

THE ADVOCATE GENERAL'S OPINION IN *ASTRAZENECA V. COMMISSION*

On 15 May 2012, the Advocate General of the EU Court of Justice issued his opinion on the appeal of the General Court's judgment in *AstraZeneca v. Commission*.¹ The Advocate General largely agreed with the reasoning and holdings of the General Court, and recommended that the Court of Justice reject all appeals, including AstraZeneca's appeal challenging the General Court's analysis of the definition of the relevant markets and the findings that AstraZeneca's regulatory activities related to its product Losec constituted an abuse of a dominant position in violation of Article 102 TFEU.

This opinion will come as a disappointment to many life science companies, which are struggling to come to terms with the new concept of an abuse of regulatory procedures. As demonstrated by the January 2012 decision against Pfizer in Italy, no clear legal standard for the finding of such an abuse exists, resulting in significant uncertainty for parties operating in this highly-regulated sector.

In this note, we first provide an overview of the facts in this case, and then analyze the key substantive issues addressed by the Advocate General.

FACTS

This case concerns two strategies adopted by AstraZeneca to protect its blockbuster anti-ulcer drug, Losec, against the erosion of profits due to generic competition and parallel trade. First, AstraZeneca applied to various national patent offices for extensions of the patent protection for Losec. Under the applicable pharmaceutical regulatory regime, it is possible for a pharmaceutical company to obtain a so-called "Supplementary Protection Certificate" or "SPC," which gives it up to five extra years of patent protection in order to compensate for the delays that can occur between the filing of a patent for a drug and the grant of the marketing authorization that allows the company to place the drug on the market.

Under the applicable EU regulation, the length of the supplementary patent protection depends on the date of "the first authorization to place the product on the market." During the 1990s, when AstraZeneca engaged in the conduct in question, the meaning of this phrase was unclear (it was subsequently clarified in a 2003 judgment of the Court of Justice in response to a request from a German court to resolve the ambiguity). A common interpretation of the phrase was that it referred to the date when the national authority granted the authorization. However, AstraZeneca adopted an alternative interpretation that was supported by two legal opinions. It did not consider that the date of the issuance of the marketing authorization was the correct date because there remained various administrative steps that had to be completed before the product could actually be placed on the market. Accordingly, it took the position that the relevant date was the first date when all administrative steps had been completed and the marketing authorization actually became effective, which was the date when the national government approved the price of the product.

While the precise facts differed according to the Member State involved, the essence of the conduct that gave rise to the abuse was that, when AstraZeneca applied for its SPCs, it did not explain its interpretation of the ambiguous provision to the patent office, but simply put the date when the market authorization became effective. According to the Commission, AstraZeneca misled the national patent offices because it knew that they were likely to simply assume that this date was the date of the grant of the market authorization. If they had known that it was the later date -- i.e. when the marketing authorization became effective -- they might not have granted the SPC, or at least not for the same length of time.

¹ Case 457/10, *AstraZeneca v. Commission*, [2012] [not yet published].

Second, AstraZeneca took the original capsule form of Losec off the market in several countries and replaced it with a new, tablet form that could be dissolved in water, which made it easier to take for older patients who had trouble swallowing pills. When it introduced the new version of Losec, AstraZeneca withdrew the marketing authorization for the original version. By doing so, AstraZeneca made it more difficult for a generic competitor to enter the market once the patent protection on the original version expired because, under the regulations in force at the time, the generic competitor could not ‘piggy-back’ on AstraZeneca’s authorization to obtain its own marketing authorization, thus preventing it from relying on AstraZeneca’s data relating to tests and clinical trials on the original version of Losec. It also prevented parallel imports of the original version of Losec from low-price Member States into those Member States that required that a marketing authorization for the imported product be in force.

In a decision adopted on 15 June 2005, the Commission found that AstraZeneca held a dominant position and that it had abused this position by engaging in these IP/regulatory strategies. The Commission fined AstraZeneca €60 million. AstraZeneca appealed this decision to the General Court.

On 1 July 2010, the General Court issued its judgment, upholding the Commission’s decision on all of the key points of law. However, it found that the Commission had failed to establish to the requisite legal standard the likely effect of the deregistration strategy on parallel imports and, thus, reduced the fine from €60 million to €52 million.

AstraZeneca appealed this judgment to the EU Court of Justice, with cross-appeals also made by European Federation of Pharmaceutical Industries and Associations, challenging the General Court’s holding that AstraZeneca held a dominant market position, and the European Commission, challenging the General Court’s holding that the Commission failed to prove that AstraZeneca’s actions restricted parallel trade in Denmark and Norway. The Advocate General recommended that the Court reject each of these appeals and uphold the judgment of the General Court in full.

MARKET DEFINITION / DOMINANCE

In its judgment, the General Court agreed with the Commission’s finding that AstraZeneca was dominant on the market for proton pump inhibitors (“PPIs”), a category of products for which Losec was the leader. The Commission declined to include H2 blockers (antihistamines) in the relevant product market even though they were the leading treatment for ulcers when Losec entered the market and continued to have a significant share of the market. In the Commission’s view, H2 blockers did not exercise a significant competitive constraint on Losec because Losec was considered to be a much better product and the only reason that it did not take over the market completely was the natural inertia in doctors’ prescribing practices rather than competition from H2 blockers.

The Advocate General agreed with the findings of the General Court, concluding that the gradual nature of the increase in the market share of PPIs and the fact that H2 blockers even had a higher share than PPIs at a particular point in time during the infringement period did not necessarily mean that H2 blockers exercised a significant competitive constraint over PPIs or create a presumption to that effect. In reaching this conclusion, both the Advocate General and the General Court rejected AstraZeneca’s argument that the advantages and disadvantages of PPIs and H2 blockers were necessarily interlinked. According to this argument, if doctors are reluctant to prescribe PPIs because of possible side effects, their decision to prescribe H2 blockers is due to the lack of such side effects. While the rationale of the General Court and the Advocate General is not entirely clear, it appears that they believed that the reluctance of doctors to prescribe PPIs was more because of some general concern about the side effects of PPIs rather than the lower risk profile of H2 blockers. In this regard, the Advocate General emphasized the Court’s finding that “the ‘inertia’ of doctors depended more on the accumulation and dissemination of information on the properties of PPIs than on the quality of H2 blockers.”

The General Court and the Advocate General failed to recognize that a product's side effects are a critical element of competition and that a concern over one product's side effects and the lack of such side effects on the part of a competing product are two sides of the same coin. As is widely known in the pharmaceutical industry, the side effects of a medicine can be equally as important as the efficacy, and forms an important element of competition. In particular, national pricing authorities and other parties responsible for funding the purchase of medicines will use the existence of such side effects as reasons to drive the price of the medicine down. Further, doctors consider the risk profile of a product alongside the efficacy in deciding whether to prescribe a product for a particular patient.

The Advocate General also rejected EFPIA's claims that the General Court failed to properly consider the role of the national governments as monopsony buyers in assessing whether AstraZeneca was dominant. The Advocate General pointed to the factual finding of the General Court that AstraZeneca was able to negotiate higher prices with the pricing authorities than other PPI suppliers as evidence that AstraZeneca was dominant.

SUPPLY OF MISLEADING INFORMATION

On the first abuse related to the extension of the patent rights, the General Court had upheld the Commission's finding that AstraZeneca had abused its dominant position by supplying misleading information to national patent offices. The Court had held that the submission of misleading information to public authorities that is liable to lead them to grant an exclusive right to which the company is not entitled constitutes a practice falling outside the scope of competition on the merits and, thus, runs afoul of the competition rules. It emphasized that whether the information is misleading must be assessed on the basis of the specific circumstances of each individual case. The Court stressed that it was not necessary to establish a deliberate intent to deceive, though such an intent would be taken into account. Finally, the Court held that it did not matter that the conduct did not actually produce the desired effects, that is that AstraZeneca was unsuccessful in obtaining SPCs granting protection beyond the original patent. According to the Court, it was sufficient that AstraZeneca's conduct was "very likely" to result in the issuance of the SPCs and that, if the SPCs had been issued, they would have produced significant anticompetitive effects.

Applying these principles to the facts, the Court examined each of the alleged instances of misconduct in detail and found that there was ample evidence that AstraZeneca's statements were objectively misleading. In reaching this conclusion, the Court found that AstraZeneca could not "reasonably be unaware" that its conduct was misleading. It also emphasized that the reasonableness of AstraZeneca's interpretation of the relevant regulation was not at issue; rather, the problem was that it failed to be transparent with the patent offices about its interpretation.

The Advocate General's analysis largely mirrors that of the General Court. He emphasizes that abuse of dominance is an objective concept, and that it was therefore not necessary to demonstrate that AstraZeneca acted fraudulently or with bad faith. Instead, it was only necessary to demonstrate that the statements made to the authorities were objectively misleading, in which case it may constitute an abuse, irrespective of whether the company believed its statements were correct.

At first blush, the position that the supply of misleading information to a patent office is abusive does not appear particularly troubling as it would seem to be a version of the fraud-on-the-patent-office violation that is well established in US antitrust law. However, on closer examination, the analysis of this issue contains unsettling features that could cause much second-guessing among corporate counsel in the context of their dealings with patent offices and other regulatory agencies. The General Court's ruling and the Advocate General's opinion appear to set a low threshold for a finding that a dominant company supplied misleading information. It is not necessary to establish that the company intended to deceive the patent office, or that its conduct had anticompetitive effects. Rather, it suffices to show that the conduct would likely mislead the patent office and that the conduct was capable of having anticompetitive effects. While the Court stressed that the issue of whether conduct is misleading depends on the circumstances of each case—and, indeed, its analysis was very fact specific—the concept is sufficiently vague that it harbors a troubling potential for IP owners.

To get a flavor of the potential issues, consider the case of a dominant company that files a patent application where it knows that there are some claims in its application that are debatable, but does not disclose these weaknesses in its application to the patent office. Is this failure to proactively disclose these weaknesses “misleading”? Does it make a difference how debatable the claims are before failure to disclose becomes ‘misleading’? Who determines this? Is it necessary to show that the patent office would not issue the patent if it knew of the issue? Or is it sufficient to show that it would be unlikely to issue the patent? Who determines this? Does the likelihood that the patent office would normally identify and investigate such a weakness during its review of a patent make any difference?

The Advocate General appeared to be at least somewhat attuned to these concerns and the potential for an overly broad interpretation of “misleading” conduct to have a chilling effect on innovation by creating uncertainty regarding the validity and enforceability of IP rights. In his opinion, he emphasized that the General Court had found that AstraZeneca’s conduct was “highly misleading” and characterized by a “manifest” lack of transparency. He stated that the approach taken by the General Court would not have a chilling effect on IP applications but “will rather curtail abuse of dominance resulting from highly misleading representations made to patent, or other intellectual property authorities.”² Thus, he may be suggesting that it may not be enough to show that the dominant company engaged in an aggressive regulatory strategy; rather, it may be necessary to establish conduct very close to deliberate deception, whether by act or omission.

WITHDRAWAL OF MARKETING AUTHORIZATION

In its judgment, the General Court upheld the Commission’s decision finding that AstraZeneca’s withdrawal of the marketing authorizations for the original version of Losec was abusive as it delayed access to the market of generic producers and restricted parallel trade in the original capsule version of Losec. According to the Court, the withdrawal of the marketing authorization did not involve the legitimate protection of an investment that came within the scope of competition on the merits because AstraZeneca’s exclusive right to make use of the data on its tests and clinical trials had expired. The Court also held that AstraZeneca had failed to establish an objective justification for the withdrawal because it did not show that the continued maintenance of the marketing authorization would result in a significant burden. Finally, the Court emphasized that the fact that AstraZeneca was entitled under the relevant pharmaceutical legislation to withdraw the marketing authorization was irrelevant to the assessment of whether the withdrawal constituted an abuse.

The Advocate General’s opinion focuses predominantly on this last finding of the General Court. The Advocate General, in line with the holding of the General Court, argues that the fact that AstraZeneca was entitled to request the withdrawal of its marketing authorization under the relevant pharmaceutical legislation “in no way causes that conduct to escape the prohibition laid down in Article 102 TFEU.”³ In particular, the Advocate General supports the Commission’s position that “the illegality of abusive conduct under Article 102 TFEU is unrelated to the compliance or non-compliance of that conduct with other legal regimes.”⁴

For companies that depend heavily on IP and regulatory strategies to protect their markets, this analysis of the withdrawal of the marketing authorization is unsettling. For these companies, the ability to use such strategies is critical to their ability to compete successfully. Taking the example of the pharmaceutical industry, innovative pharmaceutical companies typically have IP and regulatory experts whose job is to develop strategies that allow the companies to maximize the value of their IP rights, which are typically the result of many years of expensive R&D. These strategies commonly feature a series of measures designed to delay the entry of generic competitors onto the market—in this respect, AstraZeneca’s Losec strategy was typical. Indeed, if a company failed to implement such strategies, it could find itself at a serious competitive disadvantage because generic competitors have their own IP and regulatory experts who are tasked with exploring every avenue to gain entry into the market as early as possible.

² AG Opinion, ¶51.

³ AG Opinion, ¶79.

⁴ AG Opinion, ¶79.

Almost by definition, many of these strategies will be aimed at excluding competitors from the market, so the companies will be faced with a high degree of uncertainty regarding which IP and regulatory practices are permissible. For example, if a company engages in a defensive patenting strategy where it takes out a number of patents around the original patent in order to prevent companies from entering the market on the basis of a product that is a slight variation of the original product, this could conceivably be challenged as an exclusionary IP strategy that is not competition on the merits.

Such a narrow interpretation of 'competition on the merits' would not only seem undesirable because it harbors so much uncertainty and seems to run counter to what is generally accepted to be normal competitive behavior in industries where IP is a core asset and/or that are highly regulated, but also because it risks upsetting the balance struck in the IP and regulatory framework in determining the degree of exclusivity to be awarded to companies for new inventions. If the competition rules are applied in a way that handicaps dominant companies in their ability to fully exploit their IP, it is tantamount to amending the IP rules through the back door and risks upsetting the incentives that the legislator put in place. Indeed, concerns along precisely these lines were voiced by industry and the IP bar in the context of the Commission's pharmaceutical sector inquiry with regard to the Commission's initial suggestion that a wide range of common IP and regulatory practices were problematic under the competition rules. In its Final Report on the sector inquiry, the Commission appeared to recognize the validity of these concerns, stressing the importance of IP and adopting a more balanced and cautious tone in its discussion of these practices.

CONCLUSION

As the Advocate General's opinion simply upholds the conclusions of the General Court, without providing any significant guidance, dominant companies will continue to operate in a climate of legal uncertainty concerning their IP and regulatory strategies, and will have to proceed with caution. It can only be hoped that the EU Court of Justice will either depart from the conclusions of the General Court and the Advocate General, or at least provide more guidance for companies attempting to protect their legitimate IP rights and operate in highly regulated industries in compliance with EU competition law.

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