



UNIVERSITAT DE
BARCELONA

Centre de Patents



MINISTERIO
DE ENERGÍA, TURISMO
Y AGENDA DIGITAL



Oficina Española
de Patentes y Marcas

2018 Chem- Pharma- Biotech Highlights

on Patentability and Patent Infringement

Barcelona, 6 February 2018
Madrid, 7 February 2018

Outlook

As "Highlights" the organizers will be offering advanced patent training of major significance or special interest in the form of two one-day sessions to be held in Barcelona and Madrid on consecutive days.

The "Chem-Pharma-Biotech Highlights" will bring patent practitioners up to date on some of the most critical and recent issues on IP in the field of life sciences. Speakers are experienced patent attorneys and patent litigators who have handled a multitude of proceedings before patent offices and courts.

Focus will be on the patentability of life science inventions before the European Patent Office, and their enforcement before some national patent courts, with special emphasis on inventive step, claim construction, medical use claims, and product-by-process claims. Other topics of interest will be advanced strategies for enforcing pharma patents, and generics-related issues.

Join us as we discuss these recent developments and how they affect our everyday practice. Discover how to utilize these recent changes for the benefit of your companies or clients. **PASCUAL SEGURA**

Objective

This one-day course will provide an in-depth and updated analysis of some topics related to patents in life sciences, to which practitioners should pay special attention for the benefit of their employers or clients, as the topics are either problematic, controversial, challenging or new.

Who should attend

Spanish or European patent attorneys, patent lawyers, patent examiners, intellectual property consultants, experts from patent departments in industry and from technology transfer offices of research institutions or universities.



1. Technical effects in the EPO's assessment of inventive step

- The application of the EPO's problem-solution approach
- Can technical effects be relied upon if they are not mentioned in the application?
- To what extent are improvements over the prior art required?
- Data support in the application and breadth of claims

2. Therapeutic effects, experimental data and plausibility

- Applicant's position: When to file? Which data to include?
- Which therapeutic effect is relevant?
- Treatment of drug combinations

3. Claim construction in validity and infringement proceedings

- Doctrine of equivalence: *Pemetrexed* before the German and UK courts
- *De minimis* use: *Napp v. Dr. Reddy's* ([2016] EWHC 1517 (Pat)) et al.
- Claim construction in validity assessments: *Polymerschaum II* et al.
- Further recent decisions on claim construction

4. Second medical use claims

- Which product is a 'substance or composition' - When does a claim fall within the scope of Art. 54(5) EPC?
- Effect-based definition of medical indication - New clinical situation versus explanation of a known therapy
- Selection of patient group - Evolving criteria for assessment of novelty



5. Enforcement of use claims in pharmaceutical patents

- What constitutes an infringing act for use claims?
- Overview of recent German case law: what has happened since *Ribavirin* and *Buspiron*
- Infringement of use claims: direct, indirect or both?
- Ribavirin, Pregabalin & Co: European diversity
- Off label use: who is responsible?
- Rebate agreements: what can the generics do?

6. Product-by-process claims

- The EPO's current position
- 'Obtainable by' and 'obtained by': any material difference?
- Recent decisions of the British and German courts

7. Advanced strategies for enforcing pharma patents in Europe

- Effective use of competitive intelligence: early preparation is key
- Legal steps based on generic pre-launch activities: different standards country by country
- Availability of provisional injunctions in various European jurisdictions
- Use of the 'specific mechanism' against parallel imports

8. The generics' toolbox

- Torpedos and counter-measures
- Lessons from the *Pemetrexed* and *Adalimumab* litigations: NDAs regarding infringement and validity
- Early triggering of an injunction request
- Damages for unjustified injunctions



GUSTAVO FUSTER

Gustavo is a European and Spanish Patent Attorney as well as a Spanish Attorney-at-law with Hoffmann Eitle in Madrid. After several positions both in private practice and industry, he joined Hoffmann Eitle in 2011.

He advises mostly Spanish clients in the life sciences, from small molecules to cellular technologies, with an emphasis on European and international patent prosecution. He is also involved in Spanish patent litigation.

JOACHIM RENKEN

Joachim is a European and German Patent Attorney with Hoffmann Eitle in Munich and Madrid. He joined Hoffmann Eitle in 1996. He is particularly active in the field of life science patents, mainly in oppositions and appeals.

He also regularly provides strategic advice and is involved in patent litigation before the German courts.

He is co-editor of the book "The European Patent Convention for Japanese Patent Practitioners".



ESTHER PFAFF

Esther is a German attorney-at-law and joined Hoffmann Eitle in 2010. She is particularly active as a coordinator of pan-European patent litigation, particularly in the field of pharmaceutical/biotech patents and in generic/originator constellations. She also regularly advises clients on risk assessments in drug development and the regulatory context and holds a PhD on the European rules for pharmaceutical data exclusivity. She further specializes in IP transactional work such as drafting and negotiating licenses, R&D agreements and is listed as a WIPO mediator.

HENRIK SKØDT

Henrik is a European and Danish Patent Attorney with Hoffmann Eitle in Madrid. He began his career in private practice, but has also worked as in-house opposition counsel in the litigation team of a major pharmaceutical company before he joined Hoffmann Eitle in 2017. He advises clients in the life sciences with an emphasis on pharmaceuticals on all aspects of patent law, ranging from drafting and prosecution over oppositions to FTO analyses. He is also involved in Danish patent litigation.

In Barcelona

Tuesday, 6 February 2018

Parc Científic de Barcelona

Aula Fèlix Serratosa

Edifici Clúster - Baldiri Reixac 10

08028 Barcelona

www.ub.edu/centrepatents

Time

10:00 to 17:00 h

1 hour lunch break

Registration

Centre de Patents de la UB

Núria Sans

Email: nuriasans@patents.pcb.ub.es

Tel: +34 93 403 45 11

Notes

A certificate of attendance will be provided on request.

The organizers reserve the right to cancel this course or to modify any aspect thereof. In addition, they will not be responsible for the opinions expressed by the speakers.

Lectures will be delivered in English. Questions may also be asked in Spanish.

In Madrid

Wednesday, 7 February 2018

Oficina Española de Patentes y Marcas

Sala Julio Delicado (planta 16)

Paseo de la Castellana 75

28046 Madrid

www.oepm.es

Attendance Fee

250.00 EUR + 21% VAT (if applicable)

This includes course materials and lunch

Payment

By bank transfer to the account

IBAN ES4201826035430201602137/BIC BBVAESMMXXX

Account holder: Fundació Bosch i Gimpera

(VAT No. ES-G08906653)

Payment must be received by 22 January 2018

Provide invoice details

Cancellation

Fee will be refunded

(minus 4% administration expenses)

if cancellation occurs on

22 January 2018 at the latest.