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The General Court's Judgment In AstraZeneca, Lessons For Market Definition And Dominance Analysis

Thomas Graf (Cleary Gottlieb Steen & Hamilton LLP) · Tuesday, August 17th, 2010

On July 1, 2010, the European General Court rendered its judgment in the *AstraZeneca* case, dismissing for the most part AstraZeneca's appeal against the Commission's infringement decision of June 2005. In that decision, the Commission had found AstraZeneca's Losec to be dominant in the market for proton pump inhibitors, a type of medicine used for the treatment of ulcers and other gastrointestinal problems. The Commission held that AstraZeneca had abused that dominant position in two ways: (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 Denmark, Sweden, and Norway to impede generic producers and parallel traders.

The judgment contains a number of noteworthy observations both on market definition/dominance and on conduct analysis. In this post, I explore some of the Court's findings on market definition and dominance. The following three points are worth highlighting in this regard:

First, the Court confirmed that the general principles for market definition also apply in the pharmaceutical industry. The Court rejected the suggestion that state regulation of medicine prices and the reimbursement of medicines by national health insurance systems exclude the application of these principles. The Court observed that "*an economic approach based on the observation of the reaction of demand to relative price changes*" was not precluded by the particular regulatory features of the pharmaceutical industry. The Court's refusal to recognize the regulatory characteristics of the pharmaceutical industry as a reason for excluding general EU competition law principles continues the trend set by the Court of Justice in *Lelos*, which declined to treat the high degree of regulation in the pharmaceutical industry as a justification for conduct under Article 102 TFEU.

Second, the Court confirmed the need for a close analysis of the therapeutic use of a medicine for the purpose of market definition. The Commission's standard practice in pharmaceutical cases is to take the ATC 3 class of the EPhRMA classification system as a starting point for market definition. But this initial delineation can be expanded or narrowed depending on the particular therapeutic characteristics and application of the medicines at issue. The AstraZeneca case provided the first opportunity for the Court to confirm the soundness of the Commission's approach. As a consequence, pharma markets can potentially be delineated quite narrowly, as in the case at hand, which treated proton pump inhibitors as a market distinct from other ulcer medicines. But it can also result in broad markets if medicines from different classes serve the

same therapeutic purpose, such as asthma medicines, which the Commission in *Merck/Schering Plough* found to compete across several classes. Market definition in the pharmaceutical industry therefore requires a good understanding of a medicine's specific therapeutic effects and its use in medical practice.

Third, on dominance, the Court suggested that the existence of national price and reimbursement regulation may in fact be a reason to support a finding of dominance. The Court identified national reimbursement systems as an element that could "*reinforce the market power of pharmaceutical companies*" because it may allow them to maintain their prices "*at a high level without having to worry about patients and doctors switching to other less costly products*". The Court observed that national regulators had granted AstraZeneca's Losec a higher price than later "me-too" proton pump inhibitors and that AstraZeneca had been able to maintain this higher price without losing market share as a result of national reimbursement systems. In other words, the Court suggested that national pricing and reimbursement systems shielded AstraZeneca from competition.

This last point raises a number of questions. First, the classic definition for dominance is that a dominant company must be able to act independently from competitors, customers, and consumers. It seems at least debatable whether this concept can be applied to the scenario discussed by the Court. According to the Court, AstraZeneca was able to obtain a higher approved price than later proton pump inhibitors because national regulators wanted to reward AstraZeneca for its innovation. The higher price of Losec therefore appears to have been the result of a conscious policy choice by regulators. It did not reflect an ability by AstraZeneca to impose unilaterally its pricing preferences. As a result, one may query whether such a price really indicates an ability to act "independently" within the meaning of past case law.

Second, much of the Court's discussion focuses on the behavior of doctors and patients but does not to fully address the role of the state. It is of course true that in the case of full reimbursement, cost considerations will have little impact on the decisions of patients and doctors. But the question this raises is whether in cases of a reimbursed medicine, the state (rather than the patient or doctor) should be seen as the real customer. It is the state, which ultimately bears the costs of the medicine and which decides on its price. The state therefore is in effect in the position of a quasi monopsonist, which should off set market power of pharmaceutical companies at least to some degree.

The judgment contains very little discussion on this issue. In essence, the Court limits itself to an observation that prices are set "*as a result of a dialogue*" with pharma companies and that these companies have "*bargaining power*" because they can decide not to market a product in a particular country. These observations do not appear particularly convincing. Prices are often set in a "*dialogue*" and a company has always the option not to sell a product if it considers the price to be too low. That does not necessarily translate into dominance. The Court does not point to empirical evidence indicating that threats of non-launch are in effect successfully used in negotiations with price regulators. It is doubtful to what extent such threats could in fact serve as an effective tool because of both the commercial and ethical pressure to market a medicine once it has been successfully developed.

Third, to the extent that pricing and reimbursement regulation could indeed contribute to dominance this will depend on the specific nature of the regulation at issue. The Court's key finding seems to have been that the relevant national regulation enabled AstraZeneca's Losec to benefit from a "first mover advantage" *vis-à-vis* other proton pump inhibitors. Other regulatory

systems may not have such an effect. For example, in some Member States, regulators create reimbursement groups that impose the same maximum reimbursement amount for medicines of the same class or with the same indication. In such regulatory systems, there is arguably little or no scope for entrenching any possible "first mover advantage", since lower priced alternatives will reduce also the reimbursed amount for the first mover. As a result, the first mover will typically have to reduce its price or risk losing market share.

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">Dominance, Source: OECD">Market definition

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