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Case C-457/10 P, AstraZeneca v Commission, Judgment of 6 December 2012

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On 6 December 2012, the EU Court of Justice handed down judgment in the long-running AstraZeneca litigation. Practitioners hoping for an opinion that tempered some of the more extreme *dicta* of the General Court found a more measured judgment. The Court upheld the General Court's judgment in its entirety. But it refrains from endorsing the General Court's dangerously low threshold as to what conduct before the patent office will constitute an abuse of a dominant position. That said, there is no comfort to be gained on market definition. The Court brushes aside any errors that the General Court made as being a side show that would not alter the final outcome. The Commission's very broad discretion to find a narrow market, and hence a dominant position, is maintained.

Background

In 2005 the EU Commission fined AstraZeneca EUR 60 million for abusing its dominance in relation to proton pump inhibitors ("PPIs") in two ways: (i) using misleading statements to obtain supplementary protection certificates ("SPCs") that extended its exclusivity in relation to Losec and (ii) using regulatory procedures (namely the deregistration of Losec's capsule form) to delay the authorization of competing generic products. This decision was upheld by the General Court, albeit the fine imposed was reduced to EUR 52.5 million. The specifics of the allegations are now largely of historic interest since the transitional teething troubles of the SPC regulation have long since been resolved. The law has also been changed so that the withdrawal of a marketing authorization ("MA") does not (generally) prevent generics relying on the MA, even post withdrawal, as a short cut to regulatory approval under the abridged authorization procedure. However, the judgment establishes principles that are far wider than just these historical regulatory footnotes. These principles will apply to all dealings with the patent office and with regulators by companies with a "dominant" market position.

Narrow Market Definition

Rejecting pleas that PPIs gradually replaced H2 blockers, thus suggesting competitive constraints of substitutable products, the Court declined to overturn the Commission's wide margin of discretion when making complex appraisals of this kind. It found the General Court did not err in law by concluding that the gradual nature of the increase in sales for PPIs was not due to the competitive constraint exercised by H2 blockers. It also agreed that the General Court's treatment of doctors prescribing inertia in the context of market definition and the substantive examination of dominance was justifiable. So too it was unmoved by submissions that "dominant" market power was impossible where EU states exercise powers to set price and terms of supply.

This approach to market definition suggests very narrow markets can be established and defended by the Commission before the EU courts. The Commission can easily conclude that companies coming to market with innovative products commanding higher prices are likely to be dominant. This approach fails to take due account of other external factors such as the regulatory environment within which pharmaceutical medicines operate, the ability of others players to enter the market and the competitive role played by existing therapies.

Misleading Statements to the Patent Office

For practitioners, the most important part of the judgment is the treatment of the legal test established by the General Court for determining when a misleading statement to the patent office can constitute an abuse of dominance.

The General Court's test has been subject to much criticism as it sets the bar very low. It provides that any objectively misleading statement to the patent office can amount to abusive conduct. The test is an objective one – whether the statement is in fact erroneous – which takes no account of the state of mind of the person making the representation. Even a genuine and honest error made by a dominant company in the context of a patent application process, if not promptly self-corrected, can amount to an abuse under this standard. This is regardless of whether that error is ultimately corrected as part of the appropriate checks and balances systems internal to patent office.

Had this been upheld, it would have been highly damaging. The patent examination process takes years, and more than 50% of the hundreds of thousands of applications made each year do not result in a patent being issued. In each case, an invention presented as patentable was found objectively not to be so. Could the General Court seriously be saying that each unsuccessful inventor is also potentially liable to huge fines for an antitrust violation?

The Court of Justice goes some way towards tempering the extreme test set by the General Court. It examines at length the scale, deliberateness and prolonged nature of the alleged misrepresentations. It finds that this "consistent and linear conduct … characterised by … highly misleading representations and by a manifest lack of transparency" clearly engages antitrust liability (para. 93). Conversely, it explicitly gives comfort to day-to-day patenting practices. No company faces liability merely for ordinary fallibility or because the subject matter of a patent application is ultimately found not to have met the patentability criteria (para. 99).

"[T]he General Court did not hold that undertakings in a dominant position had to be infallible in their dealings with regulatory authorities and that each objectively wrong representation made by such an undertaking constituted an abuse of that position … that example is radically different from [AstraZeneca's] conduct in the present case."

"[T]he 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. It thus cannot be inferred from that judgment 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] EC."

So where does it ultimately set the bar for antitrust liability, and the high fines that follow? A simple mistake in communication with the patent office is not enough. Large scale deception plainly suffices. The Court abstains from setting a specific test between these two ends of the

spectrum. While this may need to be settled at a future date, companies at least have comfort that the Commission cannot cite unchallenged the extremes of the General Court's test.

Effect on Competition

In contrast, the Court sets a low bar for the requirement to find an effect on competition in abuse of dominance case. The Court has no difficulty in concluding AstraZeneca's allegedly misleading representations to the patent office had an effect on competition. This was notwithstanding that: (i) the company was not dominant at the time the allegedly misleadingly procured exclusive rights were to take effect; (ii) the misleading statement was in some cases detected and corrected by the patent offices before any competitors learnt of the possible grant of an SPC; and (iii) the SPC rights were in some cases not subsequently relied upon to restrict generic entry. The Court overcomes all these objections with the semantic device that even "potential" anticompetitive effects give rise to the requisite effect on competition under Article 102 TFEU

"although the practice of an undertaking in a dominant position cannot be characterised as abusive in the absence of any anti-competitive effect on the market, such an effect does not necessarily have to be concrete, and it is sufficient to demonstrate that there is a potential anti-competitive effect." (para. 149)

Practitioners may be forgiven for asking where the boundary lies between "no effect" and a "potential effect."

Misuse of regulatory procedures

The Court upholds the General Court in finding that use of a regulatory procedure to exclude competitors engages Article 102 liability, unless it can be shown there is a legitimate reason or objective justification for that regulatory act. It is irrelevant that as a regulatory matter, the company is entirely within its rights. Article 102 acts as an unseen overlay to all regulatory procedures, outlawing conduct that the regulation may on its face permit, if an ill defined boundary into dominance and competitor exclusion is crossed. Though an unsatisfactory result in terms of legal certainty, the Court's confirmation that a legitimate reason for the regulatory conduct will be sufficient to excuse exclusionary effects means the second AstraZeneca abuse is not as potentially far reaching as the first. It will be a rare fact pattern where a company uses regulation only to block a competitor and can show no other motive. For example, the Court was prepared to accept that avoiding phamacovigilance obligations might in principle be grounds for deregistration (an act which – under the then prevailing legal view – also impeded generic entry). But it found that AstraZeneca had put forward no evidence that this had been its motive. The file instead showed only anticompetitive intent.

Conclusion

The judgment is firmly rooted in the specific facts of the AstraZeneca case. It could well be that this case proves to be an outlier on the fringes of competition and IP law. The Court's efforts to temper the General Court's judgment on what constitutes an "objectively misleading" statement is to be welcomed, for all that it offers no clear standard to replace it. At minimum, the statement that simple mistakes during the patenting process are not impugned gives companies comfort, and starts to give some boundaries to an otherwise untenably broad precedent. Regulators know that any form of miscommunication cannot be seized upon as abusive. Rather they must have in mind that absent strong evidence of sustained, near-fraud type conduct, they risk failing to meet the – as yet unidentified – Court of Justice standard of abuse.

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