IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Patent Strategies for Generic Medicines and Generic Medicine Companies

4 March 27
+ 28 September 27

Navigate complex pharmaceutical patent landscapes confidently. Learn FTO analysis, opposition strategies, and UPC procedures specifically for generic drug companies.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

In the highly competitive pharmaceutical industry, patent strategy for generic medicines and pharmaceutical Freedom to Operate (FTO) are crucial for commercial success. Bringing a generic medicine to market requires navigating a complex and evolving patent landscape while avoiding infringement of originator rights.

This training course provides a practical and up-to-date understanding of IP strategies tailored specifically for generic and biosimilar medicines, equipping you with the tools to manage risk across patents and Supplementary Protection Certificates (SPCs) while also being aware of the impact of regulatory exclusivities.

You will learn how to conduct a robust Freedom to Operate (FTO) analysis to identify and assess potential patent infringement issues. Drawing on the shared experience of the expert trainers, the course explores how to map the patent landscape, evaluate legal and commercial risk, and prioritise actions for generic pharmaceutical products approaching launch.

You will gain insights into identifying and managing blocking patents, with a focus on when and where to take action, understanding the options available, for example opposition or litigation.

Staying current with recent EPO case law, particularly on inventive step and claim interpretation, is essential when challenging patent validity. The training course explains how these legal developments can strengthen opposition and revocation strategies.

Given the increasing importance of European patent enforcement, the course reflects the impact of the Unified Patent Court (UPC) and its growing role in pan-European patent disputes. This includes how UPC procedures influence enforcement risk, revocation strategies and forum selection.

The UPC is becoming a key forum for pharmaceutical patent litigation, creating new enforcement and revocation risks for innovator and generic entrants.

You will develop a clear understanding of the legal framework surrounding Supplementary Protection Certificates (SPCs) in the EU and UK. Differences between SPCs and patents, alongside recent case law on SPC validity and scope, will be highlighted. The impact of the SPC Manufacturing Waiver and the Bolar Research Exemption will also be covered.

Throughout the training course, the expert trainers use case studies and real-world scenarios to embed learning and strengthen practical understanding. You will leave with the confidence to apply these strategies within your own organisation or client context.

Key topics covered in this course include:

- IP and patent strategy for generic and biosimilar medicines
- Conducting and interpreting Freedom to Operate (FTO) analyses
- Identifying and managing blocking patents
- Strategic use of EPO oppositions, national revocation actions and UPC litigation
- Recent EPO and UPC case law on validity and enforcement
- The Supplementary Protection Certificate (SPC) legal framework and validity challenges
- Emerging impact of SPC Manufacturing Waiver
- Relevance of the Bolar Research Exemption
- Practical application of patent risk mitigation strategies

Benefits of attending

By attending this training 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 role and growing impact of the Unified Patent Court (UPC) on European enforcement and revocations strategy
- **Strengthen** your understanding of the Supplementary Protection Certificates (SPC) system, 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 training course has been specially designed for professionals with an interest in generic medicines, including:

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

Programme

Introduction and aims

Freedom to operate

- What is 'Freedom to operate' analysis?
- 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 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 situation in the EU current and future
- Situation in other jurisdictions. UK?

Exploring the validity of SPCs - lessons from the case law

- Questions that arise under Article 3, for example combination products?
- Same approach or different - EU and UK?

US perspective

- FTO and impact of File Wrapper Estoppel in the US
- Exemptions from patent infringement liability 'Regulatory safe harbour'

Bolar exemptions

- The Bolar exemption allows generic and biosimilar manufacturers to conduct the studies and regulatory preparations necessary for market authorisation before patent expiry, thereby preventing regulatory delay from extending effective exclusivity
- The Bolar exemptions in the context of the EU Pharmaceutical Reform Package
- EU's effort to harmonise the exemption across Member States to reduce legal fragmentation and litigation risk

SPC manufacturing waiver - review of recent relevant case law

- The SPC waiver allows EU-based manufacturers to produce a generic or biosimilar version of an SPC-protected medicine during the term of the SPC, if it is for the purposes of exporting to a third country outside the EU, or for stockpiling during the final six months of protection before launch onto the EU market
- What notification is necessary?
- What challenges arise?
- Case law – is there consistency?

Final questions

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.



Erin Dunston

Erin M Dunston is a Partner at Panitch Schwarze. Over the course of her over twenty-year career, her practice has been a purposeful mix of patent prosecution and litigation. Having handled many patent litigations, Erin recognises how every word in prosecution may ultimately be analysed by the fact-finder and thus strives for efficient, law- and science-driven prosecution. Her extensive prosecution experience, in turn, is invaluable when analyzing prosecution documents and issues as part of a litigation. With a background in biochemistry, she concentrates her practice primarily in the fields of biotechnology, pharmaceuticals, medical devices, and associated computer technology.

In terms of patent prosecution, counseling, and strategy, Erin learns her clients' businesses and how a given project will advance the client's business objectives, from both offensive and defensive standpoints. Erin also works closely with clients to satisfy budget constraints and assist in leveraging and monetizing patent assets.

To date, Erin has handled more than 20 district court litigations and more than 25 inter partes reviews (IPRs) and more than 40 interferences before the Patent Trial and Appeal Board (P.T.A.B). Assisting both patent owners and putative infringers/petitioners, this experience ranges from pre-filing analyses all the way through appeals to the U.S. Court of Appeals for the Federal Circuit.

Her deep experience in patent law has been recognized by several leading IP organizations and awards programs. Erin has been selected for inclusion among The Best Lawyers in America each year since 2018. She also has been recognized in IAM's Patent 1000 list – a best-in-class listing of patent prosecution, licensing, and litigation practitioners. For several years, including for 2021, she has been named an IP Star by Managing Intellectual Property and a Leading Intellectual Property Lawyer by Chambers USA. Erin also received Lawyer Monthly's Women in Law 2016 Award for her contributions to the practice of biotechnology law.

Course dates

4 March 27	**Live online** 09:30-16:45 **UK (London)** (UTC+00) *Course code 17040*	GBP **599** ~~699~~ EUR **839** ~~979~~ USD **963** ~~1,119~~ **Until 07 Jan**
28 September 27	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 17428*	GBP **599** ~~699~~ EUR **839** ~~979~~ USD **963** ~~1,119~~ **Until 03 Aug**

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

Reviews

★★★★☆

Communication was really good. [I] Gain a deeper knowledge in Data Exclusivity, Market Exclusivity, FTOs, Patent Clearance, SPC waiver, PED in order to be able to coordinate with our partner IP expert and to simpler my communication with clients who ask for this type of documents

Dimitris Patsalis
Project Coordinator
Pharmaplot
Oct 21 2025

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



Harry ALTAMONT
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