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EU Regulatory Procedures In The Pharmaceutical Sector

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Law360, New York (July 22, 2010) -- On July 1, 2010, the European Union's General Court upheld a 2005 decision from the European Commission that found that AstraZeneca PLC had abused its dominant position 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 used in the treatment of acid-related gastric diseases.

In 2005 the EC had found that AstraZeneca had abused its dominant position by: providing deliberately misleading information to patent agents, national patent offices and national courts in an attempt to acquire or preserve supplementary protection certificates to which AstraZeneca was not entitled or to which it was entitled for a shorter duration, in order to keep out generic competition; and deregistering the marketing authorizations for Losec capsules in certain countries, in combination with the substitution on those markets of an advanced form of tablet presentation (Losec MUPs) in replacement of Losec capsules.

The European Commission imposed a total fine of €60 million on AstraZeneca on account of the infringements.

AstraZeneca appealed the decision, contesting the commission's findings on market definition, dominance and the abuses.

Although the specific abuses at issue here took place in the context of the legal uncertainty surrounding the regulations on eligibility for SPCs and the effect of deregistration of marketing authorizations, which has since been clarified in case law and through regulatory reform, the judgment provides important guidance for pending and future cases before the EC on hindering competitors

through the use of regulatory procedures, an area that is under increased scrutiny from the EC following its recent sector inquiry into the pharmaceutical sector.

It is also the first EU precedent in the pharmaceutical sector to provide guidance on defining markets and determining market power in abusive conduct cases.

Misrepresentations before patent offices and misuse of regulatory procedures for the approval of drugs have previously been held to be antitrust violations by U.S. courts and by the Federal Trade Commission.

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 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.

The General Court considered the fact that in the pharmaceutical sector prices are determined or influenced by public authorities and as such may not constitute a useful indication of the degree of competition between two products. This did not, however, affect its conclusion.

It held that the difference in absolute prices of PPIs and H2 blockers reflects to a large extent the authorities' perception of a factor also taken into consideration by the EC when defining a separate market for PPIs, namely the greater therapeutic efficacy of PPIs in comparison with H2 blockers.

In addition, although the General Court recognized 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, the fact that the absence of competitive constraints may be due to the regulatory framework on the market concerned did not in its view 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 European 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 favored 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.

The first question, therefore, is whether the practice in question, taking into account 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.

Although proof of the deliberate nature of conduct liable to deceive the public authorities is not necessary for the purposes of identifying an abuse, the General Court held that that intention nonetheless constitutes a relevant factor that 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.

Finally, once it is established that certain behavior is objectively capable of restricting competition (directly or indirectly), it is not relevant whether the behavior concerned actually succeeded in restricting competition — e.g. because certain public authorities did not let themselves be misled, or because the exclusive rights concerned were revoked, or because they were never enforced.

In this respect, the judgment decision differs from U.S. 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 of the patent's fraudulent derivation.

The Second Abuse: Deregistration of Marketing Authorizations for 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 authorization of Losec capsules under the abridged procedure required the originator's authorization for that product to be in force in the country of application at the time the generic copy applied.

Deregistration, therefore, stopped such applications from being validated. The General Court observed, however, that the withdrawal from the market of Losec capsules and the introduction on the market of Losec tablets were not capable, on their own, of producing the anti-competitive 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 then considered whether AstraZeneca had an objective justification for not maintaining the marketing authorization 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 anti-competitive effects of the deregistrations in practice.

Finally, the General Court found that the existence of an alternative legal basis for generic companies to obtain copy authorizations 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 in one or more countries in the EU are likely to 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 in EU law.

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 in Europe 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, 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 U.S. procedures for obtaining and enforcing patents, and, of course, sensibilities, we expect the EU and the U.S. to follow similar but not identical paths in the development of law in this area.

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