

On 1 July 2010, the General Court of the European Union ('the Court') issued its long-awaited judgment in *AstraZeneca AB and AstraZeneca plc v Commission*, largely upholding the decision of the European Commission ('the Commission') in the *AstraZeneca* case, the Commission's first decision condemning attempts to restrict and delay generic entry. The Court disagreed with the Commission only on the issue of whether AstraZeneca's deregistration of the marketing authorisations for capsules of its anti-ulcer drug Losec impacted parallel imports in Denmark and Norway, and on that basis reduced the fine from €60 million to €52.5 million.

Background

In its decision of 15 June 2005, the Commission found that AstraZeneca engaged in two different forms of abuse of its dominant position within the meaning of Article 102 of the Treaty on the Functioning of the European Union ('TFEU').

The first abuse consisted of deliberate misrepresentations to national patent offices and national courts in various EEA Member States in an effort to obtain and defend extended patent protection for Losec beyond the period to which AstraZeneca was entitled. The second abuse involved AstraZeneca's deregistration of marketing authorisations for Losec capsules in various Member States in combination with the withdrawal from the market of Losec capsules and the introduction of Losec tablets, in order to (i) delay and make more difficult the marketing of generic products, and (ii) prevent parallel imports of Losec.¹

The Court's Judgment

The Court analysed the Commission's approach to market definition, its assessment of dominance and the alleged abuses.

Market Definition

The Court agreed with the Commission's conclusion that the relevant market was limited to oral prescription proton pump inhibitors, excluding from the market other medicines falling within the same third level of the anatomical therapeutic classification (generally the starting point of the Commission's market definition analysis for pharmaceutical products). In its analysis, the Court confirmed that substitutability, as defined in the Commission Notice on Market Definition,² was the cornerstone of the market definition exercise. The Court thereby excluded a market definition analysis based on a hypothetical market comprising a specific pharmaceutical and other formulations with the same active ingredient which has been relied on by some Member State competition authorities in cases under Article 102 TFEU or national equivalents relating to generic entry.

Dominance

The Court confirmed that the possession over time of very large market shares (in excess of 50 per cent) is evidence of the existence of a dominant position, with a market share above 70 per cent being in itself a clear indication of a dominant position. The Court also considered that the role of the Health Authorities in the determination of the prices and reimbursement levels for pharmaceuticals was not sufficient to overturn the Commission's conclusion on dominance, given AstraZeneca's ability to obtain a higher price for Losec than other companies marketing 'me-too' products.

GENERAL COURT OF THE EUROPEAN UNION

PHARMACEUTICALS

THE GENERAL COURT PROVIDES GUIDANCE ON STRATEGIES FOR DOMINANT PHARMACEUTICAL COMPANIES DEALING WITH GENERIC COMPETITION

AstraZeneca v Commission Case T-321/05

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1) Pursuant to EU law in force at the time, marketing authorisation for a generic product could be granted pursuant to a simplified procedure only if the original reference product was still registered.

2) Commission Notice of 9 December 1997 on the definition of relevant market for the purposes of Community competition law (OJ C372, 9 December 1997, at 5).

Abuse of Dominance

The Commission identified two abuses: (i) misrepresentations to national patent offices which extended Losec's patent protection beyond its correct term; and (ii) deregistration of marketing authorisations of Losec capsules coupled with their withdrawal and the introduction of Losec tablets. The Court clarified the applicable analytical framework by establishing that:

- Abuse is an objective concept with the consequence that the conduct engaged in must (i) be capable of creating regulatory obstacles to generic entry in view of the objective context in which the conduct takes place; and (ii) fall outside the scope of competition on the merits.
- Competition on the merits must be defined having regard to (i) the legitimate commercial interests of the company and (ii) consumer benefits.
- A causal link must be established between the conduct and the probable exclusionary effect, with the lack of a clear causal link being interpreted in favour of the company.
- Evidence of an intention to exclude or delay generic entry is not a prerequisite and does not by itself suffice to establish that conduct is abusive.

As concerns effects, the Court referred to a 'probable' exclusionary effect, and the fact that the conduct must be 'capable' of creating regulatory obstacles, in line with Article 102 TFEU case law, which only requires the Commission to demonstrate that the conduct concerned is 'capable' of having anti-competitive effect.³ However, the judgment also confirms that, where it is not clear from the conduct in question that it is 'capable' of having such an exclusionary effect, an actual effect has to be demonstrated along with a causal link between the conduct and the effect.

First abuse: misrepresentations to national patent offices and courts

Having regard to the objective context in which the practices occurred and after an analysis of the practices *in concreto*, the Court established that the submission to public authorities of objectively misleading information in order to obtain an exclusive right to which the undertaking in question was not entitled constituted a practice falling outside competition on the merits. The Court held that such a practice was capable of creating regulatory obstacles and thus liable to prevent or delay generic entry.

Second abuse: deregistration of Losec marketing authorisation in combination with the withdrawal from the market of the Losec capsules and the introduction of Losec tablets

In its assessment of the second abuse, the Court stated up-front that *'the preparation by an undertaking ... 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.'*

The Court subsequently distinguished the different elements of AstraZeneca's strategy and clarified that the deregistration of Losec was the central feature of the abusive conduct. The Court took the position that this conduct was designed to prevent generic manufacturers from using the pharmacological, toxicological tests and clinical trials and was not based on the legitimate protection of an investment or on competition on the merits and also not required by the decision to replace Losec capsules with Losec tablets.

³ See Judgment of the General Court of 17 September 2007 in Case T-201/04, *Microsoft v Commission*, paragraph 1089 with respect to the tying of Windows and Windows Media Player.

By contrast, the Court noted that *'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.'*

As concerns the alleged restrictive effect on parallel trade, the Court found that in view of the relevant regulatory context, the Commission had a duty to establish a causal link between AstraZeneca's conduct and its alleged anti-competitive effects. In particular, since the relevant Danish and Norwegian authorities had not withdrawn parallel import licences as a result of the deregistration of Losec capsules, the Court ruled that the Commission could not simply assume that deregistration would restrict parallel trade, even though there was evidence that AstraZeneca had intended this to be the result.

Conclusion

The Commission's press release states that the Court's judgment is *'significant not least for the follow up to the Commission's final report on its competition inquiry into the pharmaceutical sector'*. While many commentators consider that this judgment is a victory for the Commission, the judgment's broader implications suggest the need to qualify this view.

On the one hand, the *AstraZeneca* judgment confirms that the use of intellectual property rights and regulatory proceedings to delay or restrict generic entry and/or parallel trade may constitute an abuse. It also confirms the Court's case law to the effect that the Commission is not required to establish an actual anti-competitive effect as long as it can establish that a given conduct is objectively capable of having such an effect.

On the other hand, the judgment clearly states that it is legitimate for a pharmaceutical company to develop strategies aimed at minimising the erosion of its sales and enabling it to deal with competition from generic products when its conduct falls within the scope of competition on the merits.

While this is a very general and broad pronouncement, the Court does provide some guidance by focusing on the regulatory consequences and the impact on consumers of the conduct in question. Under the test adopted by the Court, certain life-cycle management strategies, including the introduction of a tablet formulation and the conversion of a capsule formulation to a tablet formulation, would be considered legitimate, whereas other forms of conduct, such as product deregistration, when they create regulatory barriers to generic entry or parallel trade and are not based on competition on the merits, would be abusive.