 22

Sort Code: 40-40-01

If you wish to pay in Euro€ or USD\$ please contact Customer Service

ADMINISTRATIVE DETAILS

Date: 25 & 26 June 2014

Time: 8.00 – 17.45

Venue: Kingsway Hall Hotel

Address: 66 Great Queen Street, Covent Garden, London, WC2B 5BX, UK

Telephone: +44 (0) 20 7309 0909

An allocation of bedrooms is being held for delegates at a negotiated rate until 25 April 2014. To book your accommodation please call Venue Search on tel: +44 (0) 20 8541 5656 or e-mail beds@venuesearch.co.uk. Please note, lower rates may be available when booking via the internet or direct with the hotel, but different cancellation policies will apply.

DOCUMENTATION IS PROVIDED BY WEBLINK

The documentation provided at the event will be available on weblink only. If you are not able to attend, you can purchase an electronic copy of the presentations provided to delegates on the day of the event. Please send us this completed booking form together with payment of £350 per copy requested. For further information please call +44 (0) 207 878 6888 or email enquiries@C5-Online.com.

CONTINUING EDUCATION

11.5 hours (conference only) plus 2 hours per workshop towards Continuing Professional Developments hours (Solicitors Regulation Authority). Please contact C5 for further information on claiming your CPD points.

PAYMENT POLICY

Payment is due in full upon your registration. Full payment must be received prior to the event otherwise entry will be denied. All discounts will be applied to the Main Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organisation.

TERMS AND CONDITIONS

You must notify us by email at least 48 hours in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorisation. If you are unable to find a substitute, please notify C5 in writing no later than 10 days prior to the conference date and a credit voucher will be issued to you for the full amount paid, redeemable against any other C5 conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. C5 reserves the right to cancel any conference for any reason and will not be responsible for airfare, hotel or any other costs incurred by attendees. No liability is assumed by C5 for changes in programme date, content, speakers or venue.

INCORRECT MAILING INFORMATION

If you receive a duplicate mailing of this brochure or would like us to change any of your details, please email data@C5-Online.com or fax the label on this brochure to +44 (0) 20 7878 6887. To view our privacy policy go to www.C5-Online.com/privacy_policy_statement.