IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Patent Strategies for Generic Medicines and Generic Medicine Companies

21 October 2025

An intensive one-day event to equip generic medicine companies with the knowledge to successfully navigate this complex patent landscape

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

In the highly competitive pharmaceutical industry, patent strategies for generic medicines are crucial for success. To successfully bring a generic medicine to market, it is necessary to navigate a complex patent landscape in order to avoid infringing existing patents.

Attending this course will give you a thorough understanding of IP strategies specifically tailored for generic medicines, equipping you with the tools to navigate the complex landscape of pharmaceutical patents and SPCs.

The course will cover how to conduct a robust Freedom to Operate (FTO) analysis to identify and analyse potential patent infringement issues. Drawing on the shared experience of the expert trainers, you will learn to navigate the patent landscape and identify the risks for generic products entering the market.

Acquiring insights into identifying and managing blocking patents, with a focus on when and where to take action, you will understand whether to pursue oppositions or litigation.

It's crucial to stay updated with the most recent EPO case law, particularly on inventive step as this is the area that has proven to be most successful when challenging patent validity. This will enable you to craft strong arguments for challenging a patent and improve your patent strategy.

Understanding the legal framework surrounding Supplementary Protection Certificates (SPCs) in the EU and UK, will ensure you are fully aware of the specific requirements for these separate IP rights when compared to the patents they are based on. Options for challenging the validity of SPCs based on most recent case law will be explored.

The expert trainers for this course will use case studies and real-world examples to help embed the learning and enhance your practical knowledge. You will leave the course with the understanding and skills to be able to apply these strategies effectively within your own context.

Key topics covered in this course include:

- Comprehensive IP knowledge for generic medicines
- Freedom to operate (FTO)
- Strategic management of blocking patents
- Latest legal insights
- SPC legal landscape
- Practical applications

Benefits of attending

By attending this course you will:

- **Get to grips** with the process of Freedom to Operate (FTO) analysis, including assessing potential patent infringement risks and understanding issues around data exclusivity
- **Develop** the ability to identify and manage blocking patents
- **Evaluate** whether to pursue oppositions at the EPO or seek revocation of a patent at the new Unified Patent Court (UPC)
- **Gain** up-to-date knowledge on EPO case law concerning inventive step, and on emerging UPC case law, and how such arguments can be used to challenge the validity of patents
- **Understand** the legal intricacies and case law of Supplementary Protection Certificates (SPCs), including strategies to challenge their validity
- **Learn** how to implement these IP strategies in the context of generic medicines, ensuring such products can effectively compete in the pharmaceutical market

Who should attend?

This course has been specially designed for professionals in generic medicines, including:

- In-house IP and patent lawyers and legal advisers
- Private practice patent lawyers
- IP managers/professionals
- Senior patent administrators and paralegals
- Other professionals responsible for managing a patent portfolio

Programme

Freedom to operate

- What is 'Freedom to operate' analysis?
- Data exclusivity
- Assessing patent infringement
- Watch out for potential specific patent issues around the following:
  - Stereochemistry
  - Polymorphs
  - New formulations
  - Process patents
  - Methods of use patents

Problem patents – assessing and managing blocking patents

- Oppositions at the European Patent office (EPO)
- Litigation at the Unified Patent Court (UPC)
- Oppositions versus litigation – factors in deciding on strategy
- Where to take action? When to take action?
- Successful strategies from case law

The latest updates from UPC and EPO case law: Inventive step

- EPO problem-solution approach to assessing inventive step
- Developing arguments for lack of inventive step
- Impact of emerging UPC case law

Supplementary Protection Certificates (SPCs)

- The EU legal framework
- The UK legal framework

Exploring the validity of SPCs - lessons from the case law

- Questions that arise under Article 3?
- Same or different - EU and UK?

Other aspects arising from SPCs

- Paediatric extensions
- Manufacturing waiver
- Regulatory exclusivities

Presenters

Marie Walsh

Marie Walsh is a European Patent Attorney and Chartered (UK) Patent Attorney with over 25 years of experience in advising clients including start-ups and SME's to large corporations. She has worked across a number of technology areas and specialises in industrial chemistry, materials science, polymer chemistry, and pharmaceutical chemistry. Marie also has in-depth experience in obtaining Supplementary Protection Certificates (SPCs).

Marie has a strong focus on providing commercially relevant, pragmatic advice based on individual clients' goals. She has an MBA from the Open University which supports her commercially focused approach to advising on IP strategy.

Marie is based in Dublin, Ireland and has worked with clients across the globe, including firms in Ireland and the UK, as well as US and Chinese clients and her objective is on clear communication with the clients' commercial aims as the central focus. Marie has previously worked with another leading firm of patent attorneys in Ireland where she had the role of Director of Operations for China and Chief Representative of the local China office.

She also has extensive experience of providing opinions and advising in relation to freedom to operate (FTO). In addition, she has represented clients at Oppositions and Appeals at the EPO and achieved successful outcomes for clients.

Lawrence Cullen

After a long career at the UK Intellectual Property Office (IPO), **Dr Lawrence Cullen** recently established his own consultancy to provide advice and develop his interests in IP, especially in the role and relevance of SPCs.

From 2007 to 2024, Dr Cullen was the Deputy Director at the Intellectual Property Office (IPO) in the UK responsible for the patent examination teams in the fields of pharmaceuticals, organic chemistry and biotechnology. He also led the team responsible for the examination and grant, or refusal, of supplementary protection certificates (SPCs) at the IPO. This included the development of UK practice in relation to SPCs and keeping the IPO Manual of Patent Practice chapter on SPCs up to date.

Dr Cullen has a wide experience dealing with questions of validity in the patent and SPC fields. As a hearing officer at the IPO, he was directly involved in over 50 patent cases across all areas of technology including computer implemented inventions as well as biotechnology and pharmaceuticals. In addition, he decided over 25 SPC cases before the IPO gaining a wide experience of UK and EU law in this area. He also has extensive experience of dealing with appeals before the UK courts and, prior to 31 December 2021, referrals to the Court of Justice of the European Union (CJEU).

Dr Cullen gained his BSc in Industrial Chemistry in Ireland and his PhD in organic chemistry in UK. He worked as a research scientist at various universities in Europe, USA and UK before joining the UK-IPO to embark on his career in IP.

Course date

21 October 2025

Live online
09:30-17:00 **UK (London)** (UTC+01)
Course code 15487

GBP **599** ~~699~~
EUR **839** ~~979~~
USD **963** ~~1,119~~
Until 16 Sep

How to book

Online:
ipi.academy/1966

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com