Practical applied training for the Pharmaceutical Industry

KEY LEARNING POINTS INCLUDE:

• **Key** intellectual property issues affecting pharmaceutical industry agreements
• **The new** Bolar provisions – when does R&D infringe patents
• **Key** commercial and legal issues affecting pharmaceutical industry agreements
• **Restrictions** and clauses which are permissible under EU competition law
• **Drafting** collaboration and licensing agreements
• **Strategies** and tactics to achieve win:win situations in your negotiations

INCLUDES practical and interactive exercises in negotiation and drafting to illustrate tips, tactics and techniques to achieve your commercial goals

A 3-DAY PRACTICAL AND INTERACTIVE seminar focusing on current contract drafting, negotiating, best practice and related issues within the pharmaceutical, biotech and life sciences sectors

“Calibre and knowledge of speakers was very high and impressive”
Isla Irvine, IP Admin Manager, Britannia Pharmaceuticals Ltd

“Enjoyable and informative”
Mike Isaacson, Company Lawyer, Dexcel Pharma Ltd

“I learnt a great deal about new areas and potential strategies to deal with these. The case studies were well thought out”
Dr Paul Madeley, Managing Director, Synth-Isis Ltd

www.falconbury.co.uk

3-5 June 2009 • London
Negotiating, Drafting and Understanding Commercial Contracts for the Pharmaceutical Industry

In such a highly regulated industry, understanding the key challenges of negotiation and drafting an effective and watertight contract on an international level is a complex topic. They can be difficult for even the most well equipped in-house lawyer and most often it is not the lawyer in the driving seat. Commercial managers from all areas of the pharmaceutical industry are leading negotiations and drafting and managing key contracts on a daily basis. It is vital that both legal counsel and commercial executives not only have the key skills and tactics to create a win:win scenario but also the knowledge to ensure any agreement is within the laws and regulations. The alternative is the exposure of the organisation to unnecessary risk and costly disputes.

Falconbury have developed this unique three-day programme that looks at both elements of the process. Using practical exercises, industry examples, and discussions to examine the key skills needed from both legal and commercial viewpoints and how they integrate.

The programme has been specifically designed for commercial managers and in-house counsel from all areas of the pharmaceutical industry to understand and perfect all stages of the process.

The programme consists of FIVE modules:

• **Module 1** will deliver an in-depth examination of intellectual property issues that affect pharmaceutical industry agreements
• **Module 2** will focus on competition regulations pertinent to pharmaceutical industry agreements
• **Module 3** analyses the commercial and legal issues affecting pharmaceutical industry agreements
• **Module 4** examines collaboration and licensing agreements
• **Module 5** is an in-depth workshop on effective negotiation skills

The key objectives of this seminar

By attending this seminar, you will:

• **UNDERSTAND** the key intellectual property issues affecting pharmaceutical industry agreements
• **FIND OUT** about the implications of SPCs for pharmaceutical industry agreements
• **GRASP** the impact of the Bolar provisions
• **LEARN** how to draft contracts to avoid anti-trust infringement
• **FAMILIARISE** yourself with the key commercial and legal issues that affect pharmaceutical industry agreements
• **GAIN** knowledge of the key issues in clinical trial agreements, contract manufacturing agreements and co-promotion, co-marketing and distribution agreements
• **UPDATE** yourself with latest developments in international privacy regulations
• **GET-TO-GRIPS** with the competitive nature of doing deals in the pharmaceutical industry and the tactics for effective and successful negotiation

Who should attend?

From R&D, clinical, regulatory, commercial, sales and marketing, manufacturing, distribution and purchasing functions, including:

• Commercial and contract managers
• Business development managers
• Purchasing and procurement
• In-house counsel
• Heads of legal departments
• Legal advisors
• Patent, IP, trademarks or licensing counsel

The delivery style

This highly interactive programme aims to deliver applied training through a balanced blend of practical learning. The presenters will use a mix of trainer input, a range of models and frameworks, practical exercises and business cases from the pharmaceutical industry to ensure you leave the programme with new skills and knowledge that can be put to use in the workplace straight away. Places are limited to ensure interactivity within the group.

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Interested in this course for your whole project team?

Please contact Caroline Glen on +44 (0)20 7729 6677 or email caroline.glen@falconbury.co.uk

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BOOK YOUR PLACE NOW! Call +44 (0)20 7729 6677 or email bookings@falconbury.co.uk
DAY ONE – 3 June 2009

0900 Registration and refreshments

Chair: Susan Singleton, Solicitor, Principal, Singletons

MODULE 1

Intellectual property issues affecting pharmaceutical industry agreements

0930 Intellectual property terms in collaboration and licensing agreements

• Ownership of internally and externally generated IP
• Joint ownership issues
• Outsourcing issues
• Improvements and grant backs

Tim Worden, Associate, Taylor Wessing

1015 SPC’s – Supplementary Protection Certificates

• What are SPC’s?
• What are the implications for pharmaceutical industry agreements?
• What does the SPC cover?
• Combination products
• The duration of the SPC
• Purified products
• Actives and quasi-actives
• Basic patents and basic follow-on SPC’s

Sarah Turner, Of Counsel, Lovells

1100 Refreshments

1115 When does R&D infringe patents? Understanding the new Bolar provisions

• Implications for clinical trials
• Limitations of experimental use defence to patent infringement
• The ‘Euro Bolar’ defence: Article 10(6) of Directive 2001/83/EC explained
• Patent infringement warranties and indemnities in clinical trials agreements

Sarah Turner, Of Counsel, Lovells

1245 Lunch

MODULE 2

Competition Law Workshop

Workshop leader: Susan Singleton

1400 Introduction to relevant EU competition law in Article 81 of the Treaty of Rome

• The Technology Transfer Block Exemption 772/2004
• Patent and know-how licensing in the EU
• Abuse of dominant market positions

1530 Refreshments

Case Study (1) – Restrictions in licences

Delegates will be given a licensing situation and a list of restrictions and clauses the parties want to include in a patent and know-how licence agreement. They will be asked in groups to analyse which restrictions and clauses are permissible under EU competition law and the Technology Transfer Block Exemption Regulation and how they may need to vary those restrictions so they are compliant with the law.

Sarah Turner

1700 Close of Day One

DAY TWO – 4 June 2009

0900 Refreshments

Chair: Susan Singleton

MODULE 3

Commercial and legal issues affecting pharmaceutical industry agreements

0930 Key issues in clinical trials and related agreements

• Pre-contractual documentation
• Key agreement terms
• General legal consideration in clinical research outsourcing
• Other background law

Laura Anderson, Partner, Bristows

1015 Key issues in contract manufacturing agreements

• The impact of the new regulatory requirements on contract manufacturing
• The importance of the GMP audit
• Issues with technology transfer
• Apportionment of risk and reward
• Secondary sources of supply
• Other key issues

Allistair Booth, Partner, Fasken Martineau

1100 Refreshments

1115 Key issues in co-promotion, co-marketing and distribution agreements

• Introduction to the agreements
• Scoping the deal
• Preparing for contingencies and termination
• Key characteristics of the distribution relationship
• Key terms – scope of rights and responsibilities, restrictions, minimum purchase requirements and territory

Stephen Reese, Partner, Olswang

1200 Dealing with privacy and data exclusivity issues

• Developments in international privacy regulation
• Personal data or anonymised information
• Data protection and personal data in contracts
• Due diligence – what are you looking for?
• Processor/controller agreements
• Licensing, transfer or sale of personal data
• Liabilities, remedies and indemnities

Cerys Wyn Davies, Partner, Pinsent Masons

1245 Lunch

MODULE 4

Collaboration and licensing agreements workshop

Workshop leader: Mark Anderson

1400 Negotiation of collaboration and licence agreements concerning pharmaceutical products

• Introduction to case study
• Attendees to discuss case study in groups
• General discussion of group findings
• Key issues arising out of the case study:
  - Use of term sheets
  - R&D collaboration; regulatory issues
  - Licensing and IP issues
  - Financial terms
  - Warranties
  - Performance obligations and termination rights
  - Boilerplate clauses, including law and jurisdiction

1700 Close of Day Two
DAY THREE – 5 June 2009

MODULE 5
Win-win negotiation skills in the pharma sector

Workshop leader: Rob McGuire

0900 Refreshments

0930 The rise and rise of the negotiator

Nothing exemplifies the modern pharma company as much as the growth of joint ventures, sub-contracting and licensing. All of these require the pharma executive to be able to negotiate and, often, to be able to lead others through the negotiation process.

- The increase in negotiated relationships
- Technical AND commercial skills
- Recognising a negotiation
- Great role models

1015 Practical exercise (including refreshments): negotiate and succeed

Working in teams, delegates are asked to resolve a multi-variable, multi-party business problem. The output of the exercise will form the backdrop for the following sessions on structure and influencing.

Structure for control

The research tells us that negotiation success is not related to any single aspect of the complex interactions that take place in any negotiation. However, above all else the party that negotiates best gets the best result. Key to negotiating well are controlling the negotiation and managing the process.

- Control for success: Key planning checklist to negotiate well
- Structure for success: The A.C.T.I.V.E™ model of negotiation
- Options for success: Creating the space to agree
- Trading for success: Understanding relative values

1245 Lunch

1400 Personal style and negotiation

This session helps us hold a mirror up so that participants can reflect on their own style. We look at why other styles irritate us – and how we negotiate with those people we find difficult to deal with.

- Our lead style (and our fall back style)
- The A to E of negotiating styles
- Personal strengths and weaknesses

1500 Refreshments

1515 Practical exercise: moving into engagement

Working in teams, delegates are asked to use their knowledge of their own style and those of others in their teams to agree strategies and tips for dealing with other styles and getting the most out of the negotiation.

Influencing and persuasion

It can be argued that the more we can influence someone to our position and the greater agreement we can build, the less we have to give away in our negotiation. This session looks at how people are persuaded and how the expert negotiator can use this knowledge to their benefit.

- Persuasion psychology
- The range of levers available
- Focussing your persuasion

1630 Close of Seminar
Date and Venue

3-5 June 2009
Grange White Hall Hotel
2-5 Montague Street
London WC1B 5BP
Tel: +44 (0)20 7580 2224
Web: www.grangehotels.com

Timetable

Registration is at 9am on the first day. The programme consists of 3 full days of training from 9am-5.00pm. The final day will start at 9.30am and finish at 4.30pm to allow extra time for travel home. Refreshment breaks and 1 hour for lunch will be scheduled each day. Participants are invited to stay for drinks at the end of day one.

Booking your place

To reserve your space on this programme please send your booking to:
Email bookings@falconbury.co.uk
Web www.falconbury.co.uk
Call +44 (0)20 7729 6677
Fax +44 (0)20 7729 6110
Post Falconbury Ltd, 10-12 Rivington Street
London EC2A 3DU, UK

Past delegate comments from other Falconbury pharma industry programmes

“Thanks for a great course”
Lars Sim Madsen, Head of Project Management, Neurosearch AS, Denmark

“Good examples from the pharma industry”
Dr Gregor Fachinger, Assistant to CEO, Schering AG, Germany

“The course was really excellent”
Dr Guiseppe Giardina, Deputy Chairman and CEO, Nikem Research, Italy

“…the standard of presenters was excellent”
Brid Brady, Solicitor, IDA, Ireland
NEGOTIATING, UNDERSTANDING AND DRAFTING COMMERCIAL CONTRACTS FOR THE PHARMACEUTICAL INDUSTRY

Yes I wish to attend:
☐ 3-5 June 2009, London, UK

For more than two delegates please photocopy this booking form

Please quote your reference number:

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5 WAYS TO BOOK

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Date and location
This training course will be held on:
3-5 June 2009
Grange White Hall Hotel, 2-5 Montague Street, London WC1B 5BP
Tel: +44 (0) 20 7580 2224 • Web: www.grangehotels.com

Fee
The fee for this three-day training programme includes all written materials, lunch and refreshments.

How to register and pay
A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit card, by bank transfer (for bank account details please see payment details section of booking form) or by cheque made payable to Falconbury Ltd and posted to the address above. VAT no. 770008751.

Any questions please contact Customer Services on +44 (0) 20 7729 6677. ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT

VAT Reclaim – International Delegates
If you are attending the course from outside the UK you can reclaim the VAT payable through HM Customs and Excise please visit their website at http://www.hmrc.gov.uk for a downloadable form or contact our customer services on info@falconbury.co.uk for more information.

Multiple booking discounts
A multiple booking discount of 10% is available on the 2nd and subsequent delegates booked at the same time from the same organisation. This discount can apply to any online discount but, unless otherwise stated this may not be used in conjunction with any other offer or the Falconbury Training Partnership Scheme.

Accommodation
Accommodation is not included in the course fee but we are able to help you find accommodation in the area. Information will be sent through on the booking confirmation. If you require information in the meantime please contact customer services at info@falconbury.co.uk, call +44 (0) 20 7729 6677 or visit our website www.falconbury.co.uk.

Always read the small print

CANCELLATIONS AND TRANSFER:
Once we have received your booking the place(s) is confirmed.
Up to 28 before the course
• Cancellations – 100% fee
• Transfers – 100% fee
• Substitute delegates – Free of charge
27 to 14 days before the course
• Cancellations – 100% fee
• Transfers – 10% fee
• Substitute delegates – Free of charge
13 to 0 days before the course
• Cancellations – 100% fee
• Transfers – 100% fee
• Substitute delegates – Free of charge
A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses.

ALL CANCELLATIONS MUST BE RECEIVED IN WRITTEN FORM

PARTNERSHIP CONDITIONS: The Falconbury Training Partnership Scheme cannot be used in conjunction with any other discount offer, including multiple booking discounts, unless otherwise stated or negotiated.

PLease note that payment must be made in advance of the event, Falconbury reserve the right to refuse admission if payment has not been received.
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