



Business Information
In A Global Context

C5's 7th Forum on

Pharma & Biotech Patent Litigation

*Preparing for the Unitary Patent Package and enforcing patent rights
in Europe and emerging markets to maximise investments*

19th – 20th March 2015 | Hotel Okura, Amsterdam, Netherlands

Up to
23.0 CPD

**Roundtable on Preliminary injunctions featuring
leading European IP judges!**

Marie Courboulay
Vice President, 3rd Chambre – Intellectual Property
Paris Court of Appeal, France

Samuel Granata
Judge, Commercial Court of Antwerp, Belgium

Rian Kalden
Senior Judge, Court of Appeal The Hague, Netherlands

**Featuring leading life sciences companies
such as:**

Keygene

Ranbaxy

Lundbeck

TEVA

Novartis

**Plan and benchmark your patent enforcement & litigation strategies in-situ and in view of the
Unified Patent Court. Topics include:**

- ★ Countdown to the Unitary Patent Package: Strategic Considerations Leading Pharmaceutical and Biotech Companies are Adopting
- ★ New Frontiers for Patentable Subject Matters: Stem Cells, Gene Sequences, Plant Varieties. What this Mean for Your Patenting Strategy
- ★ How to Obtain Supplementary Protection Certificates in Light of the Latest Case Law Developments in Europe
- ★ Obtaining Preliminary Injunctions when Enforcing a Second Medical Use Claim: Where Do We Stand?
- ★ Cross-Border Litigation Strategies: Planning, Managing and Reacting to Patent Enforcement Proceedings in Concurrent Jurisdictions

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Pharmaceutical & Biotech patent litigation is evolving at a rapid pace across Europe. As a result of countless modifications and further developments to the Unitary Patent Court, and following Spain's challenge to the validity of the entire unitary system, European patent attorneys and litigators must know what they can expect from the Courts in 2015 in order to effectively plan their litigation strategies.

Case law developments on the patentability of new subject matters, ferocious pan-European proceedings on Supplementary Protection Certificates' scope and duration, the R&D on biosimilars and personalised medicine and legislative modifications to the Bolar exception have all led to uncertainty in the Life Sciences industry.

It is therefore imperative that the European life sciences community gather to address the critical issues affecting the industry as a whole, in order to understand what can be achieved, plan strategies for the future and ultimately foster a smooth pharmaceutical patent enforcement system.

A MUST-ATTEND EVENT FOR:

Pharma, Biotech and Chemical Companies:

- General Counsel
- Director of Legal Affairs
- VP / SVP Patents
- Director / Head of IP
- Director / Head of Patents
- Patent counsel/attorney/manager
- In-house counsel
- Head of R&D

Private Practice Lawyers and Patent Attorneys specialising in:

- Life Sciences industry/practise
- Intellectual Property
- IP Litigation



Pre-Conference Workshop Wednesday 18th March 2015

2 pm – 5 pm

How to Draft Solid Pharmaceutical Patent Applications and Minimising the Time of Prosecution Before the EPO

Formal and substantial requirements for pharmaceutical & biotech patents are constantly evolving, and will change further in 2015 due to the implementation of the dual system 'unitary v. European' patent. Patentable subject matters are getting stricter, priority claims are getting broader and the basis to challenge the validity of the patent are getting larger.

How does this fast-paced mutative scenario affect the organization's patent strategy? Which considerations must be taken into account and how do rules on priority, claims drafting, disclosure and description differ in different jurisdictions and affect the stability of the organization's patent portfolio?

This intensive workshop will provide you with a legal and technical roadmap of do's & don'ts in patent drafting techniques aimed at avoiding to the largest extent possible the pitfalls during patent prosecution delay or limit the grant of solid patents in your favour.

Day 1 | Thursday, 19th March 2015

8:30 Registration and Welcome Coffee

9:00 Opening Remarks from the Chair

Paul Inman, Partner, **Wragge Lawrence Graham & Co LLP** (United Kingdom)

9:15 Countdown to the Unitary Patent Package: Strategic Considerations Leading Pharmaceutical and Biotech Companies are Adopting

Juergen Dressel, Head Global Litigation Strategy, **Novartis** (Switzerland)

Ricardo Dijkstra, Partner, **Vondst Advocaten** (Netherlands)

- The UPP ongoing saga: latest developments on the Unitary Patent Package ratification and implementation
 - How will Spain's challenges affect the solidity of the system?
- Opt-in v. opt-out: evaluating pros & cons and key considerations when devising your patenting strategy
 - How best to protect in countries that are non-Members of the UP
 - Tax implications for Swiss companies
- Casting light on key opt-in budget implications and the Unitary Patent maintenance fees
- How Supplementary Protection Certificates on Unitary Patents will be granted?
- How will second medical use claims have to be filed?
Swiss claims v. EPC2000 claims drafting

10:30 KEYNOTE ADDRESS: The UPC Preparatory Committee Explains the UPC Rules of Procedure

Alexander Ramsey, Vice Chairman, **UPC Preparatory Committee** (Sweden) *

11:00 Coffee Break

11:30 Towards the Unified Patent Court: What You Need to Know to Usefully Enforce Your Patent Rights

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

- How pharmaceutical patent litigation in Europe will look after the UPC's implementation
- Will the EPO opposition procedure be less favoured, with central revocation before the UPC being available at any time?
- How to represent clients before the UPC
- Which kind of damages can be sought before the UPC?
- Will decisions have a UK or continental style approach?
- How will appeals be reviewed? Judicial or merit review?

12:45 Networking Lunch

14:00 JUDGES ROUNDTABLE: On Which Grounds Can a Preliminary Injunction Be Granted?

Marie Courboulay, Vice President 3rd Chambre – Intellectual Property, **Paris Court of Appeal** (France)

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

Rian Kalden, Senior Judge, **Court of Appeal The Hague** (Netherlands)

- To what extent are Courts willing to consider the strength of the patent/validity of the case when deciding on granting an ex parte PI?
- What types of evidence can tip the balance of a PI petition in one direction or another?
- What weight do judges give to foreign court proceedings and decisions?
- How do Counsel impress and how do they disappoint?
- What affects the timing of a decision?
- Would the judicial approach and considerations differ when the Court considers a PI on a biosimilar as opposed to the 'normal' generic copy of the patented drug?

15:15 Coffee Break

15:30 Cross-Border Litigation Strategies: Planning, Managing and Reacting to Patent Enforcement Proceedings in Concurrent Jurisdictions

Galit Gonen, Vice President & General Counsel Europe, **TEVA Pharmaceuticals** (United Kingdom)

Sheldon Hamilton, Partner, **Smart & Biggar** (Canada)

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

- Strategic planning for multijurisdictional proceedings – claimant's perspective: which cross-border issues should you consider first?
- Being prepared and strategically responding to a multiple jurisdiction patent enforcement case: the defendant's perspective
- Key considerations to factor in when initiating concurrent enforcement actions, starting with the choice of the Forum
- Collecting documents and other evidence and being prepared to respond, taking into account different discovery obligations in US, Canada, UK, Germany
- How to evaluate how the proceedings and its outcome in one jurisdiction will affect the parallel proceedings in another jurisdiction
- Best practices in planning, managing and limiting litigation costs: managing, coordinating and aligning external counsel

16:30 **Understanding the Scope of the Bolar Exemption and How It Will Sit with the Unitary Patent**

Paul Inman, Partner, **Wragge Lawrence Graham & Co LLP** (United Kingdom)

- What has changed to the UK Patents Act after October 1st, 2014?
- How to coordinate the UK new rules for research and clinical trials
- An overview of the scope of the Bolar exemption in Europe
- How will the Unitary Patent allow for experimental uses of patented medicines?

17:15 **Conference Adjourns**

DRINKS RECEPTION
for Delegates and Speakers



Day 2 | Friday, 20th March 2015

9:00 **Opening Remarks from the Chair**

Juergen Dressel, Head Global Litigation Strategy, **Novartis** (Switzerland)

9:15 **How to Obtain Supplementary Protection Certificates in Light of the Latest Case Law Developments in Europe**

Miquel Montana, Partner, **Clifford Chance** (Spain)

Camilla Balleny, Partner, **Carpmaels & Ransford LLP** (United Kingdom)

- Understanding under which circumstances you can obtain an SPC in the context of antibody claims
- Obtaining an SPC on combinations of active ingredients for new uses
- *Neurim's, Medeva's, Georgetown's, AstraZeneca's, Merck's* aftermath: an overview of the ECJ's interpretation on development of a new indication from an old substance
- How territorial Courts have applied the ECJ's rulings: *Eli Lilly v. HGS* (UK) and *Sanofi v. Teva* (Italy)
- Carefully analysing the Market Authorisation in order to obtain a strong SPC: key considerations
- Summary of SPCs/patent extension terms in Eastern Europe and how to fit these into import/export rules and parallel imports

10:30 **Coffee Break**

10:50 **Obtaining Preliminary Injunctions when Enforcing a Second Medical Use Claim: Where Do We Stand?**

Ewan Nettleton, Senior Patent Counsel, **Novartis AG** (Germany)

Claudia Milbradt, Partner, **Clifford Chance** (Germany)

Ulrich Reese, Partner, **Clifford Chance** (Germany)

- Swiss-type v. Europe-type claims drafting in view of obtaining a PI: implications of the differences
- What are the elements of a successful preliminary injunction petition?
- How to prove the infringement of a second medical use claim in Germany
- Update on the enforcement of second medical use claims through PIs in Europe

- How should companies adapt their communications in commercials and advertisements in order to maintain an enforceable second medical use claim patent?
- Forum shopping – useful considerations when deciding strategically where to enforce the second medical use patent claim

11:50 **New Frontiers for Patentable Subject Matters: Stem Cells, Gene Sequences, Plant Varieties. What Does This Mean for Your Patenting Strategy? Recent Case Law and Issues of Legal Uncertainty**

Rob. J. Aerts, Senior Patent Attorney, **Keygene N. V.** (Netherlands)

- Added subject matter at the EPO: an update
- Patentability of stem cells and embryos: what considerations should a pharmaceutical R&D business take into account?
- How the *International Stem Cells Corp.* case affects your R&D and patent strategy
- *Broccoli, Tomatoes* and essentially biological processes to produce plant varieties: what will change? Are plants obtained by a process excluded from patentability itself patentable?
- Is the patenting of stem cells and plants a matter of EU law or of EPC law? The current hybrid system in the EU and matters of legal uncertainty
- Assessing the scope of protection of claims on tools for generating antibodies: does it extend to all antibodies generated with those tools?
- How to evaluate the new USPTO's guidelines for gene sequences after Myriad? A comparison with Europe's approach
- How to file valid patents in Canada following recent Court's interpretations

12:50 **Networking Lunch**

13:50 **Coordinating the Impact on Disclosure Policies in Clinical Trials: How These Affect Patentability?**

Henrik Skødt, Partner, **Plougmann & Vingtoft** (Denmark)

Kim Wagner, Partner, **Plougmann & Vingtoft** (Denmark)

- The established case law and public prior use in clinical trials
- *Bayer v. Hexal (Yasmine)*: a new standard?
- Implied consent and trials contract: best practices
- How to do clinical trials without destroying novelty
- The circumstances underlying T 7/07 (*Yasmine*)
- T 7/07 in view of T 2250/13

14:30 **Biosimilars Update: Opportunities, Limits, Enforcement Need-to-Knows with Particular Reference to SPCs in Europe**

Lars Conrad, Chief Patent Specialist, **H. Lundbeck** (Denmark)

- Key considerations in enforcing biosimilar patents: how to formulate your requests
- How to obtain an SPC on a biosimilar medicine?
- Would the scope of the biosimilar be covered by the originator's SPC on the patented biological product in Europe?
- The US' FDA Purple Book: which opportunities can arise? Patenting and regulatory aspects
- What is the patent litigation regime under the FDA biosimilar pathway?

15:30 **Generic Makers Roundtable: How Will the Unitary Patent Impact on European Pharmaceutical Patent Litigation and How Should Generic Makers Prepare?**

Dr. Avijit Kelkar, Director of Intellectual Property, **Ranbaxy** (United Kingdom)

- How can generic makers make use of the UP as an opportunity in terms of access to clinical trial data and speed to get to the unitary market?
- Will Freedom to Operate assessments have to be more carefully considered within the UP? Will Courts be more strict in evaluating FTOs?
- A Unitary Patent for European market players: how does this impact on generic makers' market strategy in 2015 and beyond?
- What will generic makers need to take into consideration when deciding if and where to challenge the patent's validity?

16:15 **Overcoming Challenges when Enforcing Pharmaceutical Patents outside Europe and in Emerging Markets**

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

- Patentability limits in Canada in light of the most recent case law
- Enforcing pharmaceutical patent infringement in Brazil: where do we stand?
- Being prepared to initiate a patent enforcement dispute in China: what you need to know, which standard of evidence you must have
- Patent revocations, compulsory licenses and patentability limits factors affecting India as a drugs' market

17:00 **Conference Ends**

**denotes speaker invited*

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Date: 19 – 20 March 2015

Time: 9:00 – 17:50

Venue: Hotel Okura Amsterdam

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