AstraZeneca: a new horizon for competition practices in the EU

Marleen Van Kerckhove and *Raphael Fleischer* discuss the implications for drug companies of the precedent-setting EU court ruling on abuse of a dominant position.

The December 2012 decision by the Court of Justice of the European Union on what constitutes an abuse of a dominant position in the pharmaceutical sector sets a precedent that can be expected to make it harder for innovator drug companies to fend off competition from generic drugs[1-2].

The CJEU judgment in *AstraZeneca v Commission* will make it more difficult for successful innovators holding strong IP portfolios to demonstrate their lack of a dominant position in future cases involving allegations of abuse.

The judgment also provides guidance on when behavior by pharmaceutical companies that is capable of delaying or preventing the introduction of generic products or parallel trade will be found to be beyond the scope of competition on the merits and constitute abusive conduct.

A first of its kind case

The CJEU's decision on 6 December last year upheld a 2010 judgment from the General Court and largely upheld a 2005 decision by the European Commission[3-5]. Both the General Court and the commission had found that AstraZeneca had abused its dominant position by preventing or delaying entry into the market of a generic version of its product Losec, a proton pump inhibitor used to treat acid-related gastric diseases.

The case has significant implications for branded drug companies. It was the first of its kind, outside an M&A context, to analyse the issue of market dominance in relation to branded drugs. It was also the first to provide guidance on how otherwise permissible use of regulatory procedures can breach competition rules if engaged in by a company that is in a dominant position in the relevant market.

The CJEU generally made an effort to temper somewhat the sharp edges of the General Court's judgment. However, it also confirmed fears in the pharmaceutical industry that companies that hold a high market share over a longer period of time, and also enjoy strong patent protection and first-mover status in the market, are now more likely to be found to be in a dominant position. While the CJEU has in the past confirmed that having a dominant position alone does not imply abusive conduct, lowering the bar to find dominance will also make it more difficult for companies to fend off allegations of abuse.

We will now consider the content of the judgment in more detail and look at its implications for successful innovators.

Dominance with monopsony buyers

The essential question facing the CJEU was whether, under the traditional definition of market power in EU case law[6], AstraZeneca had "the ability to operate to an appreciable extent independently of competitors and ultimately consumers" even though it operated in a market where it faced monopsony buyers for Losec (in the form of the states of several countries) and where there was little scope for price competition.

Firstly, the CJEU supported the General Court's finding that if a company holds high market shares over a long period of time, this in itself constitutes – except in exceptional cases – proof that the company is in a dominant position in that market. Both courts held that this was the case with AstraZeneca. The CJEU also ruled that the commission was entitled to give particular weight to AstraZeneca's market shares because these shares were very high during the relevant period.

Secondly, the CJEU agreed with the General Court that the specific market structure in which AstraZeneca operated was potentially relevant to its analysis of whether AstraZeneca was in a dominant position. A key feature of the market in which AstraZeneca was operating was that regulators – as monopsony buyers – were effectively functioning as a competitive constraint to AstraZeneca's power to set prices. Still, the CJEU upheld the General Court's view that, even though there was limited scope for competition on the grounds of price in the relevant market, AstraZeneca could not successfully argue that it was significantly constrained by that monopsony power.

The CJEU gave two reasons for this, supporting the General Court's findings. The first reason was that AstraZeneca was the first company in the relevant market to produce proton pump inhibitors. As a result of its first mover advantage, AstraZeneca was able to attract a higher price from the state buying authorities compared to subsequent entrants into the market.

The second reason given by the CJEU was that a branded drug company bringing a valuable new medicine into a new market faces a greater and more inelastic demand. This results in a situation in which the company concerned – in this case AstraZeneca – can, according to the CJEU: "set its price at a high level without having to worry about patients and doctors switching to other less costly products".

The CJEU also held that the commission was entitled to base – in part – its finding that AstraZeneca was in a dominant position on the fact that AstraZeneca was the first to introduce a PPI on the market and possessed strong patent protection for Losec.

The result of this judgment is that a company that brings a successful first-in-class drug to market, possesses a strong patent portfolio and enjoys a prolonged period of high market shares will find it difficult to successfully argue that it is not in a dominant position.

Misleading representations

When it upheld the commission's decision to fine AstraZeneca, the General Court had confirmed that AstraZeneca abused its dominant position in several markets by systematically providing misleading information to national patent offices, and that this recurring conduct had led regulatory authorities to grant exclusive rights (supplementary protection certificates or SPCs) to which AstraZeneca was not entitled.

When the case went to the CJEU on appeal, the General Court was criticized by AstraZeneca for having suggested that even trivial misrepresentations before regulatory authorities could lead to the finding that there had been a serious breach of competition law in the form of an abuse of a dominant position. AstraZeneca argued it was untenable that all regulatory representations had to be "infallible". In its judgment, the CJEU went to some length to explain why it thought the General Court was right and, in doing so, appears to have added one or two emphases of its own.

The CJEU found that AstraZeneca's behavior constituted unlawful conduct manifestly falling outside the scope of competition on the merits. The CJEU came to this conclusion on the grounds that, objectively speaking, AstraZeneca made highly misleading representations to regulatory authorities, which was part of consistent and linear conduct. Moreover, said the court, this was conduct that was objectively capable of leading regulatory authorities to grant exclusive rights (in the form of SPCs) to which AstraZeneca was not entitled, and AstraZeneca could not have been unaware of this fact.

The CJEU also took the view that

AstraZeneca demonstrated a manifest lack of transparency when it did not disclose to the relevant patent offices how it interpreted provisions of EU law relating to the procedures for obtaining SPCs. The CJEU stressed that: "the onus was on AstraZeneca to disclose to the patent offices all the relevant information … in order to allow them to decide, with full knowledge of the facts".

It was also this specific course of behavior, taken together with all of the above circumstances that spurred the CJEU to find, after careful investigation, that AstraZeneca could not successfully argue that it had interpreted the regulatory requirements in "good faith".

However, the CJEU explained that representations to regulatory authorities that are intended to unlawfully obtain exclusive rights can only constitute an abuse if it is established that those representations are actually liable to lead the regulatory authorities to grant an exclusive right. In order to assess whether a misrepresentation was liable to have this effect, it was relevant, according to the CJEU, to take into account that the regulatory authorities had limited resources and were under no obligation to verify the accuracy or veracity of the information provided by an entity such as AstraZeneca.

In what is arguably an effort to tone down the judgment of the General Court, the CJEU was of the opinion that the General Court did not hold that companies in a dominant position had to be infallible in their dealings with regulatory authorities. The CJEU clarified by saying that the assessment of whether representations for the purposes of improperly obtaining exclusive rights are misleading must be made in regard to the specific facts of the case and may – as a result – vary from case to case. In other words, it cannot be assumed in advance that misrepresentations will lead to the finding that there has been an abuse.

Finally, the CJEU added that there was no need to demonstrate that misleading representations to regulatory authorities would cause actual harm to competition in the relevant market, it was sufficient to demonstrate that there was a potential anti-competitive effect.

In sum, the CJEU reaffirmed the General Court's finding that misleading representations to regulatory authorities may – subject to the specific facts of a case – constitute a ground for finding an abuse. At the same time, the CJEU found that companies need not to be "infallible" when making representations to regulatory authorities. In other words, companies must be transparent as to their good faith interpretations of legal provisions – especially when they can influence the grant of exclusive rights and the erection of barriers to entry – by agencies with limited authority to review representations made to that end.

Abusive deregistering

The commission had defined the second abuse committed by AstraZeneca as a combination of deregistration of the marketing authorization for Losec capsules with the conversion of sales of capsules into tablets. However, shifting the emphasis somewhat, the General Court had held that the central feature of the abuse consisted in deregistration of marketing authorizations, the conversion of sales of capsules into tablets merely being the context in which the deregistration was carried out. The CJEU agreed with the General Court in this, having confirmed with the commission during the proceedings that it was the deregistration alone that was liable to produce the anti-competitive effects and, hence, that constituted the abuse.

In its analysis of this second abuse, the CJEU helpfully pointed out in its preliminary observation that: "the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the 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".

However, it found that on the facts of this case, AstraZeneca's conduct did not come within the scope of competition on the merits and, hence, that it was abusive. Given the special responsibility of a company in a dominant position, such a company may not use regulatory procedures otherwise open to it if the use of such procedures would amount to an abuse under competition rules.

Firstly, the CJEU reiterated the General Court's view that because under Directive 65/65 on the approximation of provisions laid down by law, regulation or administrative action relating to medical products, AstraZeneca no longer had an exclusive right to make use of the clinical results at the time of the deregistration of the marketing authorizations, it was not pursuing conduct based on the legitimate protection of an investment.

Secondly, the CJEU found no objective justification for AstraZeneca's behavior. Although it recognized that the onerous pharmacovigilance obligations spurring from a marketing authorization may constitute such justification, it held that AstraZeneca had failed to advance a factual basis for such claim.

Conclusion and outlook

The CJEU's first finding of abuse was based on what it qualified as AstraZeneca's highly misleading representations to regulatory authorities and AstraZeneca's manifest lack of transparency, which led the regulatory authorities wrongly to grant AstraZeneca exclusive rights. With respect to the second finding of abuse, the CJEU condemned the use of regulatory procedures to hinder competitors, where the use of these procedures is not based on the legitimate protection of an investment or an objective justification. Both findings, however, were grounded in what was, arguably, an unhelpful set of facts. Indeed, the CJEU has been careful not to shut the door on behavior that is less onerous and more competitive on the merits of the case.

The CJEU also underlined that a company that brings a new drug to market and that possesses a strong patent portfolio in addition to high market shares will find it very difficult to successfully argue that it is not dominant for purposes of Article 102 of the Treaty on the Functioning of the European Union.

Looking ahead, we expect that it may be easier for complainants to show dominance, but the contours of what constitutes abusive conduct remain to be further clarified. It would be prudent for first mover innovators, in particular, to carefully analyze their planned regulatory and marketing strategy of successful drugs against this precedent.

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