CEIPI | Advanced Training Program

Regulatory Affairs and Intellectual Property Protection in the Pharmaceutical + Industry

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September 2024

Center for International
Intellectual Property Studies | CEIPI
University of Strasbourg

1. Concept of the studies

The development, authorisation and commercialisation of medicinal products in the pharmaceutical sector are amongst the most regulated and complex areas of European Union (EU) law. The legal framework governing the regulation of medicinal products can affect a broad range of private rights, intellectual property law, competition law and consumer law. In particular, patents, supplementary protection certificates (SPCs) and regulatory rewards, notably regulatory data protection, constitute a sophisticated legal framework of overlapping exclusivities that impacts both innovation and competition. This complexity creates challenges for experts tasked with understanding a rapidly evolving legal and regulatory landscape.

The CEIPI Advanced Training Program on Regulatory Affairs and Intellectual Property Protection in the Pharmaceutical Industry, now in its fourth edition, is a unique educational proposal targeting regulatory and intellectual property professionals in the pharmaceutical sector. The three days of intensive training revolve around the intersections of patent and regulatory law. In this respect, issues such as SPCs and regulatory data protection, amongst other relevant topics, will be taught by leading legal professionals and experts in the field.

This interactive course aims to provide an up-to-date overview of the European pharmaceutical regulatory environment, procedures and obligations as well as on the patent and SPC related landscape. It will create a space for discussion on how to interpret and apply legislation in this sector in light of new developments. These developments include an overview of the current state of the European Commission's proposals for the revision of the EU pharmaceutical legislation and of the SPC legislation.

Case studies and discussion sessions throughout the program will help participants to explore options and strategies for key regulatory activities and to provide an opportunity to share experiences with our expert trainers and other delegates. CEIPI also offers a professional certificate for successful participation in this advanced training program.

2. Prospective participants

This program is addressed to regulatory professionals, patent attorneys and in-house lawyers, aswell as public servants working in public health organizations, who frequently have to navigatethrough the several legal domains of relevance even if they are just trained in one. For this year'sedition, we hope to expand our attendees to include a broader range of participants, includingrepresentatives from national regulatory agencies, innovators in the generics sector, and businessdevelopment experts.

3. Program duration

The advanced training program has a total duration of 18 hours, distributed in three days:

- Thursday September 19, 9:00-12:45 and 14:00-18:00
- Friday September 20, 9:00-12:45 and 14:00-18:00
- Saturday September 21, 9:00-13:00

PROGRAM - DAY 1

Thursday 19th of September

The interface between regulatory and IP exclusivities: Regulatory Data Protection and the role of Marketing Authorisations

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This module focuses on the protection that may be accorded to data and information submittedfor the granting of certain types of marketing authorisations for medicinal products for human use. The pharmaceutical dossier, the types of information protected, key concepts, the duration ofthe protection and acts against which information is protected will be discussed. The approach of the European Medicines Agency (EMA) towards reactive and proactive transparency, including, the manner in which it handles data and information pertaining to medicinal products will be discussed and analysed.

Topics include:

- The EU centralised procedure for obtaining marketing authorisations (MAs) for medicinal products for human use
- The framework of regulatory data protection
- The legislation, internal policies and case law which inform EMA's approach towards transparency
- How to enforce and challenge regulatory data protection
- Interface between regulatory data protection and competition law

COURSE LAYOUT - DAY 1

Time CET	Topic	Speakers
9.00 – 9.30	Opening and Introduction	-Yann Basire, Director General and Associate Professor at CEIPI -Thomas Lemieux, Associate Professor, CEIPI -Peter Thomsen, Chairman of the Litigation Committee of EPI -Pierick Rousseau, Former Intellectual Property Director at Pierre Fabre -Alexander Meier, VP, Head, Legal Regulatory Strategy and Global Regulatory Policy at Moderna
9.30 – 10.30	The grant of marketing authorisations (MAs) for medicinal products and its importance for exclusivity rights	Alexander Meier
10.30 – 10.45 Coffee break		
10.45 – 12.45	Regulatory data protection for medicinal products	Alexander Meier
12.45 – 14.00 Lunch break		
14.00 – 15.30	The EMA's approach to transparency: between legislation, internal policies and case-law	Helen Kerr, European Medicines Agency (EMA)
15.30 – 16.00 Coffee break		
16.00 – 17.30	How to enforce and how to challenge regulatory data protection in daily practice	Alexander Meier
17.30 –18.00	Outlook on the future of regulatory data protection	Alexander Meier

PROGRAM - DAY 2

Friday 20th of September

Supplementary Protection Certificates (SPCs) and Practical Cases

This module explores the legislative background and litigation strategies concerning Supplementary Protection Certificates (SPCs) in the European Union. Participants will become familiarized with timelines, where to apply for SPCs, substantive requirements, and the scope ofprotection during the term of protection awarded by an SPC. Controversial areas, such as which isthe product protected by the basic patent and the relationship between SPCs and patent claimsdrafting, will also be explored in this session.

Topics include:

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

COURSE LAYOUT - DAY 2

Time CET	Topics	Speaker
9.00 – 9.30	General Legal Framework	Pierick Rousseau
9.30 – 10.30	Conditions for an SPC	Peter Thomsen
10.30 – 10.45 Coffee break		
10.45 – 11.30	Filing and granting procedure	Anne Boutaric , Partner, European and French Patent Attorney at Regimbeau
11.30 – 12.00	Term of protection	Anne Boutaric
12.00 – 12.45	Scope of protection	Pierick Rousseau
12.45 – 14.00 Lunch break		
14.00 – 14.45	Selection of basic patent of an SPC	Peter Thomsen
14.45 – 15.30	Enforcement and revocation of SPCs	Peter Thomsen
15.30 – 16.00 Coffee break		
16.00 – 17.00	Outlook for the future of SPCs	Peter Thomsen Anne Boutaric
17.00 – 18.00	Roundtable Discussion with Practical Cases and Q&A	Peter Thomsen, Pierick Rousseau, Alexander Meier, Anne Boutaric
18.00 – 19.00 Cocktail		

PROGRAM - DAY 3

Saturday 21st of September

Orphan Market Exclusivity and Paediatric Extensions

The final day is devoted to orphan market exclusivity and paediatric exclusivity extensions. Orphan market exclusivity in terms of its nature, effects, and interaction with other exclusivities will be discussed, along with conditions for applying for paediatric extensions. Lecturers will address aspects such as how to obtain orphan market exclusivity, situations of mixed orphan/non-orphan indications for the same active pharmaceutical ingredient, the scope of orphan drugs exclusivity, and enforcement (strategies for breaking protection).

Topics include:

- Award of orphan market exclusivity
- Situations of mixed orphan/non-orphan indications for the same active substance
- How to enforce and challenge orphan market exclusivity
- Applying for and obtaining paediatric extension to an SPC

COURSE LAYOUT - DAY 3

Time CET	Topic	Speakers
9.00 – 10.30	Orphan market exclusivity and Outlook	Alexander Meier
10.30 – 10.45 Coffee Break		
10.45 – 12.45	Paediatric Extensions and Outlook	Peter Thomsen
12.45 – 13.00	Closing	Peter Thomsen Pierick Rousseau Alexander Meier Thomas Lemieux

Practical information

This program has been jointly designed and directed by:

- Peter Thomsen, Senior Patent Counsel IP Policy & Litigation, Novartis International AG
- Alexander Meier, VP, Head, Legal Regulatory Strategy and Global Regulatory Policy at Moderna
- Pierick Rousseau, Former Intellectual Property Director at Pierre Fabre
- Thomas Lemieux, Associate Professor of Law, CEIPI, University of Strasbourg

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Location:

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