

Current Intelligence

The AstraZeneca Judgment: Implications for IP and Regulatory Strategies

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AstraZeneca AB and AstraZeneca plc v European Commission, Case T-321/05 (judgment of 1 July 2010, not yet reported).

In a judgment issued on 1 July 2010, the General Court largely upheld the Commission's decision imposing a €60 million fine on AstraZeneca for abusing its dominant position by engaging in certain IP and regulatory strategies aimed at protecting its product against generic competition and parallel imports from other Member States.

Legal context

The significance of the General Court's ruling in AstraZeneca for both pharmaceutical companies as well as for companies in other sectors is best understood when viewed in the context of the Commission's recent pharmaceutical sector inquiry. In its Final Report on the sector inquiry, the Commission suggested that certain IP and regulatory practices used by pharmaceutical companies to maximise the value of their IP rights and protect their markets against generic competition could give rise to concerns under the competition rules. However, the Commission carefully refrained from suggesting that these practices were generally problematic and, in the case of practices involving IP rights, it explicitly acknowledged that they would only give rise to infringements in 'exceptional circumstances'.

The Final Report's tone was much more balanced and cautious than that of the Interim Report issued midway through the sector inquiry in which the Commission had described these practices as belonging to a nefarious 'tool box' of instruments used by pharma-

ceutical companies to delay generic entry. The Final Report's change in tone at least partially reflected the comments received during the public consultation following the publication of the Interim Report, many of which indicated concern with the suggestion that practices that are common, not just in the pharmaceutical sector, but in all high-tech sectors, such as taking out numerous patents around an invention, were incompatible with the competition rules. If the Commission was suggesting that these practices were generally problematic, it was espousing a position that was not only inconsistent with existing law, but that risked chilling the innovation that intellectual property rights were designed to foster.

The Court's AstraZeneca judgment could well rekindle the debate over the treatment of certain IP and regulatory strategies under the competition rules and embolden the Commission to challenge a broader range of practices. As discussed below, the judgment contains broad language that has worrying implications for not only pharmaceutical companies, but for any company that relies heavily on IP and regulatory strategies to protect its markets.

Facts

The case concerned 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 EC regulation, the length of the supplementary patent protection depends on the date of 'the first authorisation 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 ECJ in response to a request from a

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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 authorisation 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 authorisation 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 authorisation 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 authorisation. If they had known that it was the later date when the marketing authorisation became effective, they might not have granted the SPC, or at least not for the same length of time.

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 authorisation 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 it could not 'piggy-back' on AstraZeneca's authorisation to obtain its own marketing authorisation, thus preventing it from relying on AstraZeneca's data relating to tests and clinical trials on the original version of Losec. At the time, 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 authorisation 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.

In a much-anticipated judgment rendered five years after the Commission's decision, the General Court upheld 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.

Analysis

Market definition

In addressing the threshold issue of dominance, the General Court agreed with the Commission's finding that AstraZeneca was dominant on the market for protein pump inhibitors, a category of products for which Losec was the leader. The Commission declined to include antihistamines in the relevant product market even though they were the leading treatment for ulcers when Losec entered the market. In the Commission's view, antihistamines 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 antihistamines. While a discussion of the market definition issue is beyond the scope of this short comment, it is worth noting that the Court's ruling may well embolden the Commission to pursue narrow market definitions for drugs, particularly when a new drug represents a clear improvement over existing drugs. Indeed, the Commission could even apply the same line of reasoning when defining markets in other industries.

Supply of misleading information

On the first abuse related to the extension of the patent rights, the Court upheld the Commission's finding that AstraZeneca had abused its dominant position by supplying misleading information to national patent offices. The Court 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 emphasised that whether the information is misleading must be assessed on the basis of the specific circumstances of each individual case. The Court explained that 'it is

necessary to examine whether, in light of the context in which the practice in question has been implemented, that practice was such as to lead the public authorities wrongly to create regulatory obstacles to competition, for example, by the unlawful grant of exclusive rights to the dominant undertaking.' (para. 357). 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 had misled the patent offices. In reaching this conclusion, the Court found that AstraZeneca could not 'reasonably be unaware' that its conduct was misleading (para. 493). It also emphasised 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.

At first blush, the Court's holding 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 Court's 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. In particular, the Court's ruling appears 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 company should have reasonably been aware that its 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 harbours a troubling potential for IP owners.

To get a flavour 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. Under AstraZeneca, 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?

While the uncertainty surrounding the meaning of 'misleading' gives rise to a host of potential issues, a reasonable reading of the judgment suggests that it is not enough to show that the dominant company engaged in an aggressive regulatory strategy; rather, it would seem necessary to establish conduct very close to deliberate deception, whether by act or omission. If the critical concept of 'misleading' is not construed narrowly along these lines, this could have a chilling effect on innovation. An interpretation that would impose an ill-defined duty of proactive transparency on dominant companies would inject an undesirable degree of uncertainty into the legal environment surrounding the validity and enforcement of IP rights, which would undermine the value of those rights and dilute the pro-competitive incentives they are designed to foster.

Withdrawal of marketing authorization

On the second abuse of withdrawing the marketing authorisations for the original version of Losec, the Court agreed with the Commission that such conduct was abusive if it restricted access to the market of generic producers and restricted parallel trade in the original capsule version of Losec. While the Court acknowledged that a dominant company may protect its commercial interests if attacked, it held that it could not use regulatory procedures to prevent or delay the entry of competitors onto the market in the absence of grounds relating to either the defence of its legitimate interests related to competition on the merits or objective justifications. According to the Court, the withdrawal of the marketing authorisation 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. Furthermore, AstraZeneca had failed to establish an objective justification for the withdrawal because it did not show that the continued maintenance of the marketing authorisation would result in a significant burden. Finally, the Court emphasised that the fact that AstraZeneca was entitled under the relevant pharmaceutical legislation to withdraw the marketing authorisation was irrelevant to the assessment of whether the withdrawal constituted an abuse.

AstraZeneca argued that its strategy of introducing a new, improved version of Losec and withdrawing the old version was all part of a legitimate strategy for countering a competitive threat from generics and constituted competition on the merits. The withdrawal of the marketing authorisation of the old version was an integral part of this strategy because it protected the new tablet version of Losec against competition from generic versions of the old capsule version.

The Court held that a dominant company's pursuit of a strategy 'whose object it is to minimise erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process' (para. 804). However, it added an important condition: the strategy must involve only practices 'coming within the scope of competition on the merits, which is such as to benefit consumers' (para. 804).

In the Court's view, the launch of the new tablet version of Losec and the withdrawal of the capsule version were legitimate strategies because they did not raise the legal barriers to generic entry. In contrast, the withdrawal of the marketing authorisation for the old version was abusive because it raised such legal barriers and 'was not based on the legitimate protection of an investment designed to contribute to competition on the merits' (para. 812). The Court also noted that AstraZeneca had not produced evidence demonstrating that the withdrawal was necessary or useful to the introduction of the new form of Losec. According to the Court, the fact that the regulatory framework offered generics an alternative route to entry was irrelevant because the withdrawal of the marketing authorisation would have the effect of slowing generic entry.

For companies that depend heavily on IP and regulatory strategies to protect their markets, the Court's analysis of the withdrawal of the marketing authorisation 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.

The Court's judgment contains language that could be interpreted as placing severe restrictions on the ability of dominant companies to use IP and regulatory strategies to exclude competitors. The Court held that a dominant company may not pursue such a strategy even if it is entirely legal unless it is able to show that the strategy constitutes competition on the merits aimed at protecting its legitimate interests or is objectively justified.

The long-term implications of this holding will turn on the interpretation of the concepts of 'competition on the merits' and 'objective justification'. In its judgment, the Court appeared to place a very restrictive gloss on these concepts, but it did so in the very specific factual context of the case. In particular, the withdrawal of the marketing authorisation could be characterised as exploiting a loophole in the regulatory framework, so that the conclusion that this did not constitute competition on the merits would not seem remarkable.

However, if the concept of 'competition on the merits' is construed narrowly in other contexts, it could place dominant companies that rely heavily on IP and regulatory strategies at a distinct disadvantage. 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 harbours so much uncertainty and seems to run counter to what is generally accepted to be normal competitive behaviour 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 recognise the validity of these concerns, stressing the importance of IP and adopting a more balanced and cautious tone in its discussion of these practices.

Practical significance

The Court's ruling in *AstraZeneca* may well rekindle the debate that took place in the context of the pharmaceutical sector inquiry concerning the application of EC competition law to various IP and regulat-

ory strategies. While the Commission has remained openly sceptical about the merits of reverse payment patent settlements in the pharmaceutical sector, it has generally adopted a cautious tone regarding possible enforcement actions involving other IP and regulatory practices that were examined in the course of the sector inquiry. The *AstraZeneca* judgment could lead the Commission to alter its tone and pursue a more aggressive enforcement strategy. The initial target of enforcement actions would likely be pharmaceutical companies, but companies in other industries that rely heavily on IP and regulatory strategies to protect their markets could eventually find themselves in the Commission's crosshairs.

As a practical matter, the judgment means that dominant companies will be operating in a climate of legal uncertainty concerning their IP and regulatory strategies, and will have to proceed with caution. Unless the Commission provides guidance to companies on how it interprets *AstraZeneca*, the much-needed clarity in this area will have to await decisions in individual cases.

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