**SEMINAR**

FORUM
40 YEARS

# Biosimilars Market Access in the EU and USA

Settlement agreements in the USA and rights to get to market in the EU

## TOPICS

- Licencing or challenging patents in the USA
- Negotiating settlement agreements
- First to market requirements for the main EU markets
- Negotiating exclusivity rights for the EU markets

## YOUR SPEAKERS

**Jill M. Browning**
GREENBLUM & BERNSTEIN, P.L.C.
Reston, Virginia, USA

**Dr Gareth Morgan**
CMS Cameron McKenna Nabarro Olswang LLP,
London, UNITED KINGDOM

**Adam Levysohn**
Biogen International GmbH,
Zug, SWITZERLAND

**19 MAY 2020 IN BERLIN**

## Aims and objectives

This course will prepare you for a biosimilar market entry in the EU or USA. It will give you a deeper understanding of the available options for negotiating, licencing and challenging patents, and how to promote your market entry with a distinctive pre-launch communication and appropriate tenders.

## Who should attend?

This course is intended for managing directors, market access managers, legal and IP departments involved in placing a biosimilar product on EU or US markets.

## Limited number of attendees

This seminar is limited to 20 participants. This limitation, a feature of all FORUM seminars, enables participants to thoroughly discuss the complex issues covered by the programme.

## Your benefits

- Legal, IP and market access expertise rolled into one course
- A focus on the US and EU markets
- A small group to ensure there is enough time for questions

## YOUR SPEAKERS

**Jill M. Browning**
GREENBLUM & BERNSTEIN, P.L.C.
Reston, Virginia, USA

Partner, Patent Attorney

**Adam Levysohn**
Biogen International GmbH,
Zug, SWITZERLAND

Head of Global Market Access
Biogen Biosimilars Business Unit

**Dr Gareth Morgan**
CMS Cameron McKenna Nabarro Olswang LLP,
London, UNITED KINGDOM

Partner

## Quality garanteed

We follow the IMI quality criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards. An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 10.2017 -09.2018) produced a result of 1.6 (based on a school grading system of 1-6).

## Your programme 09:00 - 17:00

09:00

### Market access in the USA: Are settlement agreements essential?

**Jill M. Browning**

- Choosing the right (patent) strategy
- Identifying relevant patents, including secondary patents
- Determining whether to licence or challenge the patents
- Ways to challenge patents (Patent Dispute Resolution) in the US: patent office procedures, court actions outside the BPCIA and the BPCIA 'patent dance'
- Potential impact of proposed changes to the Biologics Price Competition and Innovation Act (BPCIA), such as the proposed Biologic Patent Transparency Act and other proposed legislation to address perceived shortcomings of the BPCIA

*10:30 Coffee break*

10:45

### How to close a settlement agreement in the USA

**Jill M. Browning**

- Negotiating and drafting settlement agreements before and during litigation
- Market and commercial activities the biosimilar applicant may engage in prior to the agreed launch date

11:45

### Biosimilars market access in the USA - main challenges

**Adam Levysohn**

*12:45 Lunch*

14:00

### Biosimilars market access in the main EU markets

**Adam Levysohn**

- Planning market entry dates - first to market requirements a top priority
- Preparing tenders (national and supranational)
- Prelaunch communication (national and supranational) - doctors, health insurance companies, ...

*15:15 Coffee break*

15:45

### Negotiating exclusivity rights to get to market in the EU

**Dr Gareth Morgan**

- Biosimilars regulatory path to market
- Design arounds, avoiding infringement of rights: secondary patent landscapes and specific issues for biosimilars
- Relevant SPC law and third party "squatting"
- SPC manufacturing waiver - what is it and will it assist?
- Tracking third parties: regulatory and product development timelines
- "Clearing the way" and other litigation strategies
- Coordinating litigation and EPO proceedings
- Considering arrow declarations

*16:45 Closing Discussion*

*17:00 Seminar end*

## Biosimilars Market Access in the EU and USA

### REGISTRATION UNDER

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## REGISTRATION FORM

Yes, I will attend

☐ Biosimilars Market Access in the EU and USA

☐ Yes, I agree that FORUM Institut may inform me about events by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

**Date and venue**
Tuesday, 19 May 2020 in Berlin
08.30 registration
09:00 - 17:00 seminar

Mercure Hotel MOA Berlin
Stephanstr. 41
10559 Berlin
Tel. +49 30 394043-0
Fax +49 30 394043-999

**Fee**
€ 1,190.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

## CANCELLATION POLICY

Our general terms and conditions (as of1 January 2016) apply and are available upon request.We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

## YOUR CONTACT

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