Hogan Lovells

Lifecycle management and antitrust

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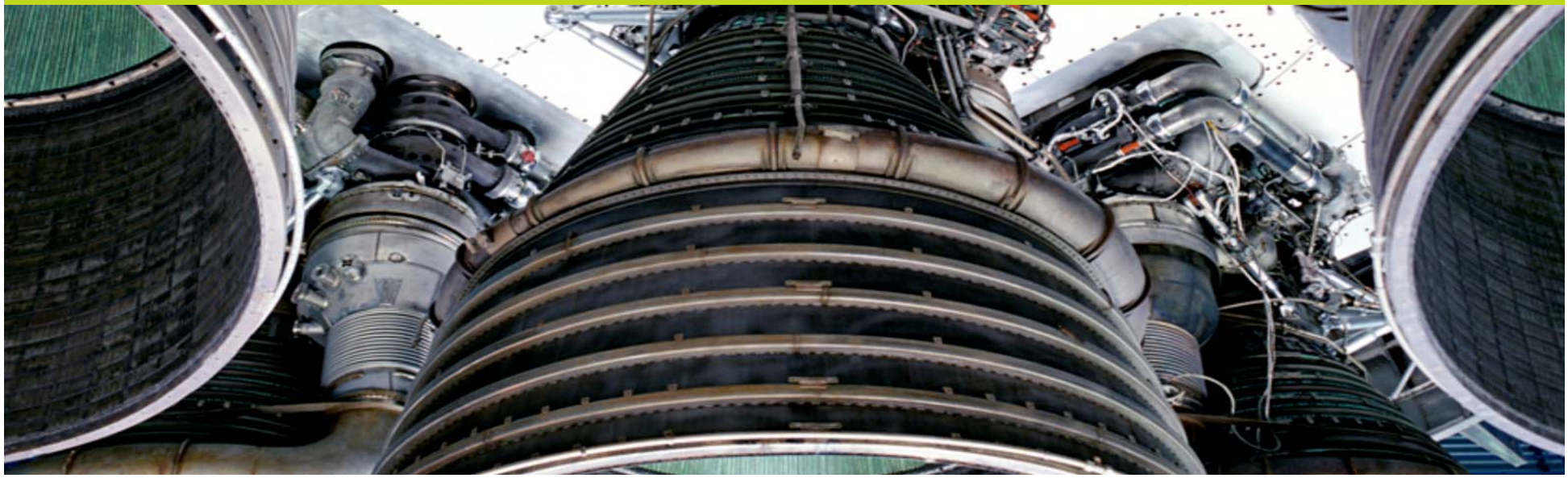
17 May 2010

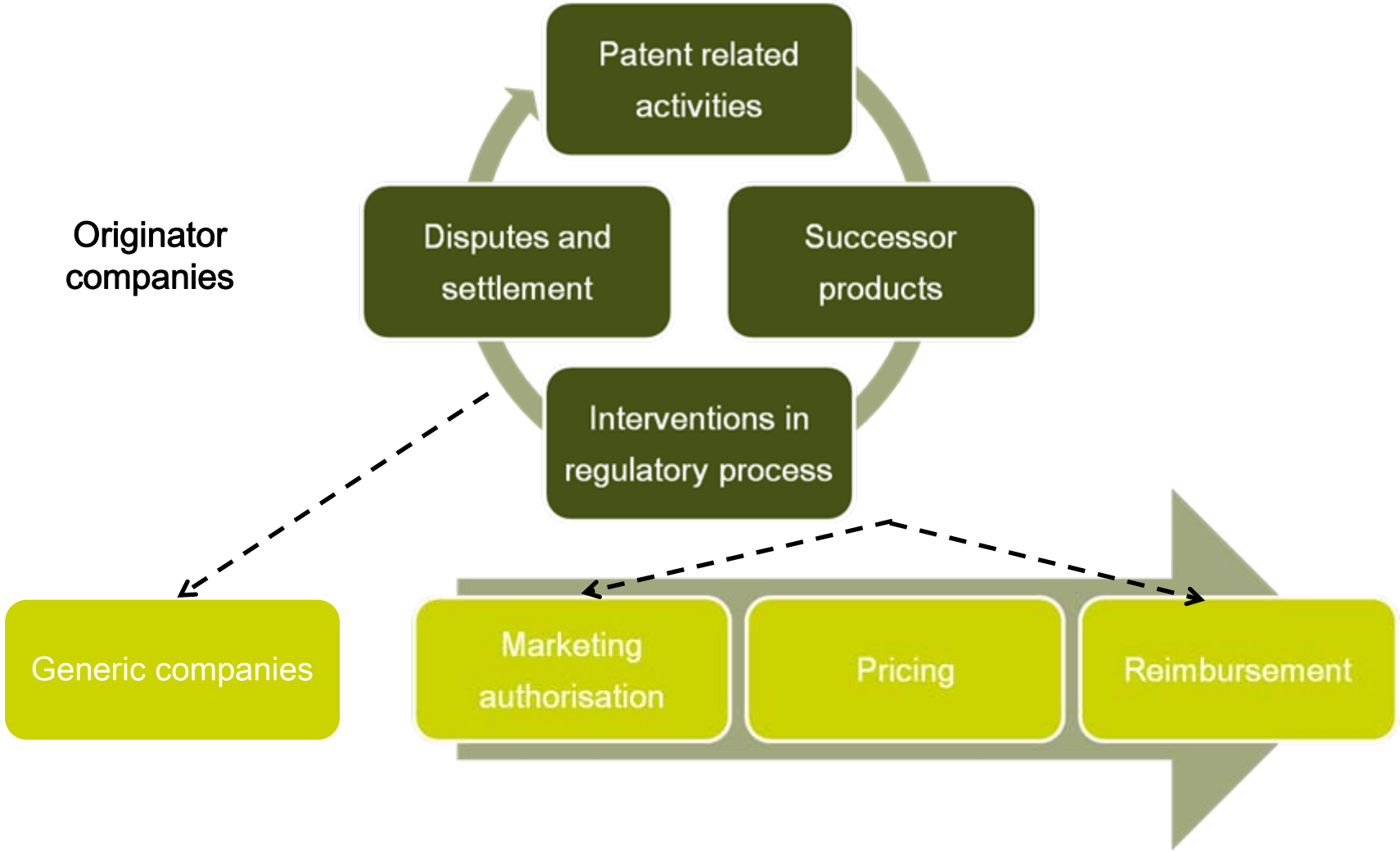
The Fourth International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum



Lifecycle management in a market and antitrust context

- Lifecycle management involving product development and regulatory and patent protection for successor products is an important aspect of the business plans of research-based pharmaceutical companies
  - Changes/ improvements in formulation or method of delivery, changes/ improvements in indications or labeling, transfer of marketing to successor drugs, withdrawal of an original drug from the market
- EU Pharmaceutical Sector Inquiry and an ongoing case in the UK (*Gaviscon*) have highlighted whether lifecycle management can be challenged under European competition law
- US antitrust cases have considered lifecycle management but no clear theory of harm

Lifecycle management and related strategies examined in the EU Pharmaceutical Sector Inquiry



EU Pharmaceutical Sector Inquiry Final Report

"The findings indicate that originator companies use a variety of instruments to extend the commercial life of their medicines. The results of the sector inquiry suggest that the behaviour of companies contributes to the generic delay."

Pharmaceutical Sector Inquiry Final Report, Executive Summary, page 10

UK Office of Fair Trading investigation

OFT issues Statement of Objections for alleged abuse of a dominant position by Reckitt Benckiser

23 February 2010

The OFT has today issued a Statement of Objections alleging that Reckitt Benckiser abused its dominant position in the market for the NHS supply of alginate and antacid heartburn medicines.

The OFT alleges that Reckitt Benckiser sought to restrict competition to its Gaviscon brand by withdrawing and de-listing its NHS packs of Gaviscon Original Liquid from the NHS prescription channel.

The OFT alleges that the withdrawal of NHS packs of Gaviscon Original Liquid from the NHS prescription channel was deliberately timed to occur before the publication of the generic name for this product so that when GPs search for 'Gaviscon' prescription packs they will identify Gaviscon Advance Liquid, which is patent protected, and not Gaviscon Original Liquid, for which an 'open' prescription could otherwise be provided.

US antitrust cases

Tricor (*Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* (2006))

- Abbott introduced a tablet form of Tricor, ceased selling the capsules and changed the code to "obsolete" in the National Drug Data File
- Court denied motion to dismiss but concluded an antitrust inquiry into the benefits provided by Abbott's products was required

Prilosec and Nexium (*Walgreen Co. et al v. AstraZeneca Pharmaceuticals* (2008))

- As the patent for Prilosec was nearing expiration, AstraZeneca introduced and marketed a successor drug, Nexium
- Court dismissed complaint; Prilosec remained on the market
- No antitrust requirement that the new product be superior to the old as that decision could be left to the market to decide

Summary principles

EU Pharma Sector Inquiry has focused attention on practices by pharma companies to seek to extend the period of exclusivity of their patent rights

Final Report displays a more tempered approach but important cases remain to be decided

Combination of several practices which are lawful will not in itself be problematic under competition law

Care needed where a risk of dominance and exclusion of generic entry

Examples of areas to watch:

Secondary patenting and successor products

Interventions before regulatory and patent authorities

Disputes and settlement

Changes in product formulations

Changes in delivery, distribution and marketing

Withdrawal of prior product from the market

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