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JUDGMENT OF THE COURT OF JUSTICE IN *ASTRAZENECA V COMMISSION*

On 6 December 2012, the EU Court of Justice dismissed AstraZeneca's appeal of the General Court's judgment in AstraZeneca v Commission. The Court of Justice affirmed the reasoning and holdings of the General Court and rejected all of AstraZeneca's arguments, including its challenge to the General Court's analysis of the definition of the relevant markets and the findings that AstraZeneca's IP and regulatory strategies related to its product Losec constituted an abuse of a dominant position in violation of Article 102 TFEU. This judgment, from the EU's highest court, solidifies the concept of an abuse of IP and regulatory procedures and thus will come as a disappointment to many life science companies.

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 "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 supplementary patent protection begins 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. In other words, AstraZeneca adopted an interpretation of the regulation that meant the SPC would begin later, which meant a longer period of exclusivity.

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 AstraZeneca was referring to the later date -- i.e. when the marketing authorization became effective -- they might not have granted the SPC, or at least not starting on the later date.

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 no longer '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 €52.5 million.

AstraZeneca appealed this judgment to the Court of Justice, with cross-appeals also made by the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), 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 Court of Justice rejected each of these appeals and upheld 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 protein 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 Court of Justice agreed with the findings of the General Court, concluding that the gradual nature of the increase in sales of PPIs (a new product) being substituted for H2 blockers (an existing product) did not necessarily mean that H2 blockers exercised a significant competitive constraint on PPIs. Furthermore, a causal link to that effect could not be assumed because, even in the absence of H2 blockers, the sales of PPIs could have evolved in the same gradual manner due to doctors' fears regarding the possible side effects of PPIs. In reaching these conclusions, the 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. The Court of Justice was not persuaded and held that "the inertia which characterized the prescription of PPIs was a result not of the therapeutic

qualities of the H2 blockers, which were far inferior to those of the PPIs, but of uncertainty concerning the side-effects of PPIs."[1]

Both the General Court and the Court of Justice 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 form 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 Court of Justice 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 Court of Justice 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 (due to its first mover status and the higher therapeutic value of PPIs compared to H2 blockers) 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 Court of Justice agreed with the General Court that abuse of dominance is an objective concept and that Article 102 prohibits a dominant undertaking from eliminating a competitor using methods other than those which come within the scope of competition on the merits. According to the Court of Justice, AstraZeneca's deliberate attempt to mislead the patent offices through "consistent and linear" conduct consisting of" highly misleading representations" and a "manifest lack of transparency," fell outside the scope of competition on the merits.[2] Even if AstraZeneca considered its interpretation was reasonable and that it had a serious chance that

[1] Id. para. 50.
[2] Id. para. 93.

its interpretation would be accepted, the onus was on AstraZeneca to disclose all relevant information to the patent office so the office could decide, with full knowledge of the facts, which authorization it wished to accept for the purpose of issuing the SPC. The Court held that AstraZeneca knowingly accepted that the patent offices granted it SPCs which they would not have issued had AstraZeneca been transparent.

The Court of Justice clarified that dominant companies do not need to be "infallible" in their dealings with regulatory authorities and that each objectively wrong representation will not necessarily be an abuse.[3] It also emphasized that "the assessment of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made *in concreto* and may vary according to the specific circumstances of each case."[4] Thus, the Court of Justice assuaged the fears of many that the loose, open-ended language of the General Court's judgment meant that even unintentional errors in communicating with patent offices and regulatory authorities would be characterized as abusive conduct.

The Court of Justice also limited the reach of the General Court's judgment by making it clear that dominant companies would not be considered to have engaged in abusive conduct simply because a patent application was struck down when challenged: "[it] thus cannot be inferred…that any patent application made by such an undertaking which is rejected on the ground that it does not satisfy the patentability criteria automatically gives rise to liability under Article [102]."[5]

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 Court of Justice acknowledged that a dominant company is entitled to adopt a strategy to minimize erosion of sales and deal with competition from generics; however, AstraZeneca's conduct was abusive for the reasons identified by the General Court. According to the Court of Justice, the fact that AstraZeneca was entitled to request the withdrawal of its marketing authorizations "in no way causes that conduct to escape the prohibition laid down in Article [102 TFEU]."[6] "[T]he illegality of abusive conduct under Article [102 TFEU] is unrelated to its compliance or non-compliance with other legal rules."[7] Furthermore, the Court of Justice noted that the possibility to deregister a marketing authorization is not equivalent to a property right meaning that the behavioral limitations placed on the dominant company by virtue of Article 102 TFEU do not constitute an "effective appropriation" of such a right or an obligation to grant a license.[8]

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[3] Id. para. 99.
[4] Id. para. 99.
[5] Id. para. 99
[6] Id. para 132.
[7] Id. para 132
[8] Id. para. 149.

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.

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 Court of Justice upheld the conclusions of the General Court without providing 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. However, there are some aspects of the judgment that suggest that relatively common IP and regulatory strategies would not necessarily be problematic. The Court stated expressly that innovative companies should not refrain from acquiring a comprehensive portfolio of intellectual property rights, nor should they refrain from enforcing them.[9] Despite this language, dominant companies will continue to struggle with the application of the Court of Justice's judgment in practice.

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[9] Id. para. 188.