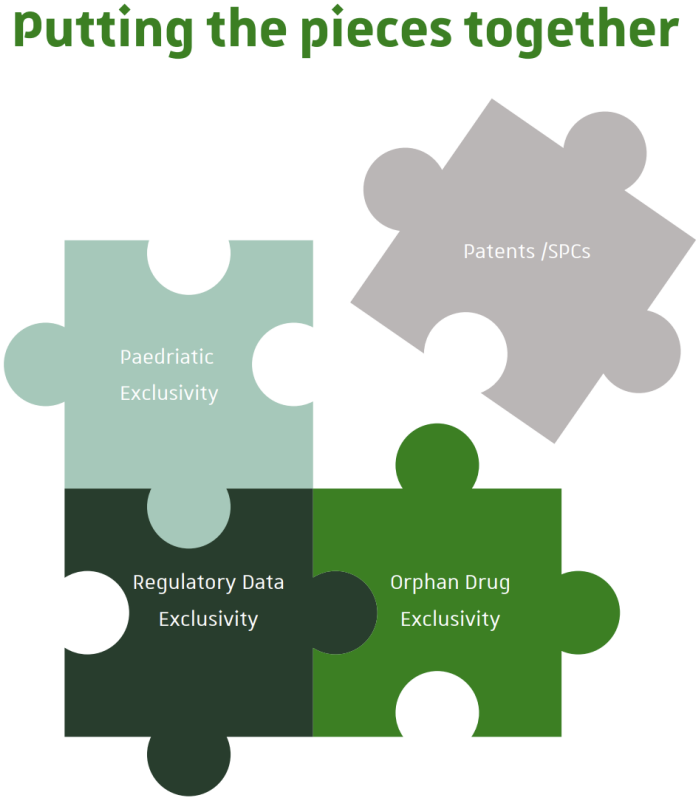
Centre d'études internationales de la **propriété intellectuelle** | CEIPI
Center for International ***Intellectual Property*** *Studies*
Institut für internationale Studien des ***geistigen Eigentums***
Université de Strasbourg

CEIPI Advanced Training Program on

REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY PROTECTION IN THE PHARMACEUTICAL INDUSTRY

12 – 13 – 14 JANUARY 2023



1. Concept of Training

The development, authorization and commercialization of medicines is among the most regulated and complex legal domains. Laws regulating pharmaceutical products can implicate a mixture of private rights, intellectual property laws, competition laws and consumer laws. Patents, supplementary protection certificates (SPCs) and regulatory exclusivities, notably test data protection, make up a sophisticated legal framework of overlapping exclusivities that impact 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 third 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 law, SPCs and regulatory data protection among other relevant topics, taught by leading legal professionals and experts in the field.

This interactive course, incorporating both live and hybrid learning, aims to provide an up-to-date overview of the European pharmaceutical regulatory environment, procedures and obligations, and create a space for discussion on how to interpret and apply legislation in this sector in light of new developments.

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

2. Prospective participants

This 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. For this year's edition, we hope to expand our attendees to include a broader range of participants, including representatives from national regulatory agencies, innovators in the generics sector, and business development experts.

3. Program Duration

The advanced training program has a total duration of 19 hours, distributed in three days:

- Thursday January 12, 9:00-12:30 and 14:00-18:00
- Friday January 13, 9:00-12:30 and 14:00-18:00
- Saturday January 14, 9:00-13:00

4. Program

DAY 1 (Thursday 12th January): The interface between regulatory and IP exclusivities: Regulatory Data Protection

This module focuses on the protection given to test data submitted for the granting of pharmaceutical marketing authorizations. The pharmaceutical dossier, the types of information protected, key concepts, the duration of the protection and acts against which information is protected will be discussed. Likewise, the EMA's extended mandate in response to the COVID-19 pandemic, as well as its policies related to the disclosure of test data, the specificities for biological products, and litigation strategies impacting test data protection, will be discussed and analysed.

Topics include:

- The EU centralised procedure for obtaining marketing authorisations
- The regulatory framework of test data protection
- How to enforce and challenge regulatory data protection
- Interface of test data protection and competition law
- The (evolving) role of the EMA: Regulatory transparency post-COVID

DAY 2 (Friday 13th January): Marketing Authorisations, 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 get familiarized with timelines, where to apply for SPCs, substantive requirements, and the scope of protection during term of protection awarded by the SPC. Controversial areas such as which is the product protected by the basic patent and the relationship between SPCs and patent claims drafting will also be explored in this session.

Topics include:

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

DAY 3 (Saturday 14th January): Orphan Drugs Exclusivity and Paediatric Extensions

The final day is devoted to orphan drugs exclusivity and paediatric extensions. Orphan drugs 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 drugs 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:

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

Course Layout:

Day 1: The interface between regulatory and IP exclusivities: Regulatory Data Protection

Time CET	Location	Topic	Speakers
9.00 – 9.30		**Opening and Introduction**	**Yann Basire**, Director General and Associate Professor at CEIPI **Natasha Mangal**, Associate Professor, CEIPI **Peter Thomsen**, Chairman of the Litigation Committee of epi **Pierick Rousseau**, Former Intellectual Property Director at Pierre Fabre
9.30 – 11.30		**Regulatory data protection for medicines**	**Alexander Meier**, Partner at Preu Bohlig & Partner Rechtsanwälte mbB
11.30 – 11.45	*Coffee break*		
11.45 – 13.45		**Regulatory data protection for medicines**	**Alexander Meier**
13.45 – 14.45	*Lunch break*		
14.45 – 16.15		**The European Medicines Agency: Biosimilars and interchangeability**	**Ruben Pita**, EMA
16.15 – 16.30	*Coffee break*		
16.30 – 18.30		**How to enforce and how to challenge regulatory test data in daily practice**	**Alexander Meier**

Day 2: Marketing Authorisations, Supplementary Protection Certificates (SPCs), and Practical Cases

Time CET	Location	Topics	Speaker
9.00 – 9.30		**General Legal Framework**	**Pierick Rousseau**
9.30 – 10.00		**Marketing authorisation forming basis for an SPC**	**Peter Thomsen**
10.00 – 10.15	*Coffee break*		
10.15 – 11.00		**Filing and granting procedure**	**Axel Berger,** Patent Attorney, BARDEHLE
11.00 – 11.30		**Term of protection**	**Axel Berger**
11.30 – 12.15		**Scope of protection**	**Pierick Rousseau**
12.15 – 13.15	*Lunch break*		
13.15 – 14.15		**Selection of basic patent of an SPC**	**Peter Thomsen**
14.15 – 15.30		**The future of SPCs**	**Peter Thomsen**
15.30 – 15.40	*Coffee break*		
15.40 – 16.30		**Vaccines and the EU's conditional marketing authorisation (CMA): Moderna's "Spikevax" MA**	**Alexander Meier**
16.30 – 18.00		**Roundtable Discussion with Practical Cases and Q&A**	**Peter Thomsen** **Pierick Rousseau** **Alexander Meier**
18.00 – 19.00	*Cocktail*		

Day 3: Paediatric Extensions and Orphan Drugs Exclusivity

Time CET	Location	Topic	Speakers
9.00 – 10.30		**Orphan drug exclusivity**	**Alexander Meier**
10.30 – 10.45	*Coffee Break*		
10.45 – 13.00		**Paediatric Extensions**	**Peter Thomsen**
13.00 – 13.10		**Closing**	**Pierick Rousseau** **Peter Thomsen** **Natasha Mangal**

This program has been jointly designed and directed by:

Peter Thomsen, Senior Patent Counsel IP Policy & Litigation, Novartis International AG
Pierick Rousseau, Former Intellectual Property Director at Pierre Fabre
Alexander Meier, Partner at Preu Bohlig & Partner Rechtsanwälte mbB
Natasha Mangal, Associate Professor of Law, CEIPI, University of Strasbourg

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Location

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