



# AstraZeneca: the EU General Court extends categories of abuse

The European General Court has largely upheld a European Commission fine on AstraZeneca for abuse of dominance. The abuse consisted of conduct hindering competitors from marketing generic equivalents of its anti-ulcer medicine Losec and impeding parallel imports. The judgment confirms that dominant companies need to exercise great care in using regulatory procedures related to intellectual property and similar rights and that their conduct may be treated as abusive even if they are exercising a legal right.

The European General Court has largely upheld the European Commission's fine on AstraZeneca for abuse of a dominant position, though it reduced the €60m fine to €52.5m. The abuse consisted of conduct hindering competitors from marketing generic equivalents of its anti-ulcer medicine Losec and impeding parallel imports. The judgment is of broader relevance. It confirms that dominant companies need to exercise great care in using regulatory procedures related to intellectual property and similar rights and that their conduct may be treated as abusive even if they are exercising a legal right within such procedures.

## Background

In 2005 the Commission fined AstraZeneca €60m for abuse of its market dominance on a number of European national markets for oral prescription proton pump inhibitors (PPIs), by hindering competitors from marketing generic equivalents and impeding parallel imports. The main PPI is Losec, an extremely successful and profitable anti-ulcer medicine. Two abuses were identified.

- The first abuse consisted of deliberate misrepresentations that AstraZeneca made to obtain and defend extended patent protection for the patented ingredient in Losec. Misrepresentations were found to have been made to patent lawyers, national courts and patent offices, with the intention of restricting competition from generic products and parallel imports.

- The second type of abuse identified was the replacement of Losec capsules with Losec tablets and requesting withdrawal of the marketing authorisation for the capsules in Denmark, Norway and Sweden. This was also found to be a strategy intended to restrict competition from suppliers of generic products and parallel importers, which were thereby prevented from relying on AstraZeneca's marketing authorisation for the capsules to obtain market access for their own products.

## The General Court's judgment

On appeal by AstraZeneca, the General Court upheld the Commission's findings of dominance and of the first abuse. It also upheld the second abuse in so far as it referred to hindrance of generic competitors and of parallel importers in Sweden. It annulled the finding of abuse as far as parallel imports in Denmark and Norway were concerned and so reduced the fine to €52.5m.

### Do high market shares and high prices equal 'dominance'?

The Commission had found the relevant market to be oral prescription PPIs, excluding sales to hospitals. This definition excluded other types of anti-ulcer drug (used within the same broad therapeutic area), thus defining the market more narrowly than those products within the same anatomical therapeutic classification (ATC) level-three class as Losec, which the Commission has historically used as its starting point for market definition. The Commission's reasoning was that PPIs

function through a much more effective mechanism, tend to be used in the treatment of different forms of medical conditions and, though more expensive, are more cost-effective. The Court, while recognising that the Commission enjoys a margin of discretion in making such an assessment, made an extremely detailed examination of the evidence before upholding the Commission's finding.

The Commission had gone on to find that a number of factors indicated AstraZeneca's dominance in this market. In particular, it had a patent for the active ingredient in Losec, which was the first and the most expensive PPI, and had very high market shares in the relevant countries (always over 50 per cent and often over 80 per cent) over several years. The Court confirmed that these very high shares, even in an innovation market, are a clear indication of dominance, as was the high price of Losec. The Court also upheld the relevance of AstraZeneca's intellectual property rights (IPRs), its 'first-mover advantage' and its financial strength. Notably, the Court also approved the Commission's conclusion that AstraZeneca's dominance was not defeated by the buyer power of national health services.

### **Can misrepresentations be 'abuse'?**

The Court then considered and upheld the finding of abuse consisting of misrepresentations that AstraZeneca made to obtain and defend extended patent protection.

It endorsed the Commission's finding of a 'consistent and linear course of conduct' by which AstraZeneca had deliberately tried to mislead the patent offices to obtain patent protection that it was not entitled to, or for longer than was justified. It observed that such conduct is not 'competition on the merits'; nor is it in keeping with the 'special responsibility' of dominant companies not to impair competition. That conduct could not be characterised as a reasonable step to protect AstraZeneca's commercial interests.

The Court went on to say that, in analysing whether the use of public regulatory procedures is an abuse, it is necessary to consider whether the practice is such as to lead the public authority wrongly to create obstacles to competition – for example, by wrongly granting an undertaking an exclusive right. The limited nature of the public authorities' discretion, and the absence of an

obligation on their part to verify information provided, is relevant in this regard. The analysis is not different where the misrepresentations were detected, so that the rights applied for were refused or revoked, because the abusive conduct consisted of the initial unjustified application for patent protection. AstraZeneca had argued that misrepresentations made in applications for IPRs could not amount to abuse unless and until the dishonestly obtained rights were or could be enforced, but the Court disagreed.

### **A duty to maintain market authorisation?**

The Court also upheld the finding of abuse consisting of withdrawal of the marketing authorisation for Losec capsules in so far as it was characterised as restricting competition from suppliers of generic products, which were thereby (and as a result of regulatory requirements in force at that time) prevented from relying on AstraZeneca's marketing authorisation to obtain market access for their own products. However, as far as hindering parallel imports was concerned, it found that there was sufficient evidence to support this finding in respect of Sweden, but not of Denmark or Norway.

The Court found that such withdrawal is not competition on the merits. A dominant company cannot use regulatory procedures to prevent or hinder market entry in the absence of grounds relating to defence of its legitimate interests or some objective justification. It is irrelevant whether there was 'malevolent intention'.

AstraZeneca argued that the abuse of dominance rules should not oblige it to maintain its marketing authorisation in order to assist its competitors. The Court said that, although there is no obligation on a dominant company to protect the interests of competitors, practices implemented solely to exclude competitors may well amount to abuse. A desire to guard against competition from generics and parallel imports does not justify recourse to practices that are not competition on the merits.

In this kind of case, where regulatory procedures are used with no basis in competition on the merits, actual effects on the market do not need to be shown. Evidence that the conduct is capable of restricting competition is enough.

## Implications for future enforcement

In the pharmaceutical sector it has been clear for some time, and in particular since 2008 when the Commission opened its sector inquiry, that any conduct hindering competition from generic products will come under close scrutiny, because generics are seen as key in reducing public expenditure on reimbursement of medicines. The Court's judgment appears to support this policy objective. The Commission welcomed the judgment, noting that the decision 'is significant not least for the follow up to the Commission's final report on its competition inquiry into the pharmaceutical sector', meaning the ongoing infringement cases in this sector. But the judgment has important broader implications.

First, it confirms that conduct in the course of intellectual property and similar regulatory procedures may constitute abuse, even if alternative legal remedies (for example, in patent law) may also be available to an allegedly excluded firm.

Second, it is striking that the Court applied a very low threshold as far as the effects of these abuses were concerned, holding that it was sufficient that the conduct be 'capable' of having anti-competitive effects (though actual evidence, and not mere assertion, of that capability is required, as shown by the fine reduction). Companies with strong market positions need to be aware that, at least in some types of cases, evidence of a strategy (rather than isolated incidents) intended to hinder competitors lowers the bar for an infringement finding. This reinforces the message that it is crucial for companies to document carefully any pro-competitive reasons for commercial strategies and decisions and to avoid creating documents wrongly suggesting a strategy of 'spoiling tactics'.

Third, the Commission took its decision in this case before the publication of its 2008 guidance on exclusionary abuse, which advocates a policy heavily focused on the exclusionary effects of alleged abuse. Although the Court examined all the evidence and arguments in great detail, its judgment continues its long-established support of the Commission's traditional, more formalistic approach in its abuse of dominance enforcement policy.

Fourth, the judgment also supports the significant weight attached by the Commission to high market

shares, even though their relevance in markets driven by huge research and development costs, short-lived serial near-monopolies and frequent major innovation can be questioned.

Finally, the Commission's press release at the time it imposed this fine stated that the fine level took into account the novel features of this case. Firms should therefore be aware that considerably higher fines can be expected in similar cases in the future.

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