WHITE & CASE

AstraZeneca v European Commission: Case C-457/10 P

6 December 2012

Introduction

On 6 December 2012, the European Court of Justice (the "ECJ") upheld the judgment of the General Court ("GC"), which found that AstraZeneca ("AZ") abused its dominant position on the market for proton pump inhibitors ("PPIs") by misleading patent authorities and misusing the regulatory system in order to prevent generic competition against its anti-ulcer medicine, Losec (omeprazole), in certain markets. The ECJ also rejected two cross-appeals brought by the European Commission ("Commission") and the European Federation of Pharmaceutical Industries and Associations ("EFPIA").

Despite not changing the outcome of the case (or the EUR 52.5 million fine on AZ), the judgment contains some interesting statements of law which may have wider relevance beyond the pharmaceutical sector. The ECJ's comments appear to limit the scope of the case in terms of precedent value for the pharma sector, confining it to relatively narrow facts. This may have a positive impact in removing uncertainty and thus helping to ensure continued innovation and dynamic competition in pharmaceuticals and related sectors.

Market Definition and Dominance

The ECJ upheld the market definition put forward by the Commission, and accepted by the GC, where the market was limited to PPIs, a new class of treatments for hyperacidity. AZ had argued that its product Losec, which was the first marketed PPI, was in competition with other medicines to treat hyperacidity, notably an older type of medicine, histamine receptor antagonists ("H2 blockers"). The GC had held that this was an asymmetric market: H2 blockers were constrained by the newer treatment, i.e. PPIs, but not the other way round. The ECJ upheld this approach. There are a few interesting points in the judgment in the way the ECJ analysed the relevant market.

First, the ECJ held (¶37) that the relevant product market must be established for the entire period of abuse. It is not sufficient for the Commission to establish the market only at the end. The ECJ analysed the evidence contained in the GC's findings and upheld the GC's approach. But the principle will be of ongoing relevance to future dominance cases in the pharmaceutical sector.

The ECJ also looked at the relevance of prescribing practices to market definition. It upheld the GC's comments that the gradual nature of the

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increase in sales of a new medicine was due to prescriber inertia, i.e. that doctors were slow to prescribe a new drug until information about its properties and in particular about potential side-effects had been disseminated (¶¶47, 50). The ECJ held that the slow increase in sales of the new product did not indicate that the existing product exercised a significant competitive constraint over the new product (¶48). The ECJ also added that prescriber inertia bolstered the market position of the first of a class of products on the market (as Losec was for PPIs) because it had already built up a solid brand image and reputation, while doctors would hesitate to prescribe other PPIs just entering the market due to inertia (¶50).

The judgment also addresses the potential relevance of price competition in terms of competitive constraint. The ECJ did not directly address AZ's argument (¶53) that the GC had applied the wrong legal standard when saying that the quantification of cost-effectiveness was likely to be particularly complex and therefore the GC would not overturn the Commission as it had not been shown the latter had made a manifest error of assessment. The ECJ rejected the argument by noting that the GC's assessment that H2 blockers did not exercise a significant competitive constraint over PPIs in terms of price constraint was founded on various elements and that even if it were wrong on one, this would not change the outcome. The ECJ in particular noted the GC's findings that (i) doctors and patients had limited sensitivity to prices and (ii) the regulatory systems in force in the relevant Member States were not designed in such a way as to enable the prices of H2 blockers to exert downward price pressure on PPIs (¶57). It also noted that price pressures would in any event not have overcome the fact that H2 blockers were not able to exercise significant competitive constraint over PPIs, having regard to the weight given by doctors and patients to the therapeutic superiority of PPIs (¶58). This paragraph suggests it would be unwise for the Commission to place too much reliance on price-driven econometric studies – it should principally rely on therapeutic substitutability.

In response to a point raised by EFPIA, the ECJ also considered the role of the state as monopsonist purchaser. The ECJ considered that the GC's analysis of the state's role (which EFPIA had criticized) was "*particularly detailed*" (¶178). The ECJ upheld the GC's finding that, although the price and reimbursement level are the decision of public authorities, the capacity of a pharmaceutical company to obtain a higher price/reimbursement level varies according to the added and innovative value of the product. Hence AZ, whose product's therapeutic value was much higher than the H2 blockers, obtained a higher price both as against existing products and "me-too" products (¶179). The ECJ also noted the advantage of "first-mover status" for the first products in a new class of medicines – they tend to benefit from relatively high reimbursement levels compared with "me-too" products (despite health authorities' efforts to reduce health spending) and they also enjoy a status that enables the company to set its price at a high level without having to worry about patients and doctors switching to less costly medicines (¶180).

Finally, the ECJ said that it is acceptable to take account of IP rights for finding dominance. However, the ECJ agreed with the GC that the mere existence of IP rights does not confer a position of dominance but rather is one of the elements that can be taken into account. Indeed, the existence and use of IP rights "*was only one of the various factors on which the Commission based the finding in this case that AZ held a dominant position*" (¶187). Under no circumstances did this mean that "*companies introducing innovative products on the market should refrain from acquiring a comprehensive portfolio of intellectual property rights or from enforcing those rights*." (¶188). Finally, the ECJ reiterated that a finding that an undertaking is dominant "*is not in itself a criticism of the undertaking concerned*" (¶188).

Overall, the ECJ's analysis of the market definition suggests that therapeutic considerations are the key to pharmaceutical market definition. However, in future the increased activity by health authorities to cut healthcare spending and ensure cost effectiveness (whether it be Health Technology Assessment reviewing new drugs or local purchasing groups such as PCTs in the UK trying to reduce spending by favouring one drug in a particular class over another) may have more of an impact on market definition, and price factors may have more importance in the analysis.

The first abuse: Misleading applications for Supplementary Protection Certificates

AZ argued that the GC had taken a legally flawed approach to "competition on the merits" when holding that AZ's non-disclosure to the public authorities of its interpretation of the law with regard to the reference date on which it based its Supplementary Protection Certificate ("SPC") applications (the date of the publication of prices as opposed to the date of the technical authorisation) did not fall within the scope of competition on the merits. According to AZ, the GC wrongly considered as an abuse the mere fact that an undertaking in a dominant position seeks a right without disclosing the elements on which it bases its opinion. In this respect "*a lack of transparency*" could constitute an abuse, rather than deliberate fraud or deceit being required. The ECJ dismissed AZ's arguments.

The ECJ started by restating the old case law, namely that a dominant company is under a special responsibility and that it is abusive for such a company to strengthen its

position by using methods other than those which come within the scope of "*competition on the merits*" (¶¶74-75).

The ECJ then summarised the facts (¶¶78-92) in what appears to be a rather harsh tone. The judgment lists a series of misrepresentations by AZ between 1993 and 2000. For example, it records that AZ notified the date of the publication of prices for Losec to the patent offices in 7 EU countries as constituting the date of the first marketing authorisation ("MA") in the EU, without informing these patent offices of the legal arguments to justify using that date or of the actual date of the first MA in the EU which was obtained in France. The ECJ held that AZ knew what it was doing was wrong, but carried on "*over the long term*" (¶¶79 and 84), despite its inconsistency in approach with regard to SPC applications for Losec and other products it marketed (¶80) and despite the fact that it could not "*reasonably be unaware*" of the consequences of its actions (¶81). The ECJ noted AZ's awareness of the consequences of its conduct was also obvious from AZ's internal documents (¶¶ 79, 88 and 90).

The ECJ concluded that "*AZ's consistent and linear conduct*", which was characterised by "*highly misleading representations and by a manifest lack of transparency*" and "*by which AZ deliberately attempted to mislead the patent offices and judicial authorities in order to keep for as long as possible its monopoly on the PPI market*" fell outside the scope of competition on the merits (¶93).

The ECJ observed that the onus was on AZ to disclose to the patent offices all the relevant information to allow them to decide which authorisations to accept. If AZ had an alternative interpretation to put forward (which it considered was reasonable and "*had a serious chance of being followed both by the national courts and by the ECJ*"), it had to disclose that approach to the authorities (¶95).

The ECJ added that AZ's "*recourse to highly misleading misrepresentations with the aim of leading public authorities into error*" was "*manifestly not consistent with competition on the merits*" or with a dominant company's special responsibility (¶98).

Finally, at ¶99, the ECJ offered some helpful clarification to the pharma sector. It rejected EFPIA's argument that dominant companies had to be infallible in dealings with regulatory authorities and that even an unintentional error which was rectified could be an abuse. The ECJ stated that this type of scenario was "*radically different from AZ's conduct in the present case*". It also noted that each case should be judged on its merits and in light of its specific circumstances. Finally, it mentioned that "*it cannot be inferred from [the GC] judgment (…) that any patent application (…) which is rejected on the grounds that it does not satisfy the patentability criteria automatically gives rise to liability under Article [102 TFEU]*" (¶99). Looked at in isolation, this sentence could give grounds for concern in that the word "*automatically*" suggests that there are situations when liability could arise because a patent application is rejected. However, when put in the context of the ECJ's overall findings, i.e. the fact that AZ's conduct was "*highly misleading*" and the ECJ's rather harsh description of AZ's conduct, it is clear that the AZ precedent is much narrower in scope.

The ECJ noted that representations designed to obtain exclusive rights unlawfully constitute an abuse only if it is shown that, in view of the objective context in which they are made, the representations are actually liable to lead the authorities to grant the exclusive right (¶106). Thus, in the countries where the misleading representations enabled AZ to obtain unlawful SPCs, this led to a significant exclusionary effect after the expiry of the basic patents and also affected potential competition even before patent expiry (¶108). In addition, the fact that the misrepresentations did not enable AZ to gain SPCs in certain countries did not change the fact that there was an abuse given that the representations were "*very likely*" to result in the granting of unlawful SPCs, in particular as AZ's conduct was part of an overall exclusionary strategy (¶111).

The ECJ concluded by noting that while the acts of a dominant company "*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*." (¶112)

The second abuse: Deregistration of Marketing Authorisation

AZ argued that the GC misinterpreted the concept of "competition on the merits" in considering that the mere exercise of a right to withdraw an MA conferred by EU law was incompatible with such competition. According to AZ, the existence of an MA imposes stringent pharmacovigilence obligations which may justify the decision to withdraw its MA in certain countries.

The ECJ dismissed AZ's arguments and upheld the GC's finding that the deregistration by AZ of its MA for Losec could constitute an abuse, notably because as a result of the withdrawal, generic applicants were prevented from relying upon test data used in the original patent in their simplified application.

The ECJ upheld the formulation of the general duty of a dominant company used by the GC. On the one hand, a company in a dominant position is not prevented from developing a strategy aimed towards preserving the existing level of sales, and such a strategy "*to enable it to*

deal with competition from generic products is legitimate and is part of the normal competitive process" (¶129). However, this conduct must not *"depart from practices coming within the scope of competition on the merits, which are such as to benefit consumers*." (¶129).

The ECJ added (¶130) that deregistration, without objective justification, and after the expiry of the exclusive right to the clinical data, by which AZ intended to hinder the introduction of generic products and parallel imports, was not competition on the merits. The ECJ noted (¶131) that deregistration was not based in any way on the legitimate protection of an investment which came within the scope of competition on the merits, as AZ no longer had the exclusive right to make use of its clinical data.

In addition, the ECJ held that the fact that under EU law (Directive 65/65) "*AZ was entitled to request the withdrawal of its MAs for Losec capsules, in no way causes that conduct to escape the prohibition laid down in Article [102 TFEU]."* (¶132) Conduct can be abusive under the competition rules irrespective of whether it is in compliance with other legal rules, especially when these legal rules pursue different objectives to Article 102 TFEU (¶¶132-133).

The ECJ confirmed that a dominant company, subject to the special responsibility, cannot: "*use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.*" (¶134) This is quite an open-ended statement which may have to be clarified in future cases. In the pharma-specific context, the ECJ also held that while in theory pharmacovigilence obligations could constitute an objective justification (¶135), AZ had not established this on the facts of the case (¶¶136-137).

The ECJ clarified that it was deregistration alone that constituted the abuse. The introduction of a new generation product by AZ constituted only the context within which the deregistration abuse occurred (¶140).

Finally, the ECJ rejected AZ's argument that the *IMS Health* case law on compulsory licensing (i.e. a refusal to license an IP right is only abusive in exceptional circumstances) should be applied to this case. It noted that the option by a dominant company to deregister a market authorisation (with the aim to prevent or render more difficult the entry of competitors on the market) is not equivalent to a property right and does not therefore constitute an "*effective expropriation but a straightforward restriction under EU law*"(¶149).

The ECJ thus explicitly distinguished this case from a compulsory licence, holding that this was "*in no way an exceptional case and does not justify a derogation from Article[102 TFEU], unlike a situation in which the unfettered exercise of an exclusive right awarded for the realisation of an investment or creation is limited*." (¶150)

Overall, the judgment suggests that the deregistration abuse may be relatively wide in ambit, in particular since the higher standard for compulsory licensing (exceptional circumstances) does not apply.

Conclusions – the implications of the Judgment

The rather severe tone of the judgment when describing the facts underlying the SPC abuse has the effect of narrowing the judgment in terms of precedent value. The narrowing of the precedent is to be welcomed. It is only a dominant company which makes "*highly misleading representations with the aim of leading public authorities into error*" which should have to fear this judgment.

On the other hand, the deregistration abuse could potentially have wider implications. Given that the rules have changed in the pharma sector such as to prevent a repeat of the facts of the AZ case, the real implications of this judgment could come in other regulated sectors where follow-on entrants seek to make use of a regulatory dossier of an earlier entrant.

Finally, as regards market definition, the judgment reaffirms the key role of therapeutic efficacy in the pharma sector. Price played a much lower role than therapeutic efficacy in choosing which drug should be prescribed during the period that AZ was concerned with (although this may have changed to some extent since then). So market definition in the pharma sector should be primarily based on the views and needs of doctors and patients, rather than econometrics and modelling.

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