

A 3-day practical and interactive seminar

15-17 November 2010, London

Negotiating, Understanding and Drafting Commercial Contracts for the Pharmaceutical Industry

PRACTICAL APPLIED TRAINING FOR THE PHARMACEUTICAL INDUSTRY

17.5

CPD Hours

Solicitors Regulation
Authority

Focus on current contract drafting, negotiating, best practice and related issues within the pharmaceutical, biotech and life sciences sectors.

Key learning points include:

- IP terms in collaboration and licensing agreements
- SPC's, R&D infringements and third party rights
- Restrictions and clauses which are permissible under EU competition law
- Drafting workshops on collaboration and R&D agreements
- Challenges in clinical trials, contract manufacturing and co-promotion
- Practical strategies and interactive exercises in negotiation and drafting to illustrate tips, tactics and techniques to achieve your commercial goals

INCLUDES PRACTICAL AND INTERACTIVE EXERCISES
in negotiation and drafting to illustrate tips, tactics and techniques to achieve your commercial goals

Places are
limited

Book early to avoid
disappointment

save
50%

See inside for details
of The Falconbury
Training Partnership
Scheme



Visit our website: www.falconbury.co.uk

"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

Focus on current contract drafting, negotiating, best practice and related issues within the pharmaceutical, biotech and life sciences sectors.

Why should you attend?

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.

The programme consists of five modules which:

- 1 Will deliver an in-depth examination of intellectual property issues that affect pharmaceutical industry agreements
- 2 Will focus on competition regulations pertinent to pharmaceutical industry agreements
- 3 Will analyse the commercial and legal issues affecting pharmaceutical industry agreements
- 4 Will examine collaboration and licensing agreements
- 5 Features an in-depth workshop on effective negotiation skills

Who should attend?

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

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

The delivery style

This unique 3-day highly interactive programme looks at all the stages of the contracting process and aims to deliver applied training through a balanced blend of practical learning. The presenters will use a mixture of practical exercises and cases from the pharmaceutical industry to ensure you leave the programme with the knowledge and skills to perfect all stages of the process.

17.5 CPD Hours Continuing Professional Development

This course is accredited for 17.5 CPD hours by the Solicitors Regulation Authority (CPD reference CSC/FALI). After successfully completing the course you will receive a certificate stating the amount of hours and type of training you have completed.

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
- **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
- **GET-TO-GRIPS** with the competitive nature of doing deals in the pharmaceutical industry and the tactics for effective and successful negotiation
- **UPDATE** your practical skills when drafting effective collaboration agreements

"The course was really excellent"

Dr Guiseppe Giardina, Deputy Chairman and CEO Nikem Research

"Enjoyable and informative"

Mike Isaacson, Company Lawyer, Dexcel Pharma Ltd

Don't forget our...

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PHARMACEUTICAL IN-HOUSE TRAINING

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Falconbury have developed an extensive range of in-house training programmes designed specifically for the pharmaceutical industry in both face-to-face and distance learning format. Each programme can be developed for your needs or we can create something new that will specifically fit your business culture and development needs. Topics include: Understanding the Pharmaceutical Industry, Drafting Contracts for the Pharma Sector, a Pharma 'Mini-MBA' and many more.

For your FREE quote, please contact Caroline Glen on **+44 (0)20 7729 6677** or email inhouse@falconbury.co.uk

DAY ONE: 15 November 2010

0900 Registration and refreshments

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

PRACTICAL WORKSHOP

Participants look in more detail at sample clauses.

Tim Worden, Partner, Taylor Wessing, Cambridge

1100 Refreshments

1115 SPC's – Supplementary Protection Certificates

- What are SPC's?
- What are the implications for pharmaceutical industry agreements
- The duration of the SPC
- What does the SPC cover?
- Combination products
- Basic patents and basic and follow-on SPC's

Dr Luke Kempton, Partner, Wragge & Co LLP

1145 When does R&D infringe patents? Understanding the new Bolar provisions

- Implications for clinical trials agreements
- Limitations of experimental use defence to patent infringement
- The 'Euro Bolar' defence: Article 10(6) of Directive 2001/83/EC explained
- Varying scope of the defence across the EU
- Patent infringement warranties and indemnities in clinical trials agreements

Lindsey Woolley, Partner, Patent Attorney, Mewburn Ellis LLP

1245 Lunch

1345 Third party IP rights – 'Freedom to Operate' searches and implications for pharmaceutical industry agreements

- Patents and patent term extensions, utility models and quasi-patent term extensions
- Managing the patent search
- Evaluating your freedom to operate
- Scope of patents and infringement
- Different approaches to infringement in Europe
- Validity of the pertinent patents
- National invalidity/renovation actions and opposition proceedings or (cross) licensing
- Strategies for obtaining freedom to operate

Gareth Morgan, Partner and **Bonella Ramsey**, Partner, DLA Piper

MODULE 2: Competition law Issues affecting the Pharmaceutical Industry

Workshop leader: Marleen Van Kerckhove, Partner, Arnold & Porter LLP, Brussels

1445 Introduction to relevant EU competition law rules

- Article 101 TFEU: restrictive agreements and practices
- The Technology Transfer Block Exemption Regulation
- Vertical Agreements Block Exemption and Vertical Restraints Guidelines
- Specialisation Agreements Block Exemption
- R&D Agreements Block Exemption
- Horizontal Co-operation Guidelines

CASE STUDY 1

Restrictions in licences/settlement agreements

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 how they may need to vary those restrictions so they are compliant with the law. We will also discuss issues that could arise out of settlement agreements.

Refreshments

CASE STUDY 2

Co-promotion/co-marketing agreements

Delegates will be presented with a case study involving a series of competition law issues, which may arise from co-operation in R&D, promotion and sales, including exclusivity restrictions in the context of these kinds of agreements.

Feedback and analysis

1700 Close of Day One

DAY TWO: 16 November 2010

0900 Refreshments

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

1100 Refreshments

1115 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 LLP

1200 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

1245 Lunch

MODULE 4: Workshop on collaboration and R&D agreements

Workshop leader: Allistair Booth

1400 Negotiation of collaboration and licence agreements concerning pharmaceutical product

- 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: 17 November 2010

MODULE 5: 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

PRACTICAL EXERCISE AND REFRESHMENTS

1015 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. The keys to negotiating well are controlling the negotiation and managing the process.

- Control for success: Key planning checklist to negotiate well
- Structure 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

PRACTICAL EXERCISE

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
- Focusing your persuasion

1630 Close of Seminar



Book now for

Please quote your reference number:

6162/

Negotiating, Understanding and Drafting

COMMERCIAL CONTRACTS FOR THE PHARMACEUTICAL INDUSTRY

Yes I wish to attend:

15-17 November 2010, London, UK

Reference: 1494

For more than two delegates please photocopy this booking form

Please note if you are an EU organisation registered for VAT in your own country please use the price before VAT

IT IS IMPORTANT TO FILL OUT ALL THE INFORMATION BELOW

First participant's details *Please tick as appropriate*

£1399 + VAT = £1643.83 €1749 + VAT = €2055.08

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Second participants details

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Email _____

Any special requirements _____

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Mr/Mrs/Ms (surname) _____

First names _____ Job title _____

Tel _____

Email _____

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DATE AND LOCATION

15-17 November 2010

Grange White Hall Hotel

2-5 Montague Street

London WC1B 5BP

Tel: +44 (0)20 7580 2224 • Web: www.grangehotels.com

FEE

The full fee for this programme includes all written material, 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**

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A multiple booking discount of 15% is available on the 2nd and subsequent delegates booked at the same time from the same organisation. This discount may not be used in conjunction with any other offer or the Falconbury Training Partnership Scheme unless otherwise stated.

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 on +44 (0)20 7729 6677 or check our website for details www.falconbury.co.uk.

Always read the small print

CANCELLATIONS AND TRANSFER:

Once we have received your booking the place(s) are confirmed.

Up to 28 days before the course

- Cancellation – 10% administration fee
- Transfers – Free of charge
- 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.

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PLEASE NOTE: Falconbury Ltd reserve the right to change the content and timing of the programme, the speakers and the date and venue due to reasons beyond their control. If in the unlikely event that the course is cancelled Falconbury will refund the full amount and disclaim any further liability.

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The speakers

Laura Anderson is a partner at Bristows in London. Since joining Bristows 12 years ago, Laura has specialised in non-contentious IP matters. She has considerable experience of commercial arrangements relating to the development and exploitation of all kinds of intellectual property rights. Laura has expertise in the competition law aspects of commercial IP transactions and has spent time working in Brussels, both at the EU Council of Ministers and in private practice. Laura acts for clients across a range of sectors including life sciences.

Allistair Booth is a partner in Fasken Martineau DuMoulin LLP and Fasken Martineau LLP (London) and a member of the technology and intellectual property and life sciences practice groups. His experience includes in and out licensing, product sales and acquisitions, contract manufacturing, distribution, clinical trials, pharmacovigilance and outsourcing agreements, intellectual property and competition law as it affects the industry.

Rob Maguire runs his own consultancy and his experience spans the full range of issues from developing an appropriate contract strategy and building a performance dashboard to negotiation and conflict resolution to deal with the inevitable management issues that arise in any long-term relationship. Through his consulting, coaching, mentoring and skills development interactions, he helps major organisations transform their thinking and approach to their commercial relationships.

Gareth Morgan is a partner in the London office of DLA Piper's intellectual property department. Gareth has experience in all areas of contentious and non-contentious intellectual property law with a particular focus in the life sciences and healthcare sector including multi-jurisdictional patent litigation and enforcement strategies; contractual disputes and High Court contract litigation, negotiating commercial agreements including licences, technology transfer agreements and collaboration and development agreements and advising on the interpretation of EU medicines law and EMEA/MHRA guidance documentation.

Dr Luke Kempton is a partner in the intellectual property team of Wragge & Co, specialising in the life sciences sector. He has a PhD in biochemistry and works closely with other members of the experienced life sciences team. He specialises in patent litigation, licensing, collaborations and manufacturing agreements in the life sciences industry.

Marleen Van Kerckhove heads up Arnold & Porter LLP's European competition practice and its Brussels office. Her practice encompasses advice and representation before EU and national antitrust agencies on merger control, abusive conduct, price fixing and other restrictive practices, as well as litigation before European courts. She also advises on international trade regulation matters. She has advised extensively on the application of EU competition law to the pharmaceutical sector, and on the interplay between antitrust and intellectual property law.

Bonella Ramsay is a partner in the technology, media and commercial group of DLA Piper in London. She heads the London IP group and is joint head of the UK pharmaceutical and biosciences practice. As an intellectual property specialist, Bonella is involved in IP rights management and strategy for a wide range of clients as well as structuring and negotiating the exploitation of IP rights, including franchising arrangements. She has a particular focus on technology transactions for the pharmaceutical and biosciences sector.

Stephen Reese is a partner at Olswang where he advises clients on both contentious and non-contentious intellectual property matters including patents, trade marks, trade secrets and copyright. He has significant experience representing those clients within the life sciences and technology fields. In connection with his life sciences practice Stephen also advises clients on UK and EU regulatory matters within that sector.

Lindsey Woolley is Partner and Patent Attorney at Mewburn Ellis LLP, which she joined in 2002. Lindsey deals mainly with drafting and prosecution work and advises on portfolio management of interrelated patent families. Lindsey also deals with patent work in the biotechnology field, in particular molecular biology, biochemistry and biotechnology. Her clients include universities, research institutions and biotechnology companies. Lindsey has a degree in plant sciences from the University of Cambridge.

Tim Worden is Partner in the intellectual property department of Taylor Wessing. His practice includes both non-contentious and contentious intellectual property and he specialises in the life sciences and healthcare sectors. Tim was previously Legal Counsel and Company Secretary at Eli Lilly and Company Limited, the UK subsidiary of the US pharmaceutical company.

Date and Venue



15-17 November 2010
Grange White Hall Hotel
2-5 Montague Street
London WC1B 5BP
Tel: +44 (0)20 7580 2224
Web: www.grangehotels.com

For information on accommodation and preferential rates visit:
www.cityhotelaccommodation.com/ghh.html

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.

Booking your place

To reserve your space on this programme please send your booking to:

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"...the standard of presenters was excellent"

Brid Brady, Solicitor, IDA

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