investigation for an indefinite period (so long as control is retained).

The level of the fine imposed by the Commission shows that it is willing to take a hard line in respect of failures to notify even in respect of cases that involve relatively complex legal analysis. Furthermore, it is clear that the Commission may impose heavy sanctions for a failure to notify even where there is no significant impact on the internal market. For example, the Commission may impose substantial fines upon parties if they fail to notify a joint venture which, although intended to operate outside of the EU, has an EU dimension due to the parent companies' European turnover.

Undertakings should therefore consider carefully whether an acquisition of a minority shareholding may give rise to a concentration under the EUMR. It is important that a prospective assessment is carried out prior to the acquisition of any interest since an *ex post* assessment risks a breach of the standstill obligation. For these purposes, the Commission's decision-making practice suggests that the attendance at shareholders' meetings should be analysed over a period of at least the previous three years. The acquirer should also assess whether any rights attaching to the shareholding or other arrangements may affect the question of control.

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Astrazeneca: Court of Justice Upholds First Decision Finding Abuse of Dominant Position in Pharmaceutical Sector

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Case C-457/10 P *Astrazeneca AB and Astrazeneca plc v European Commission* (judgment of 6 December 2012, not yet reported)

The Court of Justice confirms that the supply of misleading information in the context of a request for supplementary protection certificates and the withdrawal of a marketing authorisation within the pharmaceutical sector can constitute abuse of dominant position.

Legal context

In 2008, the Commission launched an inquiry into the pharmaceutical sector. It had suspicions that competition in the sector was distorted, as it observed a decline in innovation and delayed entry of generic medicines. In the pharmaceutical sector, two types of companies with divergent business models compete. Originator companies invest in R&D to be able to develop new medicines. Once a new medicine no longer benefits from the protection offered by patents or other exclusive rights, generic producers attempt to market generic versions of that medicine. One of the Commission's core concerns was that originator companies attempted to block or delay the entry of generics into the market. The Commission's *Astrazeneca* decision of 2005 was the first in which this issue was brought to the fore. In light of the sector inquiry, the ruling on appeal of the Court of Justice (ECJ) in the *Astrazeneca* case will be closely scrutinized.

In its inquiry report, the Commission deemed the strategic use of intellectual property rights by originator companies to be a practice susceptible of hindering the entry of generics. The case at hand applies the report's findings in practice. A peculiarity of the pharmaceutical sector is that there is a long delay between the grant of a patent for a new medical product and its entry on the market, after authorisation by regulatory authorities. That delay reduces the possibility to recoup investments in R&D. To remedy the situation, the Union legislator allows for an extension of the usual patent protection through Supplementary Protection Certificates (SPCs). The strategic use of those certificates is central in Astrazeneca's first alleged abuse.

Another practice frowned upon by the Commission is the attempt to delay the market authorisation of generic products. In *Astrazeneca*, an issue not directly raised by the inquiry report was at stake. Generic manufacturers can easily obtain a marketing authorisation by using the test results obtained by the originator company for the same medicine, in accordance with EU legislation. However, the originator company can withdraw its own marketing authorisation, raising costs

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of entry for producers of generics. Astrazeneca had made use of that right.

When investigating possible infringements of competition law in the pharmaceutical sector, major topoi of competition law scholarship inevitably crop up. The strategic use of patents and other exclusive rights evokes the interface between competition law and intellectual property rights. The strict regulation of, for instance, market authorisations elicits the debate surrounding the appropriate relation between competition law and regulatory regimes. However, the peculiarities of the pharmaceutical sector may prevent the *Astrazeneca* case from becoming a textbook application of general principles emerging from those debates, but established in other sectors.

Facts

Astrazeneca is the producer of the blockbuster medicine Losec, which revolutionised the treatment of gastrointestinal acid-related diseases by using proton pump inhibitors (PPIs). PPIs were considered superior to the existing histamine receptor antagonists (H2 blockers) due to their greater therapeutic effectiveness. Losec was originally launched at the end of the 1980s as a capsule, but Astrazeneca replaced it with tablets in 1998.

In 2005, Astrazeneca was fined €60 million for abuse of dominant position on two counts. Astrazeneca's first abuse allegedly consisted in the provision of misleading information to patent offices in order to obtain SPCs for Losec. Whether or not Astrazeneca was entitled to an SPC, and the length of the SPC depended upon the 'date of the first authorization to place the product on the market'. At the time of its requests for SPCs, that is, at the beginning of the 1990s, the meaning of that phrase was unclear. The information Astrazeneca had provided was not based upon the most common interpretation of that phrase, but on an alternative reading supported by two legal opinions drafted at its request. The fact that the information provided was based upon this alternative reading was not communicated to the patent authorities. Astrazeneca's interpretation was only formally rejected by the ECJ in a judgment of 11 December 2003 (Case C-127/00 *Hässle*), but the Commission nevertheless considered Astrazeneca's provision of information during the 1990s misleading. According to the Commission, Astrazeneca was successful in obtaining SPCs to which it either was not entitled, or to which it was only entitled for a shorter period.

Astrazeneca's second abuse allegedly consisted in the withdrawal of its market authorisation for the capsule form of Losec, when it launched an alternative tablet form of that medicine. Due to this withdrawal, generic producers could not make use of Astrazeneca's test results when applying for marketing authorisation.

Both practices had the effect of hindering the entry of generics into the market for Losec, which in the Commission's view constituted a double abuse of dominant position.

The General Court (GC) largely upheld the Commission's decision of 2005. The ECJ now finds that the General Court made no errors of law in its judgment. The ECJ found that the reasonableness and *bona fides* of Astrazeneca's interpretation of the SPC Regulation was not a criterion that could preclude a finding of abuse of dominant position. Where a finding of anticompetitive effects of the granting of SPCs was necessary, the GC had established that. The ECJ also found that the fact that Astrazeneca had a right to deregister its marketing authorisation did not automatically imply every exercise of that right constituted competition on the merits. Under the circumstance, Astrazeneca's withdrawal was considered abusive.

Analysis

Market definition

The ECJ confirmed that the Commission's finding of a narrow market definition, confined to PPIs and excluding H2 blockers, was lawful. Astrazeneca had argued that the gradual increase in the use of PPIs indicated that H2 blockers had exercised a significant competitive constraint on PPIs, so that both products had to be part of the same market. After the GC, the ECJ rejected that claim. The ECJ confirmed the GC's factual assessment that the growth in PPIs did not occur at the expense of H2 blockers. In addition, the ECJ relied upon the GC's finding that PPIs and H2 blockers had different therapeutic uses. Like the GC, the ECJ acknowledged that the inertia of doctors' prescribing practices and the lack of information on the new medicine Losec, rather than competitive constraints on H2 blockers, explained the gradual increase in the usage of PPIs. It seems, *a contrario*, that a gradual increase in the use of a product can constitute proof that it is in the same market as another product when at least the following conditions are reunited: (i) the first products grows at the expense of the second, (ii) both products have the same use, and (iii) there is sufficient information in the market. The ECJ's acceptance of a narrow market definition for innovative products could encourage the Commission to do so again in the future,

increasing the likelihood of a finding of dominance in such markets.

In the pharmaceutical sector, the exercise of defining the relevant market can be challenging. Testing the demand-side substitutability of two products is especially difficult. Doctors, rather than the end-consumers, have the decisive influence on the choice of the medicine. In addition, the price mechanism is to an extent distorted. Patients pay a relatively low proportion of the price of the medicine thanks to reimbursement schemes, and prices are often influenced or determined by public authorities. The Commission therefore predominantly relies on functional interchangeability between different medicines. This analysis is eased by the existence of classification systems based upon the properties of those medicines. The ECJ appears to endorse this approach in its emphasis on the different therapeutic uses of PPIs and H2 blockers.

In basing its reasoning upon imperfect information in the market and the inertia of doctors, the judgment reflects the influence of information economics and behavioural economics for the definition of the relevant market. Information economics relaxes the assumption of most models of perfect competition that all market actors are perfectly informed. The ECJ upheld the GC's finding that the lack of information about PPIs was a crucial factor in explaining the gradual increase in the use of PPIs. The presence of imperfect information can therefore be important in defining the relevant market. Behavioural economics relaxes the assumption that all market actors are perfectly rational. Instead, behavioural economics proposes to model human behaviour by drawing upon insights from psychology. One of these insights is the recognition of inertia, that is, the tendency of consumers to choose the status quo when confronted with a new product (Eg R Spiegler, *Bounded Rationality and Industrial Organization* (2011) 147). The role of the inertia of doctors' prescribing practices was central in the reasoning of the Court. The endorsement of the Court might encourage practitioners of competition law and economics to draw more heavily on these branches of economic theory in the future.

Provision of misleading information

The Court confirmed that the provision of misleading information to patent authorities could *in casu* be considered a non-pricing abuse. It is thereby established that not just the use of an intellectual property right, but also the request of such a right can constitute an abuse of dominant position, though this question was framed before the Court as a matter of misleading information. This holding constitutes a clear signal of the Court's willingness to draw limits to the use of aggressive regulatory strategies by pharmaceutical companies.

The fact that Astrazeneca's interpretation of the SPC Regulation was reasonable and *bona fide* could not alter that holding. Having a rights claim based upon a reasonable interpretation of a legal document will not prevent a finding of abuse of dominant position. The Court dismissed the appellant's argument in most vigorous terms, stating that the fact that one has a rights claim based upon a legally defensible interpretation of a legal document could not imply that one is entitled to use '*any means to obtain that right, and even have recourse to highly misleading representations with the aim of leading public authorities into error*' (para. 98). Such behaviour would not be consistent with competition on the merits. Rather, a dominant company bears the burden of providing public authorities with all relevant information, allowing them to develop their own interpretation of the legal document in question (para. 95). Though the Court's judgment clearly establishes a dominant undertaking's duty to disclose such information, it remains uncertain to what extent that could have prevented the finding of an abuse of dominant position if SPCs would have been obtained anyway.

The fact-bound nature of the Court's judgment makes it hard to distil a general standard on the provision of misleading information. The Court made it clear that dominant undertakings were not required to be infallible in their communication with regulatory authorities (para. 99). The Court insisted that any finding of abuse must be made *in concreto* (para. 99). The allegedly consistent and deliberate nature of Astrazeneca's behaviour was an important factor in the case at hand. The ECJ drew upon the GC's analysis that Astrazeneca was '*conscious*' (para. 79) of the effects of its behaviour and that it '*could not reasonably be unaware*' (para. 81) that it was inducing patent authorities into error. The ECJ further repeated the GC's observation that Astrazeneca's conduct over the long term suggests '*that it was motivated by the intention of misleading the patent offices*' (para. 84). On the whole, the ECJ considered Astrazeneca's conduct to be '*consistent and linear, . . . characterised by the notification to the patent offices of 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*' (para. 93). By stressing these factual findings, the Court alleviates concerns that virtually any factual error in information provided to patent authorities could lead to a finding of abuse.

The Court emphasised that a demonstration of intent is not necessary for the finding that the provision of misleading information can constitute an abuse of dominant position. The Court confirmed its long-standing case law that the abuse of dominant position is an objective concept (para. 74, referring to Case 85/76 *Hoffmann-La Roche*, para. 91). Nevertheless, the Court also observed that Astrazeneca's conduct was part of a deliberate attempt to mislead regulatory and judicial authorities. Hence, it remains unclear in what circumstances an abuse can be found when the intent to mislead cannot be established.

The ECJ's judgment raises the question to what extent the strategic use of an intellectual property right can constitute an abuse of dominant position. The Commission identified such strategic use as one of the mechanisms through which entry of generics could be delayed. However, because of the way the appeal in the case at hand was framed, the Court's holding is of limited relevance in answering that question. Rather, the judgment concerns the specific situation in which misleading information is provided to patent authorities. In its memo on the judgment, the Commission took the view the judgment was about '*misuses of regulatory procedures and systems*' rather than '*misuses of patents or other intellectual property rights*' (MEMO/12/956).

The Court confirms that the showing of an anticompetitive effect is necessary to conclude there was an abuse, though that condition will be easily met. What is required is a showing that the misleading representations made in order to obtain an exclusive right are, in light of '*their objective context*', '*liable to lead the public authorities to grant the exclusive right applied for*' (para. 106). An abuse of dominant position may therefore be found even in cases where no SPC is granted or where an SPC is later annulled.

Withdrawal of market authorisation

The Court confirmed that the use of the right to deregister a market authorisation could constitute an abuse of dominant position. A finding that a dominant undertaking deregisters a market authorisation after the expiry of its exclusive right to make use of its test results, with the intent to hinder the entry of generics and parallel imports, was sufficient to establish such an abuse (para. 130). Here, the Court was very explicit that intent was an important element in the finding of an abuse. If that is a necessary requirement for a finding that the right to deregister a market authorisation constitutes an abuse, then that would seem at odds with the Court's view that an abuse of dominant position is an objective concept. Whether the intent requirement is necessary for a finding of abuse remains uncertain, however.

In the case at hand, Astrazeneca had a legal right to withdraw its market authorisation. Nevertheless, the exercise of a legal right by a dominant undertaking can be abusive when it obstructs entry into the market. That is part of the special responsibility of dominant undertakings (para. 134). The Court explicitly separated the doctrine of abuse of dominant position from legal compliance with other regulatory regimes. Indeed, in most cases the abuse of dominant position consists in behaviour which is deemed legal under other regulatory regimes (para. 132). Unfortunately, the Court gives little or no guidance as to the circumstances under which an abuse of dominant position will be found.

The ECJ's finding of an abuse of dominant position echoes its doctrine of abuse of right. The prohibition of abuse of right is recognised as a general principle of Union law. It consists of an objective and a subjective element. The former is the '*combination of objective circumstances in which, despite formal observance of the conditions laid down by the Community rules, the purpose of those rules has not been achieved*' (Case C-110/99 *Emsland-Stärke GmbH*, para. 52). The latter consists '*in the intention to obtain an advantage from the Community rules by creating artificially the conditions laid down for obtaining it*' (ibid., para. 53). Arguably, the ECJ's finding in *Astrazeneca* rests precisely on the combination of a finding that the purpose of the rules concerning market authorisations was not achieved, despite compliance with the applicable legal regime (para. 132) and the finding of an intent to obtain an advantage by hindering the entry of competing generics producers (para. 130). One could then read the ECJ's judgment as an attempt to enlist Art 102 in the effort to systematically apply a general principle of the prohibition of abuse of rights across EU law.

The Court recognised the possibility for dominant undertakings to present an objective justification for their behaviour. For instance, dominant undertakings are entitled to attempt to minimise the erosion of sales. The Court indicated that the onerous nature of the maintenance of a specific market authorisation could constitute such a justification, though Astrazeneca had failed to do so in the case at hand. One can only speculate as to other plausible objective justifications for such behaviour.

The Court refused to apply by analogy the criteria of the *IMS* and *Magill* cases. Whereas that case law con-

cerns intellectual property rights, Astrazeneca's right to withdraw its marketing authorisation did not in the view of the ECJ constitute an intellectual property right. The provision of test results under the EU regulatory regime deprived Astrazeneca of its exclusive rights to those test results, rather than ensuring protection of such rights. Still according to the ECJ, the restriction of Astrazeneca's rights can therefore not constitute an expropriation, and the exercise of that right can be more freely restricted under EU law. By distinguishing market authorisations from the protection of intellectual property rights, the Court elegantly avoids interfering with the framework of intellectual property rights protection.

Practical significance

The ECJ's ruling in *Astrazeneca* stands for the Court's endorsement of two new non-pricing types of abuses: the provision of misleading information to patent authorities and the withdrawal, in certain circumstances, of marketing authorizations for pharmaceutical products. The judgment also stands for the clear legal proposition that although there is no special responsibility for dominant undertakings to be infallible in their dealings with regulatory authorities, dominant undertakings do bear the burden of providing authorities with all relevant information when the interpretation of legal rights is at issue before regulatory authorities. Nevertheless, legal uncertainty remains on the question when the provision of misleading information is abusive when no intent can be demonstrated. Likewise, the judgment does not provide general guidance as to when the strategic use of patent applications can constitute abuse. Beyond this core of clear legal facts remains a vast penumbra of legal uncertainty.

The judgment in *Astrazeneca* is the first ruling in appeal on a finding of abuse of dominant position in the pharmaceutical sector. The judgment can appear encouraging for the Commission's current investigations, to the extent that it endorses the view that misuse of regulatory procedures can be in conflict with the concept of competition on the merits. However, the heavily fact-bound nature of the Court's reasoning will hardly provide guidance for competition authorities or private practitioners.

The facts of the *Astrazeneca* case raise questions concerning the relationship between competition law and intellectual property rights as well as regulatory frameworks. Due to the way the appeal to the ECJ was framed, the Court avoided pronouncing itself on the first matter. As to the second issue, the Court established that compliance with regulatory regimes is unrelated to the question whether or not an abuse of dominant position can be found. The practical importance of the first new type of non-pricing abuse, the provision of misleading information, will depend on the resolution of the tension between the objective nature of the concept of abuse and the importance of the factual finding of intent in the future case law of the Court. The abuse found in the withdrawal of a market authorisation may be significant for Court's effort to systematically apply its doctrine of abuse of rights across EU law.

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Otis: Can the Commission be a Victim in Addition to Acting as a Police Officer, a Prosecutor and a Judge?

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Case C-199/11—*Europese Gemeenschap v Otis NV a.o*

In a judgment issued on 6 November 2012, the Court of Justice affirmed that the Commission, in its capacity as the European Union's representative in legal proceedings, has the right to bring an action for damages before the national courts, on behalf of the European Union, to seek compensation for the harm suffered as a result of an antitrust infringement.

Legal context

According to the Court of Justice of the European Union (Court of Justice), any victim of infringement of the EU antitrust rules (Articles 101 and 102 TFEU) should be entitled to reparation from the antitrust violation perpetrator that causes any damages. Antitrust damage actions serve not only as a means of protecting the victims' right to obtain compensation but also as a policy tool of antitrust enforcement that is complementary to public prosecution.

At the same time, a range of fundamental rights-related objections have been formulated over the years

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