GETTING THE DEAL THROUGH

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CONTENTS

Overview

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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 will continue for the next few years as litigation on these issues makes its way through the US courts. We also anticipate a continued focus on legislation regarding these issues, particularly in light of continued US appellate court and district court rejection of the legal standard advocated by the Federal Trade Commission (FTC).

Similarly, in Europe we continue to see an increased focus on practices aimed at delaying the entry of generics or innovative products, reflected both in the European Commission's findings of its sector-wide inquiry into the pharmaceutical industry, published in summer 2009, and in its subsequent enforcement activity. Meanwhile, there remains some uncertainty over the European Commission's policy and enforcement priorities with respect to restrictions on parallel trade in branded 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 might lose the possibility of earlier generic entry that might have occurred if the generic company had prevailed or because the parties would have negotiated a settlement with an earlier entry date, in the absence of 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. More recently, under the new administration, the DoJ's approach to patent settlements appears to be converging with that of the FTC, as evidenced in the DoJ's amicus brief filed in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*. 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. Adopting the standard of the Second, Eleventh and Federal Circuits, namely, applying the rule of reason and analysing whether the settlement exceeded the scope of the patent, the district denied Cephalon's motions to dismiss the case on 29 March 2010. 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 agreements 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. The US District Court for the Northern District of Georgia, applying the Eleventh's Circuit's standards, dismissed the *AndroGel* case in February 2010 on the grounds that the plaintiffs did not allege that the settlement agreements involving reverse payments exceeded the scope of the brand company's patent. It will take a number of years for the *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. Bills that seek to prohibit all but de minimis consideration as part of a paragraph IV settlement were introduced in both the House and the Senate. The House (but not the Senate) version of the healthcare overhaul bill included such a prohibition, but that was recently dropped during the reconciliation process. Nonetheless, the FTC chairman has publicly stated that a legislative ban on reverse payment settlements is likely to pass later this year.

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 in recent years also 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 and regulatory strategies aimed at keeping generics off the market and hindering parallel trade. At least two further cases alleging IP-related abuses have been brought before the European Commission since then. In addition, in January 2008 the Commission opened a broad-ranging sector enquiry into a range of practices believed to hamper competition from both generic and originator drugs (the Sector Enquiry).

The Sector Enquiry was launched because, in the words of the then-Commissioner for Competition Neelie Kroes, 'innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed'.

The European Commission conducted an in-depth analysis of more than 200 medicines (INNs), in total representing nearly 50 per cent of prescription drugs sales in the period 2000 to 2007.

Given that this was a competition investigation, the Sector Inquiry focused in the first place on company behaviour, in particular the so-called 'tool-box' that branded drug companies are alleged to apply to counter generic entry. This included patent strategies (clusters and divisional patents in particular), patent disputes and patent litigation, European Patent office opposition procedures, settlement agreements, interventions before national regulators (marketing authorisation, pricing, reimbursement), life-cycle strategies involving second-generation products, and defensive patenting (used primarily to hinder the development of competing products).

At the same time, many stakeholders urged the European Commission to take into account the impact of the restrictions and potential failures of the industry's regulatory framework and the importance of patent rights and of their efficient enforcement for the pharmaceutical industry. Not surprisingly, therefore, three of the four policy recommendations set out in the Final Report focus on patents and regulatory aspects. First, the Commission will continue to make all efforts for the rapid adoption of a Community patent and unified litigation system, and it supports various initiatives by the European Patent Office to 'raise the bar' for EPO patents, both in terms of quality and as regards the duration of procedures. Second, the Commission has various recommendations and commits to supporting national regulators in order to speed up marketing authorisation procedures, reduce discrepancies in national implementation of the EU regulatory framework, make sure that third-party interventions before marketing authorisation bodies are transparent and do not unduly delay the process, and it proposes to pursue member states who link the granting of a marketing authorisation to the patent status of the originator drug. Third, also in relation to pricing and reimbursement, the Commission proposes various measures to address delays and uncertainties in the national procedures

At the same time, the Directorate General for Competition will scrutinise the sector more closely and, where appropriate, prosecute specific companies for alleged violation of EU competition law. Following the Sector Inquiry, the European Commission has opened at least three competition law investigations and in addition has collected further information on settlement agreements from a range of companies. It is expected that this latter exercise may become a regular feature of the Commission's competition activities in the pharmaceutical industry. We expect also to see increased enforcement activity at national level, as is illustrated for example by the United Kingdom's OFT current investigation of Reckitt Benckiser's alleged abusive conduct in de-listing its NHS packs of Gaviscon Original Liquid from the NHS prescription channel (see the UK chapter).

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

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. Notable exceptions are Italy, which has already investigated the sector in the 1990s, 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 in 2009 released the results of a joint investigation into competition in the pharmaceutical sector. It is expected that the Czech authorities will open a sector enquiry into the pharmaceutical industry. We also note that in Korea the authorities are continuing to investigate the pharmaceutical sector (see separate country chapters).

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

There is a clear 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 Overview, 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. The US Hatch-Waxman Act encourages generic 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 that 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 explained above.

Pathway for approval of follow-on biologics

As part of health-care reform in the United States, in March 2010 Congress approved a pathway for 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 through a Biologics Licensing Application (BLA) under the Public Health Services Act. The new legislation provides for 12 years of market exclusivity for the innovator product. After the period of market exclusivity the Food and Drug Administration (FDA) is authorised to approve generic versions upon a showing that the FOB is biosimilar to the innovator product. The legislation also requires the FDA to determine whether the biosimilar product will be interchangeable. Supporters of the new legislation had argued that the 12 year period of exclusivity was necessary to prevent a biosimilar manufacturer from circumventing a biotech patent in making a drug that was functionally identical. Opponents of the legislation had argued that the long period of exclusivity would deprive access to cheaper alternatives to innovator drugs. The Obama administration unsuccessfully urged a seven-year period of exclusivity. Unlike Hatch-Waxman, the legislation does not provide a mechanism for the FOB manufacturer to challenge any patents covering the innovator product while FDA approval is pending.

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 101 of the Treaty on the Functioning of the European Union, TFEU) in the case of concerted measures, or as an abuse of a dominant position (article 102 TFEU) in the case of unilateral measures. For several reasons, including pending cases before the highest European Court, the European Commission has not taken enforcement action in this field in recent years, despite that fact that cases continued to be brought before it. The last such judgment was rendered in October 2009 in the *Glaxo* dual-pricing case and in which the General Court's rejection of the Commission's infringement decision against GSK remains overruled. The question, therefore, is whether the Commission will now pick up the issue again to refine its policy on the matter and, if so, how soon it is likely to do so. On the substance, we note the following recent statement from the head of the EU's Pharma Task Force (Fordham Competition Law Institute, September 2009):

> *The question therefore is: when we look at all the elements together, should we, because the prices are not yet harmonised, remove the pharmaceutical industry from the application of articles 81 and 82 [now articles 101 and 102 TFEU] altogether as far as parallel trade is concerned? In my view, the answer should be no, but of course the special features of the industry need to be taken into account when applying the law, which means that an assessment on a case-by-case basis remains required.*

Pharmaceutical enforcement activity around the globe

Apart from the national sector enquiry and related enforcement activities already referred to above, we note that further cartel enforcement in the pharmaceutical industry continues – see, for example, the recent investigations in Germany, Korea and Switzerland mentioned in the respective country chapters. Noteworthy merger control developments are also reported in Australia, Israel and Japan.

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