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The General Court's Judgment In AstraZeneca, Interacting With Regulatory Authorities

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In my last post, I discussed the General Court's findings on market definition and dominance analysis in its AstraZeneca judgment. In this post, I review the Court's findings on abuse.

In its decision, the Commission held that Astra had abused its dominant position (1) by providing patent authorities misleading launch date information when applying for a special protection certificate for Losec and (2) by withdrawing its marketing registration for an older version of Losec in certain Member States to impede generic producers and parallel traders.

The Court largely confirmed these conclusions. The Court's findings shed new light on the principles that govern the interaction of dominant companies with state authorities. In particular the following points are worth noting:

First, the Court concludes that dominant companies have a duty of candor vis-à-vis regulators (including patent authorities). In its application for a special protection certificate for Losec, Astra provided the date of Losec's first price approval, rather than the date of Losec's first technical marketing authorisation, as would have been usual. This was based on Astra's re-interpretation of the applicable SPC rules pursuant to which the relevant date was the one on which the product had obtained all regulatory approvals needed in order to be launched in a Member State. But Astra did not disclose that its indicated date was based on such a re-interpretation.

The Court agreed with the Commission that this was liable to mislead patent authorities. The Court noted that Astra "could not reasonably be unaware that, in the absence of an express disclosure of the interpretation that it intended to adopt" patent authorities would understand the date as referring to the date of the first technical marketing authorisation.

The Court observed that Astra could not expect the authorities to ask follow-up questions or verify the information provided. Instead, the Court made clear that a dominant company in Astra's situation had a duty to engage in "proactive disclosure" if the authorities would otherwise risk misunderstanding the company's communications. While the Court does not provide much guidance on the meaning of "proactive disclosure," it is clear that dominant companies should seek to ensure that their communications with regulators and patent authorities are transparent, complete, and not misleading.

Second, the Court confirms that the use of regulatory measures to obstruct competitors may be

abusive. The Court agreed that Astra's withdrawal of the registration for Losec capsules in certain Member States constituted an abuse. This was essentially because Astra's withdrawal was liable to impede generic entry and Astra had not established an objective justification for that withdrawal. The Court rejected Astra's attempt to justify the withdrawal, as being too late and contradicted by Astra's internal documents. The Court, on the other hand, disagreed with the Commission that Astra's withdrawal was also liable to impede parallel traders. The Court noted that the Commission had failed to establish that under the legal system of the Member States concerned Astra's withdrawal would have in fact forced parallel traders to withdraw from the market.

While the Court's judgment shows that Article 102 TFEU can apply to the strategic use of regulatory measures, it is worth noting that Astra's withdrawal of product registrations was a measure where the company was able to change the regulatory situation unilaterally without involvement of the regulatory authorities.

In most instances of interaction with regulatory authorities, a change in the regulatory situation requires a decision by the regulatory authorities themselves. In such instances, application of Article 102 TFEU is arguably more difficult, so long as the authorities are not misled. This is because in such cases it is the authorities that bear the responsibility for the change in the regulatory situation.

Ultimately, the Court's Astra judgment therefore dealt with two relatively narrow matters: the provision of misleading information to patent authorities and a unilateral change in the regulatory situation that was solely designed to obstruct competitors. Although the Commission in its pharmaceutical sector inquiry repeatedly referred to the Astra case as a relevant precedent, the Astra judgment therefore cannot be understood as endorsing the kind of broad theories relating to patent strategies and interaction with regulatory authorities that the Commission investigated in that inquiry.

To the contrary, the Court specifically recognized the right of pharmaceutical companies to develop and implement strategies in response to generic competition, as long as this is done through legitimate means. As the Court stated, "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, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits".

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