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AstraZeneca v Commission, Advocate-General Mazak's Opinion of 15 May 2012

Gavin Bushell (Baker McKenzie, Belgium) · Monday, June 11th, 2012

On 15 May 2012, Advocate-General Mazák delivered his long awaited Opinion to the European Court of Justice in the long-running AstraZeneca litigation. Practitioners hoping for an opinion that tempered some of the more extreme dicta of the General Court were to be disappointed. Advocate-General Mazák recommended that the General Court's judgment be upheld in its entirety. He endorses the very low threshold as to what conduct before the patent office will constitute an abuse of a dominant position – namely any objectively misleading statement to the patent office, regardless of whether it was honestly made which leads to the grant of exclusive rights and exclusion of competitors. He also recommends confirmation of the equally controversial alleged abuse, namely that of using regulation – in this case deregistration of a marketing authorization – for the purpose of restricting a competitor even if the marketing authorization holder has done no more than it is expressly entitled to do by law. That these rules apply only to companies with a dominant market position is scant comfort. As the Advocate-General's opinion makes clear, he recommends the Court defer to the Commission and General Court on the very narrow market definition used to find AstraZeneca dominant.

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 law has 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 demonstrating the competitive constraints of substitutable product, the Advocate-General acknowledged the importance of the test of substitutability when defining the relevant market. But he declined to overturn the Commission's wide margin of discretion when making complex appraisals of this kind. He 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. According to the AG, "in the case of evolving markets, sales and substitutions trends must be examined over time [and] [t]he mere fact that there were significant sales of H2 blockers at the end of the relevant period does not mean that PPIs and H2 blockers were part of the same relevant market" (para 28 of the Opinion). He 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 wholly justifiable in light of the Court's specific findings of fact and therefore its approach was neither "inconsistent nor incoherent".

If accepted by the Court of Justice, 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 Opinion is the Advocate-General's 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.

The Advocate-General did not take the opportunity to deal with the potentially damaging implications of this legal standard. He demonstrates sensitivity to the operation of the patent process by confirming that the mere non-disclosure of a novel legal argument will not be sufficient for a statement to qualify as "objectively misleading." However, this is the only bright spot on an otherwise tame review of the appropriate legal standard. AG Mazák unequivocally opposes the introduction of any fraud or subjective intent element to the test on the basis that "it radically departs from the principle that abuse of dominance is an objective concept [and] it also constitutes an attempt to apply criminal evidence standards to a procedure which the Court of Justice has stated is administrative rather than criminal in nature." It is not certain that such an argument is consistent with the obligations under Article 6 of the European Convention of Human Rights ("ECHR") (guaranteeing the right to a fair and impartial trial) and the recent jurisprudence stemming from EU cartel litigation concerning the criminal nature of antitrust fines under the ECHR. Nor is it consistent with other, analogous, abuses such as vexatious litigation (or certain predatory pricing above average variable (or avoidable) costs) where an eliminatory plan or intent is required for liability.

When examining the General Court's legal standard, AG Mazák seems to ascribe considerable weight to the "highly misleading representations" made by AstraZeneca during the SPC application procedure and the fact that these representations "clearly exceeded any bona fide

interpretation of the applicable law" (para. 51 of the Opinion). At first glance, this language could be interpreted as an attempt by the Advocate-General to narrow the General Court's precedent by introducing an intent element and requiring that the statement be "highly or deliberately" misleading in nature. But such a favorable interpretation does not survive further reading of the Opinion. Ultimately the Advocate-General re-adopts the General Court's legal test and concludes that "an undertaking in a dominant position may not make objectively misleading representations to public authorities to obtain a right, irrespective of whether that undertaking believes it is entitled to that right" (para 51 of the Opinion). This formulation confirms a dominant company will be liable for any misleading statement regardless of whether this was an honest error and without any element of fraud or intent being required.

Yet in a patent application process that can last years and in which over 50% of applications are rejected or withdrawn, can the "objectively misleading" test be a meaningful filter which distinguishes culpable conduct from honest errors? The Advocate-General rather too swiftly counters any assertion that the precedent could have a chilling effect on innovation. "Such an approach does not set a low threshold for abuse and will not in my view have a chilling effect on or delay applications for intellectual property rights in Europe by increasing the regulatory, legal and bureaucratic burden on companies." (para 52 of the Opinion). It is to be hoped that the EU Court of Justice further reflects on whether this is the appropriate benchmark for liability or whether the bar is set far too low without an appropriate "mens rea" element. It may consider that only the latter can provide a clear signpost to innovators and their advisers on what delineates honest error from liability to multi-million Euro fines.

Effect on Competition

The Advocate-General confirms that a finding of abuse requires the demonstration of anti-competitive effect and "abstract, purely hypothetical or remote assertions, not linked to the specificities of the case, will not be sufficient". When determining whether the abuse will have an effect on competition, AG Mazák adopts a "tends to restrict" test. He prefers it to the alternative "likely effects" test, which, he opines, sets the evidentiary bar too high given its similarities to the tort standard of "the balance of probabilities". Conversely a test that considers only whether conduct is "capable" of having anti-competitive effect is rejected as too remote.

Though a move in the right direction, these semantics offer little real world comfort. Even applying a "tends to restrict" test, the Advocate-General has no difficulty in concluding AstraZeneca's allegedly misleading representations to the patent office had the requisite impact. 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.

Conclusion

The Advocate-General's opinion is firmly rooted in the specific facts of the AstraZeneca case, with his emphasis on the "highly misleading" nature of the statements made during the SPC application process. It could well be that this case proves to be an outlier on the fringes of competition and IP law. However, it is a missed opportunity to rein in the more extreme implications of the General Court's judgment and to set down a clear boundary for what constitutes an "objectively misleading" statement. The General Court's current formulation of a legal rule that any objectively wrong statement to a patent office could potentially engage antitrust liability – and huge fines –

jeopardizes the proper functioning of the patent system and the innovation it promotes. The AG's opinion is not binding on the Court of Justice but is followed, at least partially, in the majority of cases. It remains to be seen whether the Court of Justice will adopt a more nuanced approach to this novel abuse.

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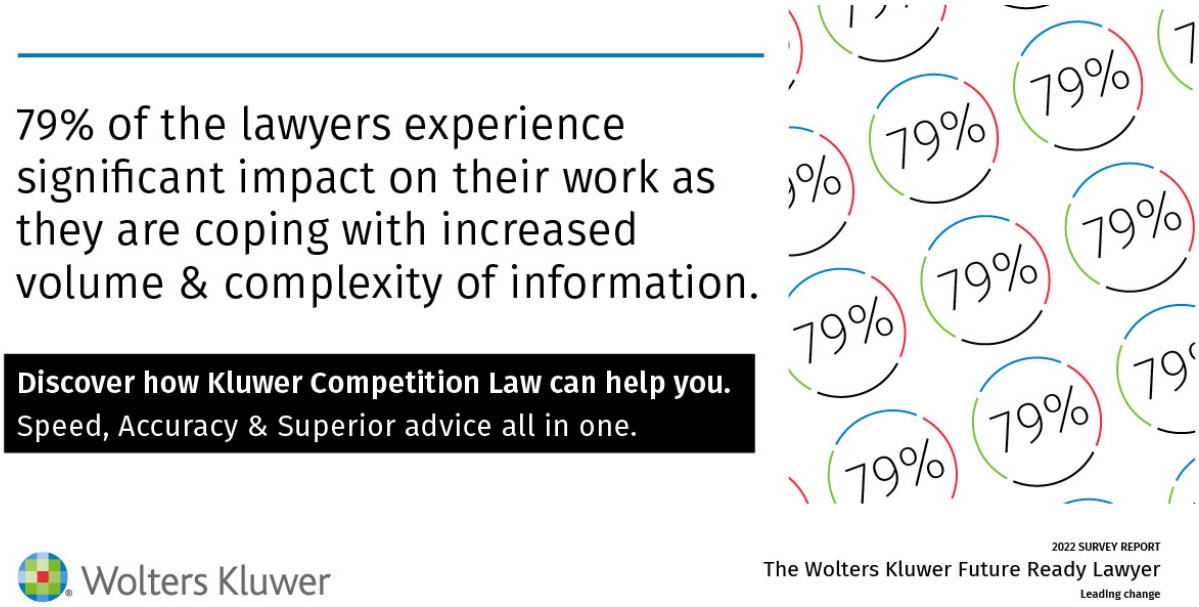

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