GETTING THE DEAL THROUGH

GCR
GLOBAL COMPETITION REVIEW

Pharmaceutical Antitrust

The application of competition regulation in 29 jurisdictions worldwide

2009

Contributing editor: Marleen Van Kerckhove

Published by
GETTING THE DEAL THROUGH
in association with:

Arnold & Porter LLP

Overview

Asim Varma and Marleen Van Kerckhove
Arnold & Porter LLP

In the United States, antitrust enforcement authorities and private litigation in the pharmaceutical sector have in the past few years focused on the antitrust implications of agreements between branded and generic drugs in settling patent litigation and on brand name pharmaceutical life cycle management strategies. We anticipate this focus to continue for the next few years as litigation on these issues makes its way through the US courts. We also anticipate an increased focus on legislation regarding these issues in the new presidential administration, particularly in light of recent US appellate courts rejecting the legal standard advocated by the Federal Trade Commission (FTC).

Similarly in Europe, we have recently seen an increased focus on practices aimed at delaying the entry of generics or innovative products, both in European Commission enforcement activity and with the opening of an EU sector-wide enquiry into these issues in early 2008. Meanwhile, there continues to be some activity also in the area of intra-brand competition from parallel traded drugs, an area that has traditionally been the main focus of the EU's enforcement policy.

US focus on patent infringement settlements between branded and generic drugs to continue

The US pharmaceutical regulatory framework encourages patent challenges by generic firms by providing for 180-day marketing exclusivity to those firms that assert invalidity or non-infringement of the patents. Patent challenges thus have the potential to yield substantial consumer savings. However, the competitive dynamic between branded drugs and their generic equivalents, creates, some argue, an incentive for brand and generic manufacturers not to resolve their patent disputes but to collude to avoid competition and share the resulting profits. In most cases in which generic entry is contemplated, the profit a generic anticipates is likely to be less than the amount of profit the brand name company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand name product; the difference between the brand's loss and the generic's gain is the money consumers save. Consequently, it is argued, it will typically be more profitable for both parties if the brand manufacturer pays the generic to settle the patent dispute and they agree to defer entry. Although both the brand name and the generic firms are better off, the consumer may lose the possibility of earlier generic entry that might have occured if the generic company had prevailed or because the parties would have negotiated a settlement with an earlier entry date, absent a payment.

While all settlements involve some form of consideration flowing between the parties, since the late 1990s the FTC has challenged patent settlements that it believes involve sharing the benefits that come from eliminating potential competition, that is, significant payments from the brand name to the generic company. In the FTC's view, these settlements, deemed reverse payment settlements, are anticompetitive. Initially, the FTC's enforcement efforts were successful, resulting in consent orders and for several years such reverse payment settlements stopped. In 2005, two appellate court decisions applied a more expansive standard. In the *Schering* case, the Eleventh Circuit Court of Appeals vacated a decision in which the FTC found two patent settlements violated the FTC Act. The FTC concluded that in each settlement Schering had paid its generic competitors to accept the settlement that provided Schering with more protection than simply proceeding with the litigation or a settlement without a payment. The Court of Appeals disagreed and held that, in the absence of an allegation of sham litigation, until the patent was proved invalid or not infringed, the patent provided Schering with the legal right to exclude the generics and the payment could not support an inference of a collusive agreement to exclude competition. The FTC sought review from the US Supreme Court. The solicitor general (who represents the United States before the Court) filed a brief on behalf of the Antitrust Division of the Department of Justice (DoJ), acknowledging the importance of the issue but arguing that the case was not the right vehicle for the Court to address them. The DoJ disagreed with the FTC's position that reverse payments indicate collusive agreements. The DoJ appeared to favour an approach under which the strength of the patent infringement case would be assessed short of a full-fledged trial of the issues that were settled along with an examination of the settlement negotiations. It is not clear whether or the extent to which the DoJ's approach to patent settlements will change with the new administration.

In June 2006, the Supreme Court declined to review the *Schering* appellate decision. The impact of the *Schering* and *Tamoxifen* decisions has been an increase in reverse payment settlements. In October 2008, the Federal Circuit Court of Appeals in the *Ciprofloxacin* case weighed in and adopted an approach similar to that of the Second and Eleventh Circuits, holding that reverse payment settlements that do not restrict competition beyond 'the exclusionary zone of the patent' do not violate the antitrust laws and refusing to examine patent strength in the absence of fraud or sham litigation.

The FTC continues to challenge reverse payment settlements in court and in an effort to further develop the law elicit the Supreme Court to address the issue. In February 2007, the FTC brought suit to challenge brand drug manufacturer Cephalon's settlements with four generic firms (all of which would have shared the 180-day exclusivity period). Each settlement involved a side-agreement including intellectual property licence payments from the brand as well as supply agreements and product development agreements under which the brand paid the generic, which the FTC argues are agreements not to compete. Unlike previous suits challenging reverse payment settlements, the FTC brought the challenge only against the brand name firm, here Cephalon. In January 2009, the FTC sued brand drug manufacturer Solvay and three generic companies challenging settlement agreements in relation to two pending ANDAs to sell generic AndroGel. The FTC alleges that these settlements involved agree-

ments by the generics to share in Solvay's continued monopoly profits through agreements to co-promote the brand product or backup manufacturing, or both, in exchange for the firms delaying generic entry for nine years. It will take a number of years for the *Solvay* and *Cephalon* litigations and other pending cases brought by private litigants to wind their way through the US court system.

The FTC is also continuing to advocate for a legislative remedy to address reverse payment settlements. While previously proposed legislation had not moved forward, the change in administration changes the political dynamics and makes legislation prohibiting all but de minimis consideration as part of a settlement more likely.

Increased scrutiny of life-cycle management on both sides of the Atlantic

The enforcement of patent rights and the settlement of patent suits in the pharmaceutical industry have for some time been issues of concern to US antitrust agencies and US courts. They have only recently captured the attention of the European Commission. In summer 2006, the European Commission imposed a €60 million fine on AstraZeneca for having abused its market power (or 'dominance') by pursuing certain intellectual property (IP) and regulatory strategies aimed at keeping generics off the market. At least two further cases alleging IP-related abuses have been brought before the European Commission since. In addition, the Commission has recently opened a broad-ranging sector enquiry into IP-related practices believed to hamper competition in pharmaceuticals (the Sector Enquiry).

On 15 January 2008, the European Commission paid surprise visits (dawn raids) to a number of branded drug companies and to several generics companies. Contrary to the European Commission's practice to date, these surprise visits were not prompted by allegations that the companies concerned had been involved in illegal practices. Instead, they signalled the start of an industry-wide investigation by the European Commission into certain practices in the pharmaceutical industry. The Sector Enquiry was launched because, in the words of Commissioner for Competition Neelie Kroes, 'innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed'. More specifically, certain practices involving filing or enforcing patents, vexatious patent litigation, and patent settlements are believed to block innovative and generic competition.

Following the surprise visits, the European Commission sent extensive questionnaires to most branded drugs and generics companies in Europe, as well as to several pharmaceutical associations and other interested parties. The replies to these questionnaires, together with the materials collected at the surprise visits, formed the basis of an interim report that the European Commission issued in November 2008.

The European Commission's preliminary findings are in the first place a summary of its fact-finding exercise, and do not yet go into substantive analysis of potential wrongdoing. Distinguishing between originator/originator competition and originator/generic competition, the preliminary findings focus on defensive patenting (aimed primarily at blocking innovation efforts from competing originator companies), evergreening patenting (aimed at prolonging patent exclusivity by adding additional patents towards the end of a product's life cycle), patent litigation, settlement agreements, product switches, and other practices allegedly aimed at excluding or delaying generic or other competition (eg, certain patent opposition procedures, certain interventions before marketing authorisation bodies, certain distrbution practices).

While the Sector Enquiry focuses on company conduct, the European Commission in its preliminary findings admits that certain improvements may also be necessary in the regulatory and IP framework, such as the introduction of a single Community patent and the creation of a unified and specialised patent judiciary in Europe. It also acknowledges that there are 'bottlenecks in the procedures for approval and marketing of medicines (including pricing and reimbursement status) which may contribute to delays in bringing products to market'.

The European Commission's definitive report is expected in summer 2009.

Meanwhile, the appeal against the European Commission's *AstraZeneca* decision is progressing through the CFI (case T-312/05). The oral hearing took place on 26 and 27 November 2008 and the judgment is expected before summer 2009.

Although most member states have similar powers under their national competition laws to conduct sector-wide enquiries, few have so far investigated the pharmaceutical sector. Noticeable exceptions are Italy, which already in the 1990s investigated the sector, the UK, which recently finished two market studies, one in relation to pricing and the other in relation to direct to pharmacy distribution strategies, and the Scandinavian countries, which have just released the results of a joint investigation into competition in the pharmaceutical sector (see separate country chapters).

The fundamental differences between the US and EU pharmaceutical regulatory frameworks and their impact on antitrust enforcement

Several commentators have already remarked on the similarity between the subject matter of the EU's Sector Enquiry and antitrust enforcement in the US with regard to both patent strategy by branded drug companies and patent settlements with generics companies. Yet, the legislative framework against which this US antitrust case law is being developed, and hence the rationale for these findings of infringement, is fundamentally different from the European regulations.

A detailed comparative study of the US and EU regimes is beyond the scope of this article, but we briefly touch on the most fundamental differences as we see them.

The mere issuance of a patent has not so far been held to be an infringement under US antitrust law. Rather, under the Walker Process doctrine, the enforcement of a patent may constitute an infringement if the patent has been fraudulently obtained, the patent owner was aware that the patent had been obtained by fraud when it filed the infringement action, and the attempted enforcement affected competition.

In addition, the US regulatory framework is such that vexatious litigation (or 'sham' litigation) has the potential to be particularly harmful to generic entry. This is not the case in the EU. The US Hatch-Waxman Act encourages generics companies to enter the market prior to the expiry of the innovator's patents. It gives them 180 days' marketing exclusivity if they assert (in what is known as a paragraph IV certification) that the patent is invalid or not infringed in their marketing authorisation application. Informed of this challenge, the branded drug company may file a patent suit, in which case the generic's marketing authorisation process will automatically be suspended until the earlier of patent expiration, or a favourable ruling in the patent litigation, or two-and-a-half years from the notice of paragraph IV certification. In the EU, in contrast, there is no such linkage between the grant of marketing authorisation and alleged patent infringement. The relevant authority will typically grant marketing authorisation, irrespective of such infringement. The patent holder will need to start litigation and, importantly, seek an injunction preventing the entry of the generic drug onto the market. This will require a prima facie case, in contrast with the US, where the stay in the authorisation process is automatic.

Turning to US settlement agreements between branded and generic firms, two points should be made. First, settlements too

should be seen against the US regulatory background. If the branded drug company, having filed a patent suit, chooses to settle the case with the first generic applicant, no other generics may be able to enter the market until the first generic has had its (delayed) 180-day exclusivity on the market. In contrast, a settlement in the EU does not stop subsequent generic entrants unless further litigation is successful. By the same token, the impact of a settlement in the EU is bound to be less significant, except in the rare circumstance where only that one generic is expected to enter the market in the short term. Second, there remains significant controversy over whether and, if so, when, settlements risk infringing US antitrust rules. As noted, the FTC takes the position that reverse payment settlements (beyond de minimis payment of litigation costs) indicate collusion between the settling parties and should be close to per se unlawful. The DoJ favours an approach that recognises the public policy supporting settlements in general and pharmaceutical patent rights in particular. Although the contours of how it would be implemented are not clear, the DoJ advocates for a standard that examines in some truncated form the merits of the patent litigation and examines in some detail the settlement negotiations. We expect the antitrust implications of patent settlement agreements to remain in flux in the US.

Increased US focus on follow-on biologics

In the United States, there will likely be renewed legislative activity aimed at facilitating regulatory approval of follow-on biologic (FOB) drugs, which encompass 'generic' biologics or 'biogenerics' and 'biosimilars.' 'Biogeneric' drugs refer to those drug products that are 'therapeutically equivalent' or 'interchangeable' with the reference product; whereas, 'biosimilars' are drug products that are comparable to the reference product. In the United States, unlike small molecule, chemically synthesised drugs, biologics are not approved through the NDA or ANDA approval process, but instead are approved though a Biologics Licensing Application (BLA) under the Public Health Services Act. As of March 2009, no avenue exists for the approval of generic copies of BLA drugs. However, such legislation has been under active consideration and we expect the new administration to support a path to FDA approval of FOBs

Indeed, the new administration in its first budget identified removing barriers to FOBs as a priority area to bring down the cost of biologic drugs and fund health-care reform. The FTC also has shown interest in this area and is exploring the likely market effects of FOB competition, of regulatory exclusivity for reference products and of regulatory incentives for FOBs, as well as patent issues and dispute resolution processes.

Highest European Court rules in parallel trade case

The protection of parallel trade – that is, cross-border trade between member states – has traditionally been the main focus of the European Commission's enforcement activity in the pharmaceutical sector. It features far less in US antitrust enforcement and litigation. The reason is that the creation and maintenance of a single EU market is one of the key objectives of the European Union. All policy, including antitrust policy, must contribute to the objective of the single market.

Primarily due to differences in national pricing regimes and health care spending, there exist substantial price differences – as high as 70 per cent in some instances – in medicines between member states. This has created a significant parallel trade activity. Wholesalers purchase in low-priced countries in order to sell in high-priced countries at or near the reimbursement price of the medicine in the country of importation, effectively arbitraging to take advantage of the price differentials. Pharmaceutical manufacturers have sought to restrict these parallel imports through unilateral means and also by agreement or concerted practice with their distributors. Such action is potentially in breach of EC competition law, either as a restrictive agreement or practice (article 81 of the EC Treaty) in the case of concerted measures, or as an abuse of a dominant position (article 82 of the EC Treaty) in the case of unilateral measures. It is on this latter issue that a judgment is now available from the EU's highest court.

On the first issue, in *GlaxoWellcome*, the Court of First Instance (CFI) held on 27 September 2006 (case T-168/01) that the Commission was right in finding that GSK's dual pricing policy had anti-competitive effects within the meaning of article 81(1) of the EC Treaty but wrong in rejecting the manufacturer's defence that this policy aimed at preserving its R&D investments for the benefit of consumers and hence merited an exemption under article 81(3) of the EC Treaty. The case is now on appeal to European Court of Justice (ECJ) (joined cases C-501, 513, 515 and 519/06P). An oral hearing took place on 17 March 2009.

On the second issue, in *Syfait* (case C-53/03) and, more recently, in *Lelos* (cases C-468/06 to C-478/06), the ECJ was asked to give a preliminary ruling on whether GlaxoSmithKline's refusal to meet all orders by wholesalers based in Greece constituted an infringement of article 82 of the EC Treaty because it restricted parallel trade out of Greece. In the first case, Advocate-General Jacobs, in October 2004, relied on sector-specific features to justify GlaxoSmithKline's conduct. In the second case, the Court in November 2008 issued a more nuanced ruling. With regard to the existence of national price regulations in the pharmaceutical sector, the ECJ held, on the one hand, that 'the degree of regulation regarding the price of medicines cannot prevent any refusal by a pharmaceuticals company in a dominant position to meet orders sent to it by wholesalers involved in parallel exports from constituting an abuse' but, on the other, that 'such a company must nevertheless be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests'. The Court also observed that a pharmaceutical company 'cannot base its arguments on the premise that the parallel exports which it seeks to limit are of only minimal benefit to the final consumers' in the pharmaceutical sector because exporters, wholesalers and pharmacies may not pass on the price advantage to the patients or the reimbursement authority in the high-price country.

Finally, there continue to be developments at the national level in this area. We reported last year on a decision from the French Conseil de la concurrence allowing a number of branded drug companies to impose supply quota systems on their wholesalers after they had offered commitments to make the system more flexible and more transparent. The decision was overturned by the Court of Appeal on procedural grounds and is now pending again before the Conseil.