

Intensive patent workshop:

How to draft, analyse and circumvent a formulation patent

26 to 27 February 2018
Berlin, Germany

Course no. 3188



Organised in partnership with Pharma Patents

Target Group

The workshop is primarily designed for pharmaceutical professionals working in drug product development who frequently encounter patent issues, either as inventors of novel formulations or manufacturing processes, or as developers of drug products in the face of substantial third-party IP whose infringement must be avoided. Moreover, the course will be useful for pharmaceutical experts engaged in technology scouting, drug delivery technology development, in-licensing activities and due diligences.

Typical roles of participants include:

- Formulation development scientists/managers
- Drug delivery technology scouts
- Project leaders in (technical/pharmaceutical) drug product development
- Liaison managers working at the interface of pharmaceutical development & IP
- Pharmaceutical experts in licensing & due diligence teams



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Programme

Monday, 26 February 2018
10:30 to 18:00

Introduction

- The interdisciplinary nature of pharmaceutical IP
- Why your patent attorney needs your help
- How this course will enable you to deal effectively with patent issues

Session 1 - Freedom to operate

Essential knowledge on freedom to operate

- Defining freedom to operate (FTO)
- A pharmaceutical industry perspective on FTO
- FTO: How much at what time in drug development?
- Patent infringement and the doctrine of equivalents
- The pitfalls: Common misunderstandings of scientists and managers

Patent searches for determining freedom to operate

- Product deconstruction techniques
- Beyond IUPAC: The challenge of drug delivery terminology
- Using patent classification: Tricks and limitations
- Patent databases: A practical guide
- Other sources of relevant information

Evaluating patent search results

- Patent landscapes: What are they good for?
- Coping with high numbers of hits
- How to select the documents that you should really read
- The structure of a patent document
- **WORKSHOP EXERCISE:**
Analysing a pharmaceutical formulation patent
- Taking the legal status of a patent into account
- Forming and communicating technical opinions
- **WORKSHOP EXERCISE:**
Identifying viable circumvention options

Freedom to operate: Putting it all together

- Getting the big picture right
- Risk assessment and risk mitigation
- Crucial follow-up work after an FTO study

Social event

On Monday, 26 February you are cordially invited to a sightseeing tour of Berlin followed by a dinner.

Take advantage of this excellent opportunity to share your experiences with colleagues in a relaxed atmosphere.



Tuesday, 27 February 2018
08:15 to 16:00

Session 2 - Obtaining Patent Protection

Beyond NMEs: Protecting pharmaceutical inventions

- The role of patents in life cycle management
- Patentability considerations with an eye on drug formulations, kits, therapeutic uses, and manufacturing processes
- A scrutinising view on prior art
- Inventiveness: Is it what we think it is?
- Other requirements and restrictions
- **WORKSHOP EXERCISE:**
Analysing inventiveness using real pharmaceutical patent cases

Identifying inventions and determining their scope

- A systematic approach to analysing R&D outcome
- How to increase the likelihood of inventions
- Designing experiments to support an invention
- **WORKSHOP EXERCISE:**
Evaluating the results of a formulation screening programme

The making of a patent application

- The team: Who should be involved?
- The art of drafting patent claims
- The underestimated role of the description
- Examples - which ones do you really need?
- Reviewing draft applications: The role of the pharmaceutical expert
- **WORKSHOP EXERCISE:**
Drafting and reviewing patent claims based on "real" R&D data

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Course Leaders

From idea to patent grant: The patenting process

- The most important events in the life of a patent application
- How to evaluate search reports
- Replying to an examination report

Wrap-up and Q&A session

- Clarifications and follow-up discussions
- Key take-home learnings
- Suggestions for further development of your patent skills

Please note that this workshop is limited to 20 participants!

Objectives

This hands-on training course was developed to enhance the patent skills of pharmaceutical professionals who already have a basic knowledge of patents and their role in the pharmaceutical industry. The main objective is to convey advanced practical patent know-how with particular relevance for IP issues regularly occurring in drug product development. The successful participant will be enabled to immediately apply the acquired skills, provide high-quality input to project teams and decision-makers, avoid common pitfalls, and collaborate effectively with in-house or external patent attorneys.

In particular, the successful participant will be able to

- Effectively communicate the technical details of potential inventions and contribute to the evaluation of their patentability
- Provide and/or review high-quality draft patent applications or invention disclosures
- Support the prosecution of patent applications by providing the responsible IP experts with useful technical insights
- Provide correct and relevant input to enable patent search experts to perform meaningful prior art and freedom-to-operate patent searches
- Collaborate with IP experts in interpreting the claims of third party patents and developing viable circumvention options
- Contribute to freedom-to-operate analyses by providing relevant technical expertise based on a solid understanding of the underlying IP issues



Karsten Cremer, PhD, brings in the ideal expertise for leading this patent course. He is a European patent attorney and a pharmaceutical scientist with 20 years of professional experience in the field of drug delivery. Through his intimate knowledge from both sides of the fence, he has become a successful trainer

for pharmaceutical professionals who tackle patent challenges relating to drug products, dosage form designs, formulations, kits, and manufacturing methods.

Karsten is the founder and managing director of Pharma Concepts GmbH, a pharmaceutical IP consultancy located in Basel (Switzerland). In previous pointments, he was CEO of Capsulation Nano Science AG, Director of Oral Drug Delivery at LTS Lohmann Therapy Systems, and Lecturer of Pharmaceutics at the University of Marburg. As a pharmaceutical IP expert, Karsten works with large pharmaceutical companies as well as small and medium-size drug delivery companies. His specialities include IP issues relating to pharmaceutical formulations and drug delivery technologies. In addition to drafting, filing and prosecuting patent applications, he is experienced in opposing and defending patents, developing and implementing tailor-made patent strategies, managing patent portfolios, establishing patent landscapes, performing freedom-to-operate analyses, and conducting technical and IP due diligences.

Karsten is an experienced speaker and tutor with a proven track record of success within the APV and other professional organisations. He is also founder and member of the APV Drug Delivery Focus Group.



Kurt Schellhaas, PhD, joined Pharma Concepts in 2016 as a Senior Associate on the basis of more than 15 years of professional experience in academia and industry. He completed his studies in Chemistry at J. W. Goethe University, Frankfurt and holds a Ph.D. in Organic Chemistry from Technical University Berlin. After his post-

doctoral studies at the Scripps Institution of Oceanography at the University of California, La Jolla he joined BASF SE as a medicinal chemist. In 2002, Kurt decided to focus his professional career on the field of Intellectual Property and joined the BASF Global IP department where he worked as a European Patent Attorney and Senior Patent Counsel in the field of vitamins and precursors thereof, APIs and pharmaceutical intermediates as well as aroma chemicals covering a broad range of technologies from lab to world scale applications. In 2009, Kurt joined Roche Diagnostics broadening his area of IP practice to consumer medical technology and devices in the area of Diabetes Care as a Senior Counsel and ultimately as Head of Patents Diabetes Care.

As Karsten, Kurt brings in relevant hands-on experience in the management of the multiple interfaces between internal and external R&D units, IP departments as well as other relevant stakeholders in the pharmaceutical industry as well as related technical areas.



Date

Course no. 3188
 from 26 Feb. 2018 10:30
 to 27 Feb. 2018 16:00

Registration fee

Industry 1490 EUR¹
 Authorities/University 745 EUR¹
 Students² 178 EUR¹
 (¹plus VAT)

Registration

APV-Geschäftsstelle
 Kurfürstenstraße 59
 55118 Mainz/Germany
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 Fax: +49 6131 9769-69
 e-mail: apv@apv-mainz.de

Hotel reservation

Maritim Hotel Berlin
 Stauffenbergstraße 26
 10785 Berlin, Germany
 Telefon: +49 (0) 30 2065-0
 Fax: +49 (0) 30 2065-1000

Location

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 Fax: +49 (0) 30 2065-1000

Coffee breaks, luncheons,
 dinner and proceedings
 included.

²Limited places for full time stu-
 dents available; written evidence
 must be submitted.

You will receive a confirmation
 of your registration with the
 invoice.

APV has reserved a limited num-
 ber of rooms in the conference
 hotel. You will receive a room
 reservation form when you have
 registered for the conference.
 Reservation should be made
 directly with the hotel. Early
 reservation is recommended.

Mainz, November 2017



Registration

As soon as you have found a seminar of your inter-
 est, it is very easy to register for it via fax, e-mail
 or online. We will process your registration
 promptly and certainly are available for any questi-
 ons that may arise.

Registration confirmation

After your registration was successfully processed,
 you will receive a confirmation.

Before the event

A few days before the event starts, you will receive
 important information about the seminar, such as
 time, date, addresses etc.

After the event

You will receive a certificate confirming your parti-
 cipation. Furthermore, we would like to ask you to
 fill-in our evaluation sheet to make sure we get
 better every time.

Follow-up

After the event, we are open to receive any
 suggestions and critique that might arise during
 the seminar and will certainly help you with fur-
 ther questions you may have.

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