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New Regulatory Actions Underscore Global Antitrust/Competition Risk of Altering Product Offerings in Light of Imminent Generic Competition



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Recent EU regulatory actions and statements by U.S. antitrust regulators have directed attention to practices employed by brand name drug manufacturers whose key products are facing patent expiration. The specific conduct in question—called ''product hopping'' or ''product switching'' by some—involves efforts to escape the financial consequences of generic entry by steering consumers to new and improved versions of the products coming off patent. The recent developments have increased the likelihood of challenges to such actions going forward and, with that, potential differences as to how the key legal questions are analyzed on both sides of the Atlantic have taken on greater significance for strategic planning.

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The EU Approach

In the EU, the UK Office of Fair Trading (''OFT'') announced in October 2010 that global drug manufacturer Reckitt Benckiser had agreed to pay a GBP 10.2 million fine in connection with the withdrawal and de-listing of Gaviscon Original Liquid from the National Health Service prescription channel in 2005.[1] The patent for Ga-

[1] See OFT Press release ''Reckitt Benckiser agrees to pay £10.2 million penalty for abuse of dominance,'' October 15, 2010. The fine was later confirmed by the OFT in a formal de-

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viscon Original Liquid had expired, and doctors were prompted to prescribe Gaviscon Advance Liquid, a newer version of the product that is patent protected until 2016. The effect of *de-listing* the older product was to deter the dispensing of the generic form of the delisted product to customers who brought in prescriptions for Gaviscon. The fine followed an allegation by the OFT that Reckitt Benckiser's action was deliberately timed to restrict competition from generic rivals. As part of its settlement, Reckitt Benckiser admitted that its actions violated UK and EU competition law.

Earlier in 2010, the EU's General Court (''General Court'') rejected an argument by AstraZeneca that the withdrawal or de-registration of product registrations for a patent protected product, Losec (omeprazole), a Proton Pump Inhibitor (''PPI'') (branded as ''Prilosec'' in the United States), was a legitimate exercise of its patent rights. The General Court found that AstraZeneca's actions had the effect of preventing or delaying for a period of between 6 and 10 years the launch of generic equivalents to Losec in Scandinavia, to the benefit of AstraZeneca's new formulation of Losec. The General Court concluded that AstraZeneca's actions were *intended* to delay generic entry, and that there was no objective justification for the withdrawals other than to make generic entry more difficult. In its judgment, the General Court noted that the fact AstraZeneca was not in a dominant position when the abusive behavior produced its effects did not matter: When the acts were committed, AstraZeneca had a responsibility not to abuse its position and impair genuine competition on the market.

The pharmaceutical industry has also come under recent scrutiny in Italy. On October 26, 2010, at the instigation of a generic manufacturer, the Italian competition authority conducted a surprise inspection of Pfizer's offices and informed Pfizer that it had launched an investigation to establish whether the company had artificially extended the patent for latanoprost, the active ingredient in Xalatan (used in the treatment of glaucoma) to prevent or delay generic competition. According to the authority, the purpose of Pfizer's conduct was to obstruct or delay access to the market of a new generic drug. In May 2011, Pfizer offered undertakings to the authority in order to close the investigation. Pursuant to these undertakings, Pfizer will, *inter alia*: (i) offer to all interested parties an irrevocable royalty free license on the divisional patent covering latanoprost in Italy; (ii) refrain from seeking further patent protection in relation to the paediatric use of latanoprost; (iii) discontinue any legal proceedings against generics manufacturers in respect of their marketing of latanoprost; (iv) settle claims brought by the generics manufacturers that have sued Pfizer in the Italian courts; and (v) publish a press release on its website informing consumers of the availability of cheaper generic latanoprost.[2]

The U.S. Approach

In the United States, ''product hopping'' has been addressed in a few court cases and enforcement actions, and as recently as November 2010 was identified as a subject of potential concern in a speech by a Federal Trade Commission member.[3] The earlier of the leading cases, *Abbott Labs. v. Teva Pharmaceuticals U.S.A., Inc.*,[4] was decided in 2006 and reflected an unusually determined and aggressive program by Abbott Laboratories to avoid generic competition. On three separate occasions, the court found, Abbott had sought approval of slightly different dosage strengths and forms of TriCor (fenofibrate) so as to stay one step ahead of approvals of generic copies. Teva, which had challenged the patent for TriCor, sued Abbott, claiming a violation of the U.S. antitrust laws. The court denied Abbott's motion to dismiss the complaint, presuming without discussion that Abbott was a monopolist in a market for fenofibrate, and concluding that Abbott's removal of the older formulations of TriCor from the market blocked the introduction of generic fenofibrate. Whether Abbott had a legitimate pro-competitive reason for its actions was left for trial; the company's intent was not determinative.

The outcome in the second leading case, *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*,[5] in 2008 was different. There, the plaintiff drug store chain alleged that AstraZeneca aggressively promoted Nexium, a successor product to Prilosec, and ceased to promote Prilosec as Prilosec's patent was about to expire. The point, allegedly, was to shift Prilosec patients to Nexium, which had several more years of patent exclusivity, or to the then newly-approved Prilosec OTC. AstraZeneca did not, however, take Prilosec off the market. The court cited this fact in distinguishing the *Abbott Labs.* decision, noting that ''Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace.'' As was the case in *Abbott Labs.*, the court did not consider AstraZeneca's subjective intent to be a factor in its decision.

The U.S. Federal Trade Commission had similarly addressed charges of illegal ''product hopping.'' For example, the agency declined to block a 1998 deal in which Eli Lilly & Co., which manufactures Prozac (fluoxetine), licensed the rights to Sepracor's subsequently developed isomer of Prozac's active ingredient. Six years later the FTC inserted terms in a consent decree with Warner Chilcott regarding Ovcon that Warner Chilcott could not delist the product or, for three months, destroy any existing inventory.[6] In November 2010, FTC Commissioner J. Thomas Rosch noted in a speech before the World Generic Medicine Congress that the practice of ''product hopping'' would continue to receive close regulatory scrutiny.[7]

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cision; see OFT Press release ''OFT issues decision in Reckitt Benckiser case,'' April 13, 2011.

[2] See the full text submitted by Pfizer to the Italian competition authority: ''Documento Non Riservato, Formulario Per La Presentazione Degli Impegni Ai Sensi Dell' Articolo 17-ter Della Legge N.287/90'' at http://www.osservatorioantitrust.eu/fileadmin/storage/osservatorio/counters/testo%20impegni_A431.pdf.

[3] Remarks of J. Thomas Rosch before the World Generic Medicine Congress, Nov. 17, 2010, available at http://www.ftc.gov/speeches/rosch/101117roschworldspeech.pdf.

[4] 434 F. Supp. 2d 408 (D. Del. 2006).

[5] 534 F. Supp. 2d 146 (D.D.C. 2008).

[6] *FTC v. Warner Chilcott Holdings Co. III*, 2006 WL 3302862, *4 (D.D.C. Oct. 23, 2006).

[7] *Supra* note 3.

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Lessons For Actions in The United States and the EU

Broadly, pharmaceutical companies are free to market branded products for the duration of the patent life and introduce new products at the end of the original product's patent life in any way they see fit, without running afoul of antitrust/competition law. This includes launching new generation drugs, as well as launching products with only incremental improvement in efficacy or with similar formulation to the original product. Pharmaceutical companies, even when ''dominant'' (EU terminology) or possessing monopoly or the lesser ''market'' power (U.S. terminology) are free to compete on the merits with generic products without violating competition law. Concerns will arise only where the brand name manufacturer's actions, taken individually or collectively, could be seen as precluding effective competition by the generic.

Differences between the European and American approaches exist, and the extent to which those differences may alter the outcome of an investigation or a court case will turn on the circumstances. The decisions in *AstraZeneca* and *Reckitt Benckiser* demonstrate the importance of intent in European investigations into dominant companies' protection against generic entry. And, of course, the role of ''dominance'' status in the EU remains critical, triggering the ''special responsibility'' imposed by Article 102 of the Treaty for the Functioning of the European Union, which prohibits abuse of dominant position.

In the United States, in connection with evaluating the lawfulness of ''product hopping,'' intent is less important than an objective economic evaluation of the market and the likely consequences of the brand manufacturer's series of actions. And in this area differences in approaches among regulatory authorities persist despite efforts to ''harmonize'' enforcement. In the EU, pharmaceutical markets are typically defined, as a starting point, by reference to the therapeutic indication of the drug found in ''Anatomical Therapeutic Chemical'' classification, with the Commission's 2008 decision in the *Teva/Barr* merger and the *AstraZeneca* decision reflecting a willingness to consider additional market factors. U.S. market definition is more market-focused, and among enforcement agencies for a decade has included an emphasis on real-word economic evidence of pricing as distinct from what an economic analysis might predict in the abstract would occur.

A manufacturer's decision how to proceed must thus take into consideration potential disparities in legal rules, and to complicate matters, will likely be required years in advance as follow-on branded products are being set for development and modeled for likely success. In the EU, it is prudent to keep a close eye on market developments across countries that affect historic market definitions, in particular in the years leading up to patent expiry. In the United States, evidence of competition reflected in pricing decisions and bidding on managed care rebate and discount contracts should be consulted. In the United States and the EU, the actual withdrawal of products about to face generic competition, (or measures with a similar effect), must be considered presumptively likely to attract scrutiny.