CEIPI | Advanced Training Program

on Regulatory Affairs and Intellectual Property Protection in the Pharmaceutical Industry

28
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October 2021

Centre d'études internationales de la **propriété intellectuelle** | CEIPI
*Center for International **Intellectual Property** Studies I[illegible]titut für internationale Studien des **geistigen Eigentums***
Université de Strasbourg

www.ceipi.edu

1 Concept

The development, authorization and commercialization of medicines is among the most regulated and complex legal domains. When it comes to pharmaceutical products, branches of law of administrative nature become tied to private law. The interfaces between pharmaceutical law, intellectual property law, competition law and consumer law are numerous. Patents, supplementary protection certificates and regulatory exclusivities, notably test data protection, make up a sophisticated legal framework of overlapping exclusivities that impact both on innovation and competition. The *CEIPI Advanced Training Program on Regulatory Affairs and Intellectual Property Protection in the Pharmaceutical Industry* is a unique educational proposal targeting regulatory and intellectual property professionals in the pharmaceutical sector. The three days of training revolve around the interface between patent law, supplementary protection certificates and test data protection.

2 Addressees

This training program is addressed to regulatory officers, patent attorneys and in-house lawyers, as well as public servants working in public health organizations, who must frequently navigate through the several legal domains of relevance even if they are just trained in one.

3 Duration

The program has a total duration of 18 hours, distributed in three days:
Thursday October 28, 9:00-12:30 and 14:00-18:00
Friday October 29, 9:00-12:30 and 14:00-18:00
Saturday October 30, 9:00-13:00

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Program

Thursday 28 | The interface between regulatory and IP exclusivities

This module focuses on the protection given to test data submitted for the grating of pharmaceutical marketing authorization. The pharmaceutical dossier, the types of information protected, key concepts, the duration of the protection and the acts against which the information is protected will be discussed. Likewise, EMA policies relating disclosure of test data, the specificities for biological products, and litigation strategies impacting test data protection will also be the object of analysis.

Topics include:

- Setting the scene
- The role of the EMA
- The regulatory framework of test data protection
- How to enforce RDP and how to challenge RDP
- The interface between test data protection and competition law

Friday 29 | Supplementary Protection Certificates

This module explores the legislative background and litigation strategies concerning Supplementary Protection Certificates in the European Union. EC Regulation 469/2009 will allow to discuss time lines, where to apply, substantive requirements, and scope of protection during term of protection awarded by the SPC. Controversial areas such as which is the product protected by the basic patent, pediatric extensions and the relationship with patent claims drafting will be explored in this session.

Topics include:

- The legal framework
- The interface between competition law and SPCs
- Patent claims and SPCs
- Strategies to obtain and hallenge SPC-protection
- Manufacture for export waiver

Saturday 30 | Orphan Drugs Exclusivity

The final day is devoted to orphan drugs exclusivity, its nature, effects and interaction with other exclusivities. Lecturers will address aspects such as how to obtain this exclusivity, situations of mixed orphan/non-orphan indications for the same active pharmaceutical ingredient, scope and breaking protection of orphan drugs exclusivity, how to enforce orphan drugs exclusivity.

Topics include:

- Award of orphan drugs exclusivity
- Situations of mixed orphan/non-orphan indications for the same active pharmaceutical ingredient
- How to enforce and how to challenge orphan drugs exclusivity

The program has been jointly designed and directed by

- Oleksandr Bulayenko, Education & Scientific Coordinator, Researcher at CEIPI
- Peter Thomsen, Chairman of the Litigation Committee of the Institute of Professional Representatives before the European Patent Office
- Pierick Rousseau, Former Intellectual Property Director at Pierre Fabre

For information & contact

- pharma-seminar@ceipi.edu
  +33 (0)3 68 85 80 27

Location: University of Strasbourg as well as remotely

Tuesday, Wednesday and Thursday October 28, 29 & 30, 2021

Université de Strasbourg
Bâtiment le CARDO
7 rue de l'Ecarlate
CS 20024
67082 Strasbourg Cedex

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