SETTLEMENT AGREEMENTS AND PATENT ABUSE IN THE PHARMACEUTICAL SECTOR

AN EU/US COMPARISON

20 October 2010, The Stanhope Hotel, Brussels

Chairman: Stephen Kon, Partner, SJ Berwin LLP

Delegates will receive practical analysis and advice on:

- AstraZeneca and the Commission’s pharma policy
- Market definition and dominance in the pharma sector following AstraZeneca – what does it mean for your company?
- Unilateral conduct – when does it risk infringing antitrust rules? A view from the EU and the US
- EU and US approach to settlement agreements
- Roundtable: a follow up on the EU inquiry at national level

Speakers from the European Commission, law firms, economic consultancies and industry include:

Dominik Schnichels
Head of Pharma Task Force
DG Competition, European Commission

Cameron Firth
Partner
SJ Berwin LLP

Mike Walker
Vice President
Charles River Associates

Gavin Robert
Partner
Linklaters LLP

Marleen van Kerckhove
Partner
Arnold & Porter LLP

Jeffrey Schmidt
Partner
Linklaters LLP

Asim Varma
Partner
Arnold & Porter LLP

Melanie Thill-Tayara
Partner
Norton Rose

James S. Venit
Partner
Skadden Arps Slate Meagher & Flom LLP

Jordi Faus
Partner
Faus & Moliner Abogados

David Rosenberg
Vice President, Corporate IP Policy
GlaxoSmithKline

Thomas Wessely
Partner
Freshfields Bruckhaus Deringer LLP


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6 CPD hours
The pharmaceutical sector continues to be one of the main focus areas for competition authorities throughout the world. This conference provides an update on the major developments affecting the sector including the General Court’s recent judgment in the AstraZeneca case — the first judgment on dominance and abusive practices in the pharmaceutical sector.

On 1 July 2010, the General Court handed down its long-awaited judgment upholding a 2005 decision from the European Commission that found that AstraZeneca had abused its dominant position, in breach of Article 102. The judgment sets an important precedent that will be taken into account by the Commission in its ongoing investigations and is likely to be used as the basis for increased focus on practices adopted by originator pharmaceutical companies with a view to fending off generic competition.

This is the first judgment relating to the application of Article 102 in the pharmaceutical sector and also where misuse of a regulatory procedure has been found to constitute abusive conduct. The use or misuse of regulatory procedures is one of the areas identified by the Commission in its recent Sector Inquiry as requiring increased scrutiny.

Our panel of expert speakers will provide important guidance on key issues emerging from the judgment and the Commission’s Sector Inquiry including:

- Market definition and assessment of dominance or market power taking into account the specificities of the pharmaceutical sector;
- Abusive conduct taking into account various life cycle management practices used in the industry and, in particular, the relationship between the competition rules and intellectual property rights and also between the competition rules and regulatory procedures.

The Commission also identified the need to monitor patent settlement agreements between originator companies and generic producers. The Commission recently published the first results of its monitoring exercise of patent settlements between originator companies and generics producers showing a decline in those agreements that the Commission considers problematic. The report provides little guidance to companies on how best to structure settlement agreements to ensure compliance with the competition rules, although it is anticipated that ongoing investigations by the Commission may provide some guidance in this area.

Settlement agreements have been under focus in the US for some time with the House of Representatives recently passing a package of amendments intended to curb pharmaceutical patent settlement agreements – the ‘pay-for-delay’ deals between research based pharmaceutical companies and generic drug makers. It is anticipated that the EU will draw upon the US experience when determining whether to challenge patent settlement agreements and our panel of EU and US speakers will be providing crucial guidance on these issues.

Speakers at this conference include senior lawyers and economists from both the EU and US, the European Commission and industry who will address these issues, the recent rulings and current investigations and their implications for the pharmaceutical sector in years to come.

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## PROGRAMME

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<td>09.10</td>
<td>Keynote address <strong>AstraZeneca and the Commission’s pharma policy</strong></td>
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<td>Dominik Schnichels, Head of the Pharma Task Force, DG Competition, European Commission</td>
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<td>09.35</td>
<td>Market definition and dominance in the pharma sector following <strong>AstraZeneca</strong> – What does it mean for your company?</td>
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<td>- Market definition in the presence of innovation, patents and price regulation</td>
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<td>- Dominance: power over price vs. power to exclude</td>
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<td>Mike Walker, Vice President, Charles River Associates</td>
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<td>10.10</td>
<td>Coffee</td>
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<td>Unilateral conduct – When does it risk infringing antitrust rules?</td>
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<td>A view from the EU and the US</td>
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<td>- Use and misuse of regulatory procedures</td>
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<td>- Patent filing and patent enforcement</td>
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<td>- Product switching</td>
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<td></td>
<td>Marleen van Kerckhove, Partner, Arnold &amp; Porter LLP</td>
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<td>Asim Varma, Partner, Arnold &amp; Porter LLP (Washington DC)</td>
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<td>11.50</td>
<td>Roundtable discussion and Q&amp;A session</td>
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<td>The speakers will be joined by</td>
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<td>James S. Venit, Partner, Skadden Arps Slate Meagher &amp; Rom LLP</td>
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<td>Cameron Firth, Partner, SJ Berwin LLP</td>
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<td>David Rosenberg, Vice President, Corporate IP Policy</td>
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<td>GlaxoSmithKline</td>
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<td>12.40</td>
<td>Lunch</td>
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<td>EU and US approach to settlement agreements</td>
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<td>- Recent legal developments</td>
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<td>- FTC investigations and US court case law</td>
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<td>- The EU Pharma inquiry, and follow-up monitoring</td>
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<td>Gavin Robert, Partner, Linklaters LLP</td>
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<td>Jeffrey Schmidt, Partner, Linklaters LLP (New York)</td>
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<td>Roundtable: A follow-up on the EU Inquiry at National Level</td>
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<td>A series of short presentations on specific Member States</td>
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<td>France: Mélanie Thill-Tayara, Partner, Norton Rose</td>
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<td>Spain: Jordi Faus, Partner, Faus &amp; Moliner Abogados</td>
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<td>Germany: Thomas Wessely, Partner, Freshfields Bruckhaus Deringer LLP</td>
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<td>£550 + 21% TVA = £665.50</td>
<td>£450 + 21% TVA = £544.50</td>
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<td>After 15 September 2010</td>
<td>£650 + 21% TVA = £786.50</td>
<td>£550 + 21% TVA = £665.50</td>
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## Administrative details

**Date**  
Wednesday 20 October 2010

**Venue**  
The Stanhope Hotel  
Rue de Commerce 9  
1000 Brussels  
Belgium  
Tel: +32 2 506 9031  
www.thonhotels.be/stanhope

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- Mail this completed form to GCR Conferences, Global Competition Review, 87 Lancaster Road, London, W11 1QQ

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