European Forum on

PHARMA/BIOTECH
IP DUE DILIGENCE

28 and 29 October 2008
Radisson SAS Amsterdam, Netherlands

Top IP practitioners, experienced in-house counsel, valuation experts and tech-transfer officers will provide you with valuable insight on preparing for your next diligence review and cut through the complexities of:

- Drafting the checklist and managing the due diligence team
- How to reposition your due diligence strategies in light of European and US patent reforms
- The diligence review in transactions involving venture capitalists
- Finding the target’s prior contractual obligations
- Evaluating the scope, validity, and enforceability of the target’s patents
- Complex multi-jurisdictional and multi-party transactions
- Uncovering hidden issues with ownership and inventorship rights
- Competition law issues and their impact on due diligence

Maximise Your Learning With the Post-Conference Master Class on:
Drafting an Effective Due Diligence Report

Get industry insight from:
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NKT Holding
Global Bioscience Development Institute
Lundbeck
Celgene Corporation
IPSEN – SCRAS
Valuation Consulting
Cambridge Healthcare and Biotech
Columbia University
Bavarian Nordic
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Best Practices for Conducting Successful and Cost-Effective IP Due Diligence Reviews

The continued growth of collaborative activity in the life sciences space, ranging from M&A, spin-outs and licensing, to divestitures and joint product development, mean that IP due diligence is a central concern for life sciences companies. Failure to conduct due diligence properly can result in significant reputational damages, decreased investment value and open the door for future debilitating litigation.

As the person responsible for ensuring the IP’s value, you need to have expert knowledge about deal structure, which assets are important and fully understand the business drivers behind the transaction. The range of due diligence failures by biotech and pharma investors and companies that have come to light in courtrooms in recent years should serve as a caution to every person involved in life sciences to do more than just scratch the surface in IP due diligence.

With this in mind C5 has developed the European Forum on Pharma/Biotech IP Due Diligence. An unparalleled faculty will provide you with best practices for conducting a successful and cost-effective IP due diligence review.

Add value to your attendance by taking advantage of the Master Class for Drafting an Effective Due Diligence Report. This in-depth workshop will provide practical advice and the tools you need to draft a comprehensive report of findings.

Take advantage of ample networking opportunities with your peers and colleagues and benefit from the extensive written materials prepared by the speakers especially for event.

Reserve your place at this invaluable conference today! Register now by calling +44 (0) 20 7878 6888, by faxing your registration form to +44 (0) 20 7878 6896 or by registering online at www.C5-Online.com/IPDD

WHO SHOULD ATTEND

In-house IP Counsel at
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Lawyers specialising in
  • Life Sciences, Pharmaceuticals and Intellectual Property

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FACULTY-AT-A-GLANCE:

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President
Global Bioscience Development Institute Inc

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Director, Sterne Kessler Goldstein Fox

Richard Girards
Patent Counsel, Celgene Corporation

Richard Williams
Partner, Harrison Goddard Foote

Dr Li Westerland
Vice President Global IP
Bavarian Nordic

Tim Powell
Partner, Powell Gilbert Solicitors

Kelvin King
Director, Valuation Consulting

Anette Hegner
former IP Manager NKT Holding A/S,
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Vice President, Corporate Intellectual Property, IPSEN – SCRAS

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Jeroen den Hartog
Of Counsel, Howrey LLP

Natalie Derzko
Special Counsel, Covington & Burling LLP

Martyn Postle
Director
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Sangeeta Puran
Senior Associate
Mayer Brown International LLP

James Marshall
Partner, Taylor Wessing LLP

Patrick Lee
Partner, Advent Venture Partners LLP

Anna Griffiths-Johnson
Senior Patent Attorney, AstraZeneca

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8.00 Coffee and registration

8.35 Chair’s Opening Remarks

Jeroen den Hartog
Of Counsel, Howrey LLP

8.45 European and US Patent Reform Developments and How They Impact Your Due Diligence

Panellists:

Dr John Kilama
President, Global Bioscience Development Institute, Inc.

Dr Brian Del Buono
Director, Sterne Kessler Goldstein & Fox P.L.L.C

Morag Peberdy
Of Counsel, Herbert Smith LLP

Tim Powell
Partner, Powell Gilbert Solicitors

- How proposals to reform US Patent Law will affect the diligence process
  - reforms to give judges authority to direct juries on infringement compensation
  - post-grant review and establishing cost-effective alternatives to litigation
  - complex applications and the need for patent quality at the front end of the process
- Assessing the consequences GlaxoSmithKline v USPTO injunction
  - the reason for the objection to the rule changes
  - impact on European companies with US portfolios
- European Commission proposed patent reform
  - the European Patent Litigation Agreement (EPLA)
  - establishing a ‘European Patent Court’ and a workable litigation scheme for European patents
- Revival of applications for unintentional versus unavoidable abandonment

9.30 Assessing the Scope of Due Diligence Required According to the Importance and Complexity of the Transaction

Richard Girards
Patent Counsel, Celgene Corporation

Kate Taylor
Senior Associate, Harrison Goddard Foote

- Identifying what “IP due diligence” means to the parties involved and adjusting strategies accordingly
- Conducting a cost-effective due diligence review based on the company’s needs
- Timing of due diligence actions: what should come first?
  - balancing the risk of “contamination” and potential walk away disputes against the need to be first to the deal
- Determining the appropriate scope, depth and budget of IP due diligence necessary for
  - internal IP assessment
  - audits
  - venture based financing
  - strategic alliances
  - spin outs
- mergers and acquisitions
- Multijurisdictional transactions
  - which jurisdictions are covered by the transaction?
  - establishing which jurisdiction will lead the due diligence work
- Dealing with the issue of worldwide rights
- Patent portfolio development with future due diligence in mind
  - thinking proactively about multi-jurisdictional patent applications
  - discrepancies between owner and inventor in China and Japan

10.15 Morning Refreshments

10.45 Tips For Drafting the Checklist and Selecting and Managing the Due Diligence Team

Dr Li Westerlund
Vice President Global IP, Bavarian Nordic

- Defining technologies and focussing on the most important issues
- obtaining the full list of IP assets
- defining the term of patents
- Identifying and prioritising business considerations
- Updating the checklist based on the type of the transaction
- patent life cycle issues
- violative marketing or pricing concerns
- fraud and abuse or anti-kickback issues
- clinical trials
- regulatory considerations
- product supply and manufacture issues
- trade secrets and other proprietary information
- what is in the pipeline?
- When should you deviate from the checklist?
- Choosing and managing the team
  - getting in-house IP and patent counsel involved early in the deal
  - outside counsel selection
  - are other experts necessary?
- Creating and incentivising a core IP diligence team
- Assigning roles for senior management and involving the supporting players
- Developing mechanisms for supporting cross-functional teams and optimising their efficiency
- Minimising liability and expenses by managing the process with respect to timelines, budget and resources
- Examples from different checklists

11.30 Valuation Methodologies Critical to the Due Diligence Review

Kelvin King
Director, Valuation Consulting

- The nature of valuation for patent-protected products and related intangibles such as brands
- Identifying the factors that business executives use to arrive at a starting value
- Factors impacting IP valuation including type of acquisition, deal objectives and type
- Balancing investment risks, rewards and adjusting diligence review during the valuation process
- Assessment of valuation methodologies
  - unique IP due diligence concerns
  - impact of licensing transactions on IP due diligence
- How securitisation/monetisation of IP and royalty streams affect valuation

12.15 Lunch


Martyn Postle
Director, Cambridge Healthcare and Biotech

Sangeeta Puran
Senior Associate, Mayer Brown International LLP

Get first-hand insight into the results of a recent study conducted with life sciences market participants on the methods being used to identify commercially viable innovation, including differences in approaches taken, key challenges in forecasting and valuation and financial deal terms (including upfront and events payments). Further analysis will be given via analysis of recent license, co-development and alliance deals in relation to:

- Key legal diligence issues relevant to addressing assumptions and risks underlying valuations.
- Typical contractual controls relevant to risks and assumptions underlying financial modelling used to address completion of:
  - development (discovery, pre-clinical, clinical, regulatory) phases:
    - discovery, pre-clinical and clinical
    - commercialisation phases
- Launch, promotion and pricing within forecasted timelines and controls in connection within investments.
- Grant of rights underlying market forecasts

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16.30 The Growing Importance of Secondary-Patents and Resulting Impact on the Due Diligence Process

Andre Bourgouin  
Vice President, Corporate Intellectual Property, IPSEN – SCRAS  
- How recent case-law decisions on secondary-patents have affected the due diligence process  
- Assessment of key developments in inventions and the resultant challenges relating to:  
  - new chemical entities  
  - salts  
  - enantiomers  
  - metabolites  
  - pharmaceutical compositions  
  - new formulations in particular slow release formulations  
  - new combinations  
  - medical use of the product  
  - new indications  
  - new group of patients  
  - new regimen of administration

17.00 Update on Regulatory Provisions and Regulator Enforcement Priorities Affecting the Due Diligence Process

Dr. Lincoln Tsang  
Partner, Arnold & Porter LLP  
- Understanding the risks related to the regulatory process and to product development generally  
- regulatory exclusivity  
- How past regulatory non-compliance affects the product value and what this means for your report  
- Assessing the acquirer’s intention for the product and the regulatory impact of the intended final use  
- Working with the US FDA on transactions affecting US assets  
  - FDA critical path and its impact on due diligence  
  - EMEA perspective on transactions involving IP  
- Collaborative pharma/bio regulation between the FDA and EMEA: how will this affect multi-jurisdictional deals?

17.30 Spotting and Responding to Competition Law Red Flags in Target IP Portfolios

Jolling De Pree  
Partner, De Brauw Blackstone Westbroek  
- Recent competition enforcement activity in the pharma/biotech sector  
  - EU Commission dawn raids  
  - new approach to evaluation of licensing arrangements on the EU and national level  
  - how is unreasonable conduct currently being interpreted  
  - potential for abuse of market power with the use of intangible assets  
  - current definition of dominant position  
- Identifying possible infringements of competition law in target IP portfolios to avoid future fines, damages and invalidity actions  
  - field of use, territorial and other limitations in existing licensing agreements  
  - previous mergers and transactions  
- What to do if you find evidence of anti-competitive behaviour  
- Utilising patent pools in the biotech industry to prevent non-compliance with competition law

18.00 Chair’s Closing Remarks and End of Day One

Main Conference Day Two: October 29 2008

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12.10 How Do the US Hatch-Waxman Backdrop and Possible Developments in Follow-On Biologics and Biosimilars Impact Due Diligence?

Natalie Derzko
Special Counsel, Covington & Burling LLP

- How will recent changes affect a global IP portfolio?
- The European Medicines Agency (EMEA) approval scheme for distinguishing biosimilars and generic drugs
- Why has the generic approach been deemed inappropriate?
- Clarifying the US statutory pathway for the approval of follow-on biologics
- Understanding the complexities of biologics when compared with small molecule chemical drugs
- Identifying critical aspects of FDA regulation relative to an IP due diligence review
- Pharmaceutical patent life cycles and related Hatch-Waxman Act backdrops
- 1984 law and MMA reforms
- Patent and non-patent exclusivities
- 30-month stay
- Patent extensions
- Safe harbor provisions
- How the "useful" life cycle of a patent impacts transaction value and associated risks
- Projecting the scope of exclusionary rights on the product
- Confirming the target's analysis of the expiration date of the patent
- Assessing patent terms through adjustments and extensions

12.50 Chair's Closing Remarks

14.00 – 17.30 Drafting an Effective Due Diligence Report

James Marshall
Partner, Taylor Wessing LLP

The surge of M&As, private equity investments, and IPOs in the life sciences industry, as well as the need to present findings by IP right, product, and R&D activity have made drafting an effective due diligence report a critical skill.

This master class is designed to provide you with tools to enable efficient and comprehensive drafting of the due diligence report. Common mistakes and pitfalls will be identified and best practice examples given during an intensive, expert-led session. Your master class leader will instruct you on how to draft a comprehensive and effective report of due diligence findings. You will discover how to tailor your diligence report to your specific business needs while taking into consideration the following:

- Ascertaining the structure and essential elements of due diligence reports for:
  - Private equity investments
  - Acquisitions
  - IPOs
  - Plain technology transfers
  - Determining the scope of, and any limitations on the investigation
  - Drafting the executive summary
  - Presenting the search results and patentability/validation analysis
  - Assessing the scope of available patent protection
  - Addressing any obligations associated with the use of the technology to be transferred
  - Presenting the freedom-to-operate search results and analysis
  - Identifying other risks or problems and stating whether they have been resolved
  - Assessing potential exposure and the chance of the adverse party
  - Weighing the effect of any disclaimers and limitations of liability
  - Factoring in risks associated with future products and agreements in the works
  - Noting post-completion recommendations: what the buyer should do once the deal is finalised
  - Knowing what else should be included in (and excluded from) the report
  - Limiting distribution of the report to preserve confidentiality and privilege

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ADMINISTRATION DETAILS

CONFERENCE
Date: 28-29 October 2008
Time: 8.00am (Registration and distribution of documentation from 8:15am)
Venue: Rusland 17
1012 CK Amsterdam, Netherlands
Phone: +31 20 5208300
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Post-Conference Workshop Drafting an Effective Due Diligence Report
Date: 29 October 2008
Time: 2:30pm - 5:30pm

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