

All in a Life Cycle

The UK Office of Fair Trading has alleged abuse of dominance in pharmaceutical life cycle management. Suzanne Rab and Robert F Leibenluft of Hogan Lovells investigate the legal landscape around this case and set out the different arguments involved

Sales of branded drugs decline considerably after expiration of their patent and regulatory data protection, once generic entry occurs. For this and other reasons, branded manufacturers typically consider various strategies to develop and improve their products to extend the life of their product lines. Life cycle management practices – including improvements in formulation or method of delivery, changes in indications or labelling, transfer of marketing to successor drugs or the withdrawal of an original drug from the market – go to the heart of the business strategies of research-based pharmaceutical companies.

An ongoing investigation by the UK OFT has highlighted whether certain practices associated with life cycle management can be challenged under UK competition law, particularly in circumstances where the branded manufacturer has introduced a successor drug and withdrawn and delisted its prior version of the product from the NHS prescription channel.

The UK OFT has recently issued a Statement of Objections to Reckitt Benckiser (RB) alleging that RB has abused its dominant position in the market for the NHS supply of alginate antacid heartburn medicines (1). The OFT alleges that RB deliberately withdrew Gaviscon Original Liquid (which no longer had patent protection) from the NHS prescription channel before the product was assigned a generic name within the channel. This meant that doctors searching for Gaviscon would be presented with Gaviscon Advance – a second generation product which is still protected by a patent – rather than a competing generic product. When a patent for a drug has expired and a generic name has been assigned to it,

doctors in the UK are able to use the NHS prescribing software to search for a branded product and then provide a prescription that lists the generic name. The OFT considers that the choice given to pharmacies to dispense either the relevant brand or the generic (cheaper) medicine is important for consumer choice and price competition in the UK.

While the use of successor drugs as a life cycle management strategy has not been addressed specifically in antitrust decisions in Europe, there have been cases in the US. Put very simply, these cases essentially involve allegations of shifting consumers from an old version of a drug to a new version, undermining the ability of generic versions of the original drug to compete. However, the analysis in these cases has not been straightforward and many different standards for evaluating the antitrust issues have been suggested.

This ongoing case provides an important opportunity for the OFT to clarify whether, or when, life cycle management strategies in the pharmaceutical sector can be challenged under competition law. This

article reviews the issues raised by this case in light of the positions advanced to date in Europe and in the US.

EUROPEAN COMPETITION LAW PERSPECTIVES

The Gaviscon case involves a novel theory of antitrust harm in the UK and in Europe, which was not specifically explored in great detail by the European Commission ('Commission') in its recent pharmaceutical sector inquiry between January 2008 and July 2009, or at least there was no definitive conclusion on the issues. Given the unique nature of the UK system of pricing and reimbursement of medicinal products, there is no equivalent process in any other Member State. The Commission's findings and comments on life cycle management and similar practices in its July 2009 final report, which concluded its 18-month probe into the pharmaceutical sector, are summarised in *Findings of the EC Pharmaceutical Sector Inquiry – Life cycle management* (see page 42).

The 2005 case involving AstraZeneca provides the only example of the Commission finding conduct by an



allegedly dominant pharmaceutical company to amount to an infringement of EU competition law. AstraZeneca was fined €60 million (£52 million) for two allegedly abusive practices: making misleading representations to obtain Supplementary Protection Certificates in respect of Losec; and selective withdrawal of Losec so that generic suppliers did not have a reference product to support their authorisation. This case is on appeal to the General Court; before the case is resolved, legal precedent suggests some caution in stretching the boundaries of European case law in this area.

It is worth comparing the two cases and how the situation involving RB may be distinguished. On its face, there is an analogy in that a product was withdrawn (from the national market in the AstraZeneca case and from the NHS system in the case of RB) allegedly in an attempt to subvert competition from generic versions of the withdrawn product. However, unlike the AstraZeneca case, RB's withdrawal of Gaviscon Original from the NHS prescription channel would not exclude the possibility of an authorisation of a generic version of this product. Furthermore, the amended provisions of the Community Code permit a generic authorisation even if the 'reference product' on which that authorisation is based has been withdrawn from the EU market (2). As an aside, it should be noted that due to changes in the relevant EU legislation, the fact pattern that constituted the subject of the alleged abuse in the AstraZeneca case, relating to misuse of regulatory procedures, could not now form the basis of an allegation of abuse.

US EXPERIENCE

The issue of successor products has been addressed in antitrust litigation in the US. Although the cases take place against a different regulatory framework, they have raised the question of when the introduction of a successor drug, and the shifting of demand from an original drug (off-patent) to the successor drug, can be viewed as an unlawful strategy.

Tricor

Abbott Laboratories versus Teva Pharmaceuticals US, Inc concerned a challenge to a patent covering Tricor capsules, manufactured by Abbott (3). In anticipation of the introduction of a generic form of Tricor capsules, Abbott allegedly introduced a tablet form of the drug, ceased selling the capsules, and changed the code for Tricor capsules in the National Drug Data File (NDDF) to 'obsolete'. According to the antitrust plaintiffs, this prevented pharmacies from filling Tricor prescriptions with a generic capsule formulation. Then, when the tablet patent was challenged and generics were reportedly poised to enter, Abbott allegedly switched its tablet to a different dosage form and withdrew the tablet form from the market.

Teva claimed that Abbott had manipulated the regulatory framework to prevent generic competitors from having an opportunity to enter the market, contrary to Section 2 of the Sherman Act – the broad equivalent to the Chapter II prohibition of the UK Competition Act 1998 or Article 102 of the Treaty on the Functioning of the EU. Abbott filed a motion to dismiss, arguing that the

introduction of a new drug, even with the alleged withdrawal of the old formulation from the market, does not contravene antitrust law because, among other things, there is no obligation to assist competitors. The court denied the motion to dismiss, however, and concluded that an antitrust inquiry into the benefits provided by Abbott's new formulation was required.

The court did not require the plaintiff to allege that the new formulations were absolutely no better than the prior formulations, or that the only purpose of the new formulation was to eliminate the product of a rival. Instead, the court proposed to balance the benefits of the new formulations against the impact of change on competition from generics. The court also noted the difficulty in assessing the quality of innovation: "because, speaking generally, innovation inflicts a natural and lawful harm on competitors, a court faces a difficult task when trying to distinguish harm that results from anti-competitive conduct from harm that results from innovative competition."

Prilosec and Nexium

Walgreen Co et al versus AstraZeneca Pharmaceuticals involved the heartburn drugs Prilosec and Nexium (4). The plaintiffs' complaint was that AstraZeneca had contravened Section 2 of the Sherman Act by switching the market from Prilosec, which was off-patent and thus subject to competition from generics, to a new drug Nexium, which was still

Findings of the EC Pharmaceutical Sector Inquiry – Life cycle management

While the Final Report, dated 8 July 2009, highlighted potential concerns with life cycle management, it stopped short of condemning as abusive the practices that are under discussion in the UK case. Secondary patenting: The Final Report recognises on page 14 that: “Incremental research is important as it can lead to significant improvements of existing products, also from the perspective of patients.” However, it notes that: “The launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product. The companies have an incentive to do so in order to avoid generic exposure for the second generation product.”

The statements in the Final Report are far from a clear indication that the filing of secondary patents near the end of the protection period is abusive, but they do indicate that the risk of an antitrust challenge is greater where there is no objective justification for seeking the patent, or the patent is highly vulnerable to challenge. Regarding promotion of a secondary product, the Commission

expressed a concern in its Final Report on pages 14 and 15 that: “In order to successfully launch a second generation medicine, originator companies undertake intensive marketing efforts with the aim of switching a substantial number of patients to the new medicine prior to the market entry of a generic version of the first generation product. If they succeed, the probability that generic companies will be able to gain a significant share of the market decreases significantly.” However, the Commission has stopped short of condemning such practices under EU competition law.

Relating to the conduct of doctors and physicians, the Final Report notes on page 14 that: “Originator companies devote a significant part of their budgets to marketing their products with medical doctors and other healthcare professionals. The sector inquiry produced indications that some originator companies sought to put into question the quality of generic medicines, as part of a marketing strategy, and even after the generic product was authorised by the relevant authorities.” Again, the Commission has stopped short of condemning such practices under EU competition law.

protected by patents. The successor drug, Nexium, was an isomer of the active ingredient in Prilosec. In addition, AstraZeneca introduced a new over-the-counter version of Prilosec. The original prescription version of Prilosec, however, remained available.

The plaintiffs argued that Nexium was not an improvement over Prilosec and that, by promoting Nexium over Prilosec, AstraZeneca had engaged in exclusionary conduct, undercutting the ability of competitors to sell generic forms of Prilosec. The court, however, dismissed the complaint and found that the fact that the new product siphoned off some of the sales of the old product and in turn depressed sales of the generic alternative, did not give rise to an antitrust cause of action. The court emphasised that:

- AstraZeneca did not interfere with competitors’ right to compete because Prilosec remained on the market
- AstraZeneca’s practices expanded consumer choice even though this was allegedly to the disadvantage of generic alternatives

- There was no antitrust requirement that the new product be superior than the old as that decision could be left to the market to decide
- The decision of whether to write a prescription for Nexium instead of Prilosec would be made by doctors, thus limiting the likelihood that the market would be unable to assess whether Nexium provided true benefits over Prilosec

RELEVANT LEGAL PRINCIPLES

Among the positions advanced in the cases above, some of which are not entirely consistent, the following are of note:

- The development of new drugs is pro-competitive and ordinarily should not be second-guessed by courts
- While it is possible that the introduction of a new drug that is not an improvement over the original drug solely to disrupt generic substitution could harm competition, as long as the original drug is left on the market we can presume that the market will not accept an attempt to shift →

The key issue for antitrust purposes is under what obligations, if any, might a pharmaceutical company have to: take steps to enable its generic rivals to compete, or perhaps, alternatively and more likely to result in liability, to refrain from adopting a course of conduct that will foreclose rivals from the market.

demand to a costlier drug that provides no incremental benefits

- Where the original drug is withdrawn from the market, we may not be able to rely on the market to assess the relative merits of the new product as compared with the alleged detrimental effect on competition, and a judicial inquiry may therefore be necessary

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Where the change in conduct involves a product switch that appears to have at

least a modest benefit for patients, the courts and regulators are almost certain to be reluctant to get involved in weighing that benefit against the potential foreclosure effect of the new product. This is particularly so where the plaintiff or complainant is not absolutely barred from the market and could take steps (albeit somewhat costly) to continue to compete. Determining whether incremental improvements are ‘significant’ enough to avoid an antitrust violation may be virtually impossible in practice, even with economics input. Such an approach could also stifle innovation with brand owners being reluctant to withdraw old products or release new drugs based on incremental improvements, even where protected by a valid patent.

CONCLUSION

The Gaviscon case clearly raises complex factual and legal issues and

will be important in defining the future direction, at least in the UK, of competition law investigations into life cycle management and similar practices. Unfortunately, the US cases leave unclarified the question of whether a pharmaceutical company has an obligation to assist generic companies by continuing to make available a product that is subject to generic substitution. The US cases do, however, suggest that if the OFT follows a similar approach to the US courts, then pharmaceutical companies concerned about antitrust ‘second-guessing’ of their successor products could limit their potential exposure by clearly documenting the therapeutic or safety benefits of their successor products, and choosing to leave the original (and potentially outdated) product on the market.

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