

A 3-day practical and interactive seminar

7-9 June 2010, London

Negotiating, Understanding and Drafting

# COMMERCIAL CONTRACTS FOR THE PHARMACEUTICAL INDUSTRY

17.5

CPD Hours

Solicitors Regulation  
Authority

PRACTICAL APPLIED TRAINING FOR THE PHARMACEUTICAL INDUSTRY

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

**Key learning points include:**

- Key intellectual property issues affecting pharmaceutical industry agreements
- 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

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*"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

## THE PROGRAMME

# NEGOTIATING, UNDERSTANDING AND DRAFTING COMMERCIAL CONTRACTS FOR THE PHARMACEUTICAL INDUSTRY

7-9 June 2010, London

0900 Registration and refreshments

*Chair: Susan Singleton, Solicitor, Principal, Singletons*

**DAY ONE: 7 June 2010**

### 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, Partner, Taylor Wessing*

1045 Refreshments

1100 SPC's – Supplementary Protection Certificates

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

*Alison Blakey, Patent Counsel, IP Director, Prosidion Ltd*

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

*Lindsay Woolley, Partner, Patent Attorney, Mewburn Ellis LLP*

1245 Lunch

1345 Third Party IP rights, 'Freedom to Operate' searches and implications for pharma 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

*Sarah Turner, Of Counsel, Lovells*

### MODULE 2: Competition law workshop

*Workshop leader: Susan Singleton*

1445 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

#### 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.

1530 Refreshments

#### CASE STUDY 2

#### Other agreements encountered in the pharma industry

Delegates will be presented with a case study involving a series of competition law issues which arise from agreements such as R&D, clinical trial, consultancy and distribution agreements including exclusivity restrictions in the context of these kinds of agreements.

#### Feedback/analysis

1700 Close of Day One

**DAY TWO: 8 June 2010**

0900 Refreshments

*Chair: Allistair Booth, Partner, Fasken Martineau*

### 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

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- General legal consideration in clinical research outsourcing
- Other background law

*Laura Anderson, Partner, Bristows*

1030 Refreshments

#### 1045 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*

#### 1145 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: Collaboration and licensing agreements workshop

*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: 9 June 2010

### 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

#### 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. 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

#### 1345 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
- Focussing your persuasion

1630 Close of Seminar

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## 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**:

- 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 Analyses the commercial and legal issues affecting pharmaceutical industry agreements
- 4 Examines collaboration and licensing agreements
- 5 Is 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 business cases from the pharmaceutical industry to ensure you leave the programme with the knowledge and skills to perfect all stages of the process.

### *“The course was really excellent”*

Dr Guiseppe Giardina, Deputy Chairman and CEO Nikem Research

### *“Enjoyable and informative”*

Mike Isaacson, Company Lawyer, Dexcel Pharma Ltd

### *“...the standard of presenters was excellent”*

Brid Brady, Solicitor, IDA

## 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.

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## 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 licensing agreements

## Part of the Pharma LEGAL WEEK

This programme is part of the Falconbury Pharma Legal Week. Also attend:

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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.

**Alison Blakey** is the Patent Counsel and Senior Director of IP at Prosidion Ltd Chartered Patent Agent and European Patent Attorney. Alison entered the patent profession in 1990. She trained as a patent attorney with Fisons (now part of Sanofi-Aventis) and spent subsequent periods with Astra Pharmaceuticals, Zeneca, SmithKline Beecham, GlaxoSmithKline, Oxford GlycoSciences and Sagittarius Intellectual Property Consultants Ltd based in Marlow, UK. In October 2004 Alison joined Prosidion Limited, the Oxford based subsidiary of OSI Pharmaceuticals, Inc. which is focused on the identification of small molecule therapies for diabetes and obesity, as Patent Counsel and Senior Director of IP.

**Allistair Booth** is a Partner in Fasken Martineau LLP and a member of the Life Sciences Practice Group. Allistair has been providing commercial, regulatory and intellectual property advice to companies in the life sciences sector since 1997. Prior to joining Fasken Martineau, Allistair had specialised in intellectual property law for 10 years. He is on the Finance and Taxation Advisory Committee of the UK BioIndustry Association and is one of the firm's representatives to BioLegis, its European wide network of life sciences specialist law firms. Allistair has extensive experience with substantial, often pivotal, licensing transactions, product sales and purchases, strategic product development and life cycle management advice and large scale outsourcing.

**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.

**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.

**Susan Singleton** is a solicitor with her own London firm, Singletons, which specialises in intellectual property law, including trade marks and competition law and Internet law and general commercial law. Articled at Nabarro Nathanson, she joined Slaughter and May's EC/Competition Law Department on qualifying in 1985, moving to Bristows in March 1988, where she remained until founding her own firm in 1994. Since then she had advised over 410 clients. In 2002 she acted for the claimant in the first damages action for breach of the EU competition rules to come before the English courts *Arkin v Borchard and Others*.

**Sarah Turner** is Of Counsel in the Intellectual Property Group of Lovells. She is based in London and is a member of the firm's Life Sciences Team. Sarah advises on all aspects of intellectual property but specialises in patent litigation and the protection of confidential information. Sarah has a particular interest in the pharmaceutical and biotechnology sectors and has acted for companies in these sectors in large pan-European patent infringement and revocation actions.

**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 a partner in Taylor Wessing LLP's intellectual property department, and is based in the firm's Cambridge and London offices. He specialises in transactional, non-contentious and regulatory intellectual property in the life sciences, IT and hi-tech sectors. He advises on a range of IP, IT and commercial agreements, such as technology and software licences, collaboration agreements, research and development agreements, clinical trials agreements, a range of services agreements and regulatory issues in the pharmaceutical industry. 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



**7-9 June 2010**  
**Grange Holburn Hotel**  
**50-60 Southampton Row**  
**London WC1B 4AR**  
**Tel: +44 (0)20 7242 1800**  
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For information on accommodation and preferential rates visit:  
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## 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.

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FEE

The full fee for this programme includes all written material, lunch and refreshments.

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