ARNOLD & PORTER LLP

ADVISORY July 2010

First EU Judgment on Abusive Conduct Through Use of Regulatory Procedures in the Pharmaceutical Sector

On July 1, 2010, the General Court issued its ruling in the AstraZeneca case[1] and upheld a 2005 decision from the European Commission which found that AstraZeneca had abused its dominant position, in breach of what is now Article 102 TFEU, by preventing or delaying the marketing of a generic version of its Losec (omeprazole) product and hindering parallel imports of Losec capsules in certain countries. Losec is a proton pump inhibitor (PPI) used in the treatment of acid-related gastric diseases[2]

The Judgment is particularly noteworthy because it is the first EU precedent in the pharmaceutical sector to provide guidance on defining markets and determining market power in abusive conduct cases, and the first to rule on when certain life cycle management practices may infringe EU competition rules. Misrepresentations before patent offices and misuse of regulatory procedures for the approval of drugs have previously been held to be antitrust violations by US courts and by the Federal Trade Commission (FTC).

Although the specific abuses at issue here took place in the context of the legal uncertainty surrounding the regulations on eligibility for supplementary protection certificates (SPCs) and the effect of deregistration of marketing authorisations, which has since been clarified in case law and through regulatory reform, the Judgment provides important guidance for pending and future cases before the Commission on hindering competitors through the use of regulatory procedures, an area that is under increased scrutiny from the Commission following its recent Sector Inquiry into the pharmaceutical sector.[3]

The Decision

In 1999, following complaints from two generic manufacturers, the Commission opened an investigation into AstraZeneca's practices regarding Losec in a number of EU countries. The Commission's investigation was aimed at assessing whether AstraZeneca had abused a dominant position by hindering the entry

1 Judgment of the General Court of July 1, 2010, Case T-321/05, *AstraZeneca AB and AstraZeneca plc* v. *Commission*.

2 Commission Decision of 15 June 2005, Case COMP/A. 37.507/F3—AstraZeneca.

3 http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf.

Brussels
+32 (0)2 290 7800

Denver
+1 303.863.1000

London
+44 (0)20 7786 6100

Los Angeles
+1 213.243.4000

New York
+1 212.715.1000

Northern Virginia
+1 703.720.7000

San Francisco
+1 415.356.3000

Washington, DC
+1 202.942.5000

on the market of generic versions of omeprazole and by hindering parallel trade in Losec capsules.

The Commission found that AstraZeneca had abused of its dominant position by:

i. Providing deliberately misleading information to patent agents, national patent offices, and national courts in an attempt to acquire or preserve SPCs to which AstraZeneca was not entitled or to which it was entitled for a shorter duration, in order to keep out generic competition; and

ii. Deregistering the marketing authorizations for Losec capsules in certain countries, in combination with the substitution on the market of an advanced form of tablet presentation (Losec MUPs) in replacement of Losec capsules.

The Commission imposed a total fine of €60 million on AstraZeneca.

The Judgment

AstraZeneca appealed the Decision, contesting the Commission's findings on market definition, dominance, and the abuses.

The Market Definition

One of the cornerstones of the Decision is the Commission's position that PPIs and H2 blockers, drugs also used in the treatment of acid-related gastric diseases but less advanced than PPIs, belonged to separate product markets.

The General Court noted that PPIs and H2 blockers were prescribed to treat the same conditions and that both constituted first-line treatments. Still, it found that the Commission had rightfully concluded that H2 blockers did not represent a competitive constraint on PPIs because the greater effectiveness of PPIs led to a difference in the use between the two drugs, with PPIs being used to treat the severe forms of gastrointestinal acid-related conditions and H2 blockers being used for the less severe forms of those conditions.

Furthermore, the General Court ruled that the slow transition of the market from H2 blockers to PPIs did not indicate that H2 blockers were a competitive constraint on PPIs. The General Court considered that this was the result of the normal caution that doctors have in prescribing a new drug, rather than of the competitive interaction between PPIs and H2 blockers.

In reply to AstraZeneca's claim that the Commission had excessively relied on the different therapeutic characteristics of the two products (primarily their different mode of action), without taking account of their same therapeutic uses, the Court concluded that the Commission had taken proper account of the products' respective therapeutic uses and, as already mentioned, rightly considered them to be different.

Finally, AstraZeneca argued that the Commission had attached too much importance to the price difference between the two products, despite the fact that in the pharmaceutical sector prices are determined or influenced by public authorities and as such do not constitute a useful indication of the degree of competition between two products.

The General Court noted, first of all, that the bargaining position that pharmaceutical companies have with public authorities depends significantly on the added value and efficacy of their products compared to other products on the market, and that the price of a new pharmaceutical product typically reflects the authorities' perception of its relative therapeutic value compared to existing products. The difference in absolute prices of PPIs and H2 blockers, therefore, reflects to a large extent the authorities' perception of a factor also taken into consideration by the Commission when defining a separate market for PPIs, namely the greater therapeutic efficacy of PPIs in comparison with H2 blockers.

The General Court recognised that the reimbursement levels granted to PPIs to a large extent prevented the lower prices of H2 blockers from exercising a competitive constraint over PPIs, but held that the type or nature of the factors that shield a group of products from any significant competitive constraint is of limited relevance. In other words, the fact that the absence of competitive constraints may be due to the regulatory framework on the market concerned, does not undermine the conclusion on market definition.

The Findings on Dominance

The Commission's assessment of AstraZeneca's dominance was challenged on appeal with respect to five key factors: (i) AstraZeneca's high market shares over a long period of time; (ii) AstraZeneca's ability to maintain higher prices than those of its competitors, while retaining a much higher market share; (iii) the strength of AstraZeneca's patent portfolio; (iv) AstraZeneca's first-mover status; and (v) AstraZeneca's financial strength.

Consistent with past case law, the General Court confirmed that the possession over time of a very large market share is in itself, save in exceptional circumstances, evidence of the existence of a dominant position.

The General Court agreed with the Commission that AstraZeneca's ability to obtain higher prices than "me-too"

PPIs in its negotiations with national authorities reflected the advantages that it derived from its first-mover status on a market that it pioneered. This, together with its continued high market share, meant that AstraZeneca was able to maintain higher revenues than those of its competitors, without the various players in the market (patients, prescribing doctors, national social security systems, and competitors) being able to challenge that privileged position. It mattered little in the opinion of the General Court that this position was made possible or favoured by social security systems.

The General Court also confirmed that the strong intellectual property rights enjoyed by AstraZeneca and their exercise, although not abusive, enabled the company to impose significant constraints on some of its competitors which in itself is an indicator of a dominant position.

Finally, the Court agreed that the Commission's findings regarding AstraZeneca's financial strength although not conclusive in themselves, constituted relevant *indicia* to support a finding of dominance.

The Abuses

The First Abuse: Misleading Representations to the Patent Offices

The General Court's starting point was that the submission to public authorities of misleading information liable to lead them into error, and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, is a practice that falls outside the scope of competition on the merits, and that may be particularly restrictive of competition. Such conduct, therefore, when engaged in by a dominant undertaking, is likely to be abusive.

It then listed a number of important principles of assessment that derive from the objective nature of the concept of abuse, based also on previous case law.

First, the misleading nature of representations made to public authorities must be assessed on the basis of objective factors. Proof of the deliberate nature of the conduct and of the bad faith of the undertaking in a dominant position is not required.

Second, although proof of the deliberate nature of conduct liable to deceive the public authorities is not necessary for the purposes of identifying an abuse, intention nonetheless constitutes a relevant factor which may be taken into account by the Commission. In other words, intention is a factor that can play a role in supporting the conclusion that the undertaking concerned abused a dominant position, but that conclusion should first and foremost be based on an objective finding that the abusive conduct actually took place.

Third, once it is established that certain behaviour is objectively capable of restricting competition, it is not relevant whether the behaviour concerned actually succeeded in restricting competition. Thus, the mere fact that certain public authorities did not let themselves be misled and detected the inaccuracies in the information provided in support of the applications for exclusive rights, or that competitors obtained, subsequent to the unlawful grant of the exclusive rights, the revocation of those rights, is not a sufficient ground to consider that the misleading representations were not in any event capable of succeeding. Similarly, it is not relevant whether or not an exclusive right obtained as a result of misleading representations has been enforced. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since the law requires them to respect that exclusive right. It cannot be the case that the application of Article 102 TFEU is conditional on the contravention by competitors of the law by infringing the exclusive right of an undertaking. In this respect, the Judgment decision differs from US law, which holds that to support an antitrust violation, the patent must be shown both to have been awarded by fraud and enforced with the knowledge that the patent's fraudulent derivation.[4]

Turning to the abusive conduct itself, the first question, according to the General Court, is whether the practice in question, taking into its context, was such as to lead the public authorities wrongly to create regulatory obstacles to competition (e.g. by the unlawful grant of exclusive rights to the dominant undertaking). The limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors in this respect.

Interestingly, the Court added that in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility not to impair genuine undistorted competition in the market requires it, at the very least, to inform the public authorities of this so as enable them to rectify those irregularities. In the same vein, the General Court recognized that there was uncertainty surrounding the application of the SPC regulations but it objected to AstraZeneca's failure to make transparent its reasoning in interpreting those regulations.

4 *Unitherm Food Systems, Inc.* v. *Swift-Eckrich, Inc.*, 546 U.S. 394 (2006).

As regards the effect on competition of the abusive behaviour, the General Court found that it is sufficient to establish that, in view of the economic or regulatory context, the practice concerned is capable of restricting competition, even if the ability of the practice to restrict competition is only indirect. This is so because the practice concerned cannot in any way be regarded as normal competition between products on the basis of an undertaking's performance. Still, representations designed to obtain exclusive rights unlawfully constitute an abuse only if it is established that, given the context in which they are made, those representations are actually liable to lead the public authorities to the grant the exclusive right applied for.

Finally, the General Court found that, on the facts, the European Commission had correctly concluded that AstraZeneca had adopted a consistent course of conduct and that there were numerous items of evidence that support the conclusion that AstraZeneca had deliberately tried to mislead the patent offices. The General Court concluded, therefore, that the misleading representations made by AstraZeneca constituted a practice based exclusively on methods falling outside the scope of competition on the merits and that such conduct solely served to keep manufacturers of generic products, wrongfully away from the market by means of the acquisition of SPCs in a manner contrary to the regulatory framework establishing SPCs.

The Second Abuse: Deregistration of Marketing Authorizations for Losec Capsules

The Commission in its Decision defined the abuse as a combination of the deregistration of Losec capsule marketing authorizations with the conversion of sales of Losec capsules to Losec tablets. However, in reply to questions by the General Court and at the hearing the Commission stated that the central feature of the abuse consisted in the deregistration of the marketing authorizations, and that the conversion of sales of Losec capsules to Losec tablets was merely the context in which the deregistrations were carried out. This prompted the General Court to observe that the withdrawal from the market of Losec capsules and the introduction on the market of Losec tablets, was not capable, in and of itself, to produce the anticompetitive effects alleged by the Commission in this case, namely the creation of regulatory obstacles to market entry by generic products and to parallel imports of Losec capsules.

The General Court found that AstraZeneca had abused its dominant position because it used regulatory procedures solely to prevent or hinder market entry by competitors, without there being an objective justification for such conduct or a legitimate interest as part of competition on the merits. At the relevant time, an application by a generic company for a copy authorisation of Losec capsules under the abridged procedure required the originator's authorisation for that product to be in force in the country of application at the time the generic copy applied. Deregistration, therefore, stopped such applications being validated.

The General Court noted that once AstraZeneca's exclusive rights to use to the results of the Losec pharmacological and toxicological tests and clinical trials had expired, manufacturers of essentially similar medicinal products were entitled to benefit from those data to obtain marketing authorisation under the abridged procedure. Hence, AstraZeneca's conduct designed to prevent manufacturers of generic products from making use of this right was not based in any way on the legitimate protection of an investment within the scope of competition on the merits. Rather, it was solely aimed at preventing the manufacturers concerned from taking advantage of the abridged procedure for obtaining marketing authorisation.

The General Court then considered whether AstraZeneca had an objective justification for not maintaining the marketing authorisation given the burden of updating it and the pharmacovigilance obligations connected with it. The Court found that AstraZeneca had failed to demonstrate that the additional burden would have been so significant that it would have constituted an objective ground for justification.

Similar to its findings regarding the first abuse, the Court went on to say that once it is established that AstraZeneca's conduct was such as to delay or prevent the introduction of generic products and parallel imports, there was no need to show an intention to cause harm (albeit that on the facts of the AstraZeneca case the Commission did find such intent), nor was it necessary to show the anticompetitive effects of the deregistrations in practice.

The General Court found that the existence of an alternative legal basis for generic companies to obtain copy authorisations through the making of an application based upon published literature was not decisive. Given the context in which the conduct was implemented, the deregistrations were such as to enable AstraZeneca to delay, at least temporarily, the significant competitive pressure that generic products were to exert on it by preventing them to use the quickest and easiest route to market that the EU regulations provided for. However, it also found that the Commission had failed to

establish to the requisite legal standard that the deregistration of the Losec capsule marketing authorization was capable of restricting parallel imports of Losec capsules in Denmark and in Sweden. Accordingly, it reduced the total amount of fines on AstraZeneca from €60 million to €52.5 million.

What Are the Implications of This Judgment?

First, new drugs that have the same indication as existing drugs but which through their greater effectiveness are able to command a significantly higher price and end up being used for different phases of treatment are likely be found to compete in separate markets.

Second, high market shares and high prices over a prolonged period of time combined with a particularly strong patent portfolio and first-mover status likely will lead to a finding of dominance. The fact that these elements of dominance may in whole or in part be the result of the regulatory framework that is applicable to the pharmaceutical industry does not affect this conclusion, nor is it relevant that this regulatory framework may prevent the undertaking concerned from behaving independently on the market.

Finally, the judgment provides guidance on when raising legal barriers that are capable of delaying or preventing the introduction of generic products or parallel trade will constitute abusive conduct in breach of Article 102 TFEU. The General Court found with respect to both types of abuse that they did not constitute competition on the merits but solely served to restrict generic entry and/or parallel trade. The first abuse, through its misleading character, was such as to lead the public authorities wrongly to create regulatory obstacles to competition. The second abuse made market entry more difficult for generic products and parallel imports without there being a legitimate interest within the scope of competition on the merits or an objective justification on the side of AstraZeneca. Although in both instances evidence of intent to foreclose supported the findings of abuse, neither anticompetitive intent nor anticompetitive effect are required in the analysis of the Court to lead to a finding of abuse.

This is the first EU case where misuse of regulatory procedures has been found to amount to an abuse of dominant position under competition rules. It sets precedent that could make it harder for other pharmaceutical companies to fend off generic competition. Because of differences between EU and US procedures for obtaining and enforcing patents, and, of course, sensibilities, we expect the EU and US to follow similar but not identical paths in the development of law in this area.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

Marleen Van Kerckhove
+32 (0)2 290 7817
Marleen.VanKerckhove@aporter.com

Asim Varma
+1 202.942.5180
Asim.Varma@aporter.com

Marco Ramondino
+32 (0)2 290 7813
Marco.Ramondino@aporter.com