

The General Court of the European Union's judgment in Case T-321/05 AstraZeneca v European Commission

5 July 2010

Introduction & Summary

On 1 July 2010, the General Court of the European Union ('the GC') handed down its long-awaited judgment in the AstraZeneca case.

The GC rejected most of the arguments put forward by AstraZeneca ('AZ'). In doing so the GC made a number of broad pronouncements about the fact that AZ's conduct did not constitute "competition on the merits", without giving an explanation of what is covered by this concept. This potentially broad standard may have consequences going forward for the application of EU competition law to the pharmaceuticals sector and beyond.

That said, the GC described the abuses themselves in relatively narrow terms. For example, AZ would not have been guilty of an abuse had it told the relevant patent offices of its reasons and arguments for seeking an SPC. Nor would it have been found to abuse its dominant position just for having stopped selling the earlier generation product (Losec capsules) when it introduced the more advanced, later generation product (Losec MUPS).

Moreover, the specific conduct at issue is historical and could not occur today. The SPC abuse related to the transitional period following the adoption of the SPC Regulation in 1992. Equally, regarding the deregistration abuse, since 2005, a generic company can apply for a marketing authorisation under the abridged procedure foreseen by Directive 2001/83, even after the marketing authorisation of the reference medicinal product has been withdrawn and since 2002, a parallel import licence is no longer automatically revoked once the original marketing authorisation for a medicinal product is withdrawn. As a result, while the broad legal principles which the GC enunciates may become significant in the future, their present application to AZ's specific conduct is likely to be mainly of historical relevance.

The Commission's Decision

On 15 June 2005, the European Commission ('the Commission') adopted a decision imposing a fine of EUR 60 million on AstraZeneca ('AZ') for two abuses of a dominant position contrary to Article 102 of the Treaty on the Functioning of the European Union ('TFEU' – ex Article 82 of the EC Treaty).

We advise leading pharmaceutical multinationals and the major US and EU industry associations on EU and national law and policy affecting the pharmaceuticals sector. Our work covers competition law, including licensing and distribution issues, regulatory matters, intellectual property, data protection, and national implementation of EU measures, notably on pricing and reimbursement.

For further information on this alert please do not hesitate to contact:

Ian Forrester, Partner
+32 2 239 2536

James Killick, Partner
+32 2 239 25 52

Pontus Lindfelt, Partner
+32 2 239 25 60

Jacquelyn MacLennan, Partner
+32 2 239 25 63

Mark Powell, Partner
+32 2 239 25 78

Axel Schulz, Partner
+32 2 239 25 87

This document is prepared for the general information of our clients and other interested persons. Due to the general nature of its content, it should not be regarded as legal advice.

We believe this information will be of interest to you. However, if you do not wish to receive further similar information about events or legal issues from White & Case, then please e-mail unsubscribe@whitecase.com.

White & Case LLP
Avocats-Advocaten
rue de la Loi, 62 Wetstraat
1040 Brussels
Belgium

Telephone: +32 2 239 26 20
Facsimile: +32 2 219 16 26

www.whitecase.com

The first abuse was that between 1993 and 2000, AZ engaged in a pattern of deliberate misrepresentation to patent attorneys, national courts and patent offices in order to obtain SPCs for Losec (omeprazole) ('the SPC abuse').

The second abuse was that in 1998/1999, AZ operated a strategy of selectively withdrawing its Losec capsules, replacing them with Losec tablets, and requesting deregistration of the marketing authorisations for the capsules in Denmark, Norway and Sweden ('the deregistration abuse').

AstraZeneca was fined EUR 60 million for both abuses, EUR 30 million per abuse. It appealed the Commission's Decision in September 2005. An Oral Hearing took place before the Sixth Chamber of the GC on 26 and 27 November 2008. EFPIA intervened in support of AZ.

The GC's judgment

Market definition

AZ submitted that the Commission incorrectly defined the relevant market as being only that of proton pump inhibitors ('PPIs') and not the combined market for PPIs and histamine receptor antagonists ('H2 blockers'). Although the scientific community accepted from the early 1990s that PPIs were therapeutically superior to H2 blockers, the increase in use of PPIs was only gradual as prescribing doctors did not recognise that superiority immediately and continued to prescribe both drugs for the same diagnosis. This gradual increase shows that H2 blockers exerted a competitive constraint on PPIs, otherwise substitution would have taken place earlier. In response, the Commission said that the therapeutic superiority of PPIs means that from 1993, PPIs were part of a different market than H2 blockers.

In its judgment, the GC found that the Commission had not committed any manifest error of assessment when defining the relevant market. The Commission was entitled to reject the argument that the gradual nature of the increase in sales of PPIs at the expense of H2 blockers meant that H2 blockers exercised a significant competitive constraint over PPIs and that H2 blockers had, for that reason, to be included in the relevant product market (paragraphs 83 to 107). This leads to the strange result that while PPIs exercised a competitive constraint over PPIs, the same could not be said for H2 blockers over PPIs. Equally, the Commission did not err in basing its market definition on the greater efficacy of PPIs, the differentiated therapeutic use of PPIs and H2 blockers (PPIs were generally prescribed to treat severe conditions while H2 blockers were generally prescribed to treat milder or less serious forms), price indicators, such as they resulted from the regulatory framework in place, and

the market entry of other patented PPIs on generic H2 blockers in Germany and of generic H2 blockers in the United Kingdom (paragraphs 147 to 218). The GC's analysis is detailed, spanning many paragraphs.

Dominance

AZ argued that the Decision failed to take account of the unique characteristics of the pharmaceutical sector i.e. that competition in the pharmaceutical sector is based on a virtuous circle of innovation. In particular, the Commission placed too much emphasis on price differences between PPIs and H2 blockers which were the result of government price controls and not AZ's alleged dominance. In response the Commission claimed that the fact that AZ was dominant as it was able to obtain higher prices for Losec than other manufacturers for H2 blockers.

The GC agreed with the Commission. First, it held that the Commission was entitled to consider that AZ's particularly high market shares during the relevant period (consistently above 60%) was "*an entirely relevant indicator of its market power, which was out of all comparison to those of the other market players*" (paragraph 253).

Second, the Commission did not commit a manifest error of assessment by taking into account price-based indicators for the purpose of assessing AZ's competitive position on the market (paragraphs 255 to 269). The GC noted that AZ was able to price its product higher than rival PPIs, while maintaining its market share, which suggested it had market power as regarding pricing and reimbursement bodies (paragraph 266).

Third, because pharmaceutical markets are characterised by inertia on the part of prescribing doctors, the Commission was entitled to take into account AZ's first-mover status and incumbency on the PPI market (paragraphs 276 to 283).

Finally, although AZ's financial strength (paragraphs 284 to 286) was not a sufficient factor in itself to support the conclusion that AZ held a dominant position, it did permit the inference that AZ had superior resources to its competitors.

The SPC abuse

AZ considered that misleading representations made in the course of applications for IP rights cannot in law amount to an abuse unless and until the dishonestly obtained rights are enforced or are capable of being enforced. By contrast, the Commission argued that it is sufficient that a dominant company misuses regulatory procedures with exclusionary intent in order for such conduct to constitute an abuse.

The GC accepted the Commission's arguments, holding that

“the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market” (paragraph 355).

In that regard, the limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to constitute an abuse (paragraph 357). Moreover, an undertaking in a dominant position is required *“at the very least”*, to inform the public authorities of errors so as enable them to rectify those irregularities (paragraph 358). Finally, the fact that certain public authorities did not let themselves be misled and detected the inaccuracies in the information provided by AZ, or that competitors obtained, subsequent to the unlawful grant of the exclusive rights, the revocation of those rights, is not a sufficient ground to consider that the misleading representations are not anti-competitive (paragraph 360).

Applying this legal test, the GC found that between 1993 and 2000, AZ engaged in a pattern of deliberate misrepresentation to patent attorneys, national courts and patent offices in order to obtain SPCs to which it knew it was not entitled (paragraphs 474 to 613). However, the GC did find that AZ's abuse only started when the SPC applications were transmitted to the national patent offices and not when AZ transmitted its instructions to the patent attorneys (paragraphs 370 to 372).

The deregistration abuse

AZ contended that Article 102 TFEU does not impose on an undertaking holding a dominant position an obligation to maintain a marketing authorisation for a product they no longer marketed, merely because this would make it easier for generics and parallel traders to compete with it. In response, the Commission argued that although AZ's conduct was not contrary to the then applicable EU pharmaceutical laws, a dominant company is under a special responsibility to use its public entitlements

reasonably, and not with the clear purpose of eliminating competition.

The GC started by narrowing the scope of AZ's abusive conduct identified by the Commission:

“The abuse of a dominant position identified by the Commission consists solely in the deregistration of the Losec capsule marketing authorisations in Denmark, Norway and Sweden, in combination with the conversion of sales of Losec capsules to Losec MUPS, that is to say the launch of Losec MUPS and the withdrawal from the market of Losec capsules” (paragraph 805).

“Although [the Commission] defined the abuse of a dominant position as the combination of those elements, the central feature of the abuse consists in the deregistration of the Losec capsule marketing authorisations, the conversion of sales of Losec capsules to Losec MUPS being the context in which the deregistrations of the marketing authorisations were carried out” (paragraph 807).

It then sets out the scope of the legal test applicable to that conduct:

“in the absence of grounds connected with the legitimate interests of an undertaking engaged in competition on the merits and in the absence of objective justification, an undertaking in a dominant position cannot use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market” (paragraph 817).

In that regard, the GC stated that while AZ was entitled to request the withdrawal of its marketing authorisations for Losec capsules, its conduct could not escape the prohibition laid down in Article 102 TFEU (paragraph 677). While an undertaking in a dominant position is under no obligation to protect the interests of competitors, this *“does not justify recourse to practices falling outside the scope of competition on the merits”* (paragraph 816). The pharmacovigilance obligations to which AZ was subject in Denmark, Norway and Sweden also cannot constitute an objective ground of justification for the requests for deregistration of the marketing authorisations for Losec capsules in those countries:

“the burden arising from the pharmacovigilance obligations was never mentioned in AZ's internal documents relating to its commercial strategy. That absence of any mention in those documents of that objective ground of

justification meant that the Commission was unable to take cognisance of it and in any event makes it scarcely credible that the deregistration of the marketing authorisations was due to that ground” (paragraph 688).

The Court also noted that AZ remained subject to the same pharmacovigilance obligations for Losec capsules in other EU countries.

In light of the above, the GC concluded that the deregistration of the Losec capsule marketing authorisations impaired the introduction on the market of generic versions of omeprazole and thus constituted an abuse of a dominant position “since that conduct solely served to exclude from the market, at least temporarily, competing manufacturers of generic products” (paragraph 835).

However, the GC found that the Commission had failed to prove that the fall in parallel imports of Losec in Denmark and Norway was caused by AZ’s conduct. As a result, it reduced AZ’s fine from EUR 60 million to EUR 52.5 million.

Implications of the judgment

The GC’s judgment is long and dense (over 900 paragraphs). Time will be required to assess in detail its full implications. However, at this stage, it is already possible to identify what appear to be the key findings of the judgment.

Positive findings

First, the judgment seems to diminish the role of intent in abuse of dominance cases. Although the intention of a company in a dominant position to restrict competition may be a relevant factor, the concept of abuse is first and foremost an objective concept. Indeed, this is part of the reason why the GC annulled the Decision’s finding that the deregistration abuse was capable of restricting parallel imports in Denmark and Norway:

“At the very most, there are grounds for considering that that document shows AZ’s intention to exclude parallel imports by deregistering the Losec capsule marketing authorisation. However, the Court would point out that, although the intention of an undertaking in a dominant position to restrict competition by methods falling outside the scope of competition on the merits may be taken into consideration in the identification of an abuse of a dominant position, that identification must first and foremost be based on the objective finding of conduct which, in the context in which it is

implemented, is such as to restrict competition” (paragraph 849).

Second, had AZ been transparent about the fact that it was defending a particular interpretation of the SPC Regulation and corrected the mistaken information it had initially given to patent offices, then the judgment suggests that AZ’s conduct may not have been abusive:

AZ’s “conduct, characterised by a manifest lack of transparency, is contrary to the special responsibility of an undertaking in a dominant position not to impair by its conduct genuine undistorted competition in the common market” (paragraph 493).

“Given that AZ was seeking to defend a particular interpretation of Regulation No 1768/92 the onus was on it to communicate the various relevant items of information in a transparent manner, in order to enable the public authority to adopt the appropriate decision and not to be misled as a result of an undisclosed ambiguity” (paragraph 565).

At the same time, the judgment also says that as it held a dominant position, AZ was obliged to correct any mistaken or inaccurate information it gave to patent offices and courts:

“in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility not to impair, by methods falling outside the scope of competition on the merits, genuine undistorted competition in the common market requires it, at the very least, to inform the public authorities of this so as enable them to rectify those irregularities” (paragraph 358).

“AZ’s refusal to rectify the SPC granting it a period of protection longer than that to which it knew it was entitled amounts to unacceptable behaviour by an undertaking in a dominant position” (paragraph 533).

Third, the judgment suggests that the launch of follow-on products may not raise concerns under EU competition law, since it is part of the normal competitive process:

“the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise 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, which is such as to benefit consumers” (paragraph 804).

Indeed, the GC considered the abuse to be the deregistering of Losec capsules, not the fact that AZ stopped selling the capsules once a follow-on product was launched:

“the conversion of sales of Losec capsules to Losec MUPS, namely the withdrawal from the market of Losec capsules and the introduction on the market of Losec MUPS, was not capable, in itself, of producing the anticompetitive effects alleged by the Commission in the present case, namely the creation of regulatory obstacles to the market entry of generic omeprazole and to parallel imports of Losec capsules” (paragraph 808).

“there is no reason to reproach AZ either for launching Losec MUPS or for withdrawing Losec capsules from the market, since those acts were not such as to raise the legal barriers to entry complained of by the Commission that were capable of delaying or preventing the introduction of generic products and parallel imports” (paragraph 811).

These statements seem to qualify the findings of the pharmaceutical sector inquiry which had suggested that in certain circumstances, the launch of follow-on products could be considered anti-competitive.

Negative findings

First, conduct may still be classified as anti-competitive even where such conduct is remedied prior to it deploying its effects:

“the fact that, in Germany, the SPC was revoked in June 1997, prior to the expiry of the basic patent, as a result of a legal action brought by Ratiopharm, a generic manufacturer, does not affect the legal classification of the conduct of AZ, which obtained an SPC in those countries on the basis of its misleading representations. That SPC was destined to continue after the expiry of the basic patent and to extend the exclusivity conferred by that patent. If no proceedings had been brought by competitors, that SPC would have thus produced significant anticompetitive effects, assuming that the mere existence of an SPC were not already, in itself, able to produce such effects even prior to the expiry of the basic patent” (paragraph 605).

Second, the judgment’s findings, particularly in relation to the deregistration abuse, could strengthen the Commission’s hand in pursuing antitrust cases against any originator companies that may have used regulatory instruments in order to delay generic entry:

“whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests when they are attacked (...), it 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” (paragraph 672).

Third, the statement in paragraph 355 that *“the submission to the public authorities of misleading information liable to lead them into error (...) constitutes a practice falling outside the scope of competition on the merits”* could in the future have broader implications than in the present case.

Finally, the GC rejects some of the key policy arguments which the pharmaceutical industry has traditionally put forward in order to claim that pharmaceutical companies cannot be said to hold a dominant position. In particular, the GC finds that A2 was able to negotiate pricing and reimbursement levels with national authorities; at least for Losec:

“Since prices or reimbursement levels of medicines are necessarily set by public authorities as a result of a dialogue with pharmaceutical undertakings, at the very least in so far as the latter must provide them with relevant information for this purpose, the Commission was entitled to take the view that pharmaceutical undertakings had bargaining power vis-à-vis the national authorities, which varied according to the added therapeutic value that their products offer in comparison with pre-existing products” (paragraph 257).

The GC also said that the health systems may even increase the market power of pharmaceutical companies since the Member States generally reimburse products:

“health systems which characterise markets for pharmaceutical products tend to reinforce the market power of pharmaceutical companies, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic” (paragraph 262).

Worldwide. For Our Clients.

36 Offices. 25 Countries.

Europe, Middle East, Africa

Abu Dhabi
Almaty
Ankara
Berlin
Bratislava
Brussels
Bucharest
Budapest
Doha
Düsseldorf
Frankfurt
Geneva
Hamburg
Helsinki
Istanbul
Johannesburg
London
Moscow
Munich
Paris
Prague
Riyadh
Stockholm
Warsaw

Americas

Los Angeles
Mexico City
Miami
New York
Palo Alto
São Paulo
Washington, DC

Asia

Beijing
Hong Kong
Shanghai
Singapore
Tokyo

www.whitecase.com

In this publication, White & Case means the international legal practice comprising White & Case LLP, a New York State registered limited liability partnership, White & Case LLP, a limited liability partnership incorporated under English law and all other affiliated partnerships, corporations and undertakings.