

AstraZeneca AB & AstraZeneca plc v European Commission, 6 December 2012
(Court of Justice of the European Union, 6 December 2012, C-457/10 P,
ECLI:EU:C:2012:770)

Prepared by UNCTAD's Intellectual Property Unit

Summary

The Court of Justice of the European Union (CJEU) upheld the General Court's decision that AstraZeneca abused its dominant position by excluding from the market competing manufacturers of generic products. The CJEU concluded that AstraZeneca's attempt to mislead the patent offices amounted to an abuse of a dominant position and that the deregistration of the marketing authorizations (MAs) for its anti-ulcer medicine with the principal intention of preventing generic market entry was inconsistent with European competition law.

Article 102 of the Treaty on the Functioning of the European Union¹

Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

The facts

AstraZeneca is a pharmaceutical group active worldwide in the development and marketing of pharmaceutical products. One of their main products is known as "Losec", a proton pump inhibitor (PPI) which is used for the treatment of ulcer. AstraZeneca has secured a "Supplementary Protection Certificate" (SPC) for Losec which extends the patent protection for an additional five year period. AstraZeneca deregistered the MAs for the Losec capsule and launched in parallel a tablet formulation of Losec. Under the EU regulatory law, a generic copy can only be admitted to the market if there is a registered reference product. AstraZeneca's newly introduced tablets could therefore not be used as a reference product for generic capsules. In 2005, the European Commission imposed a fine of 60 million Euros on AstraZeneca for having committed two abuses of a dominant position prohibited under Article 102 of the Treaty on the Functioning of the European Union (TFEU), namely :

¹ Formerly Article 82 of the Treaty establishing the European Community.

- having misled patent offices when filing SPC applications, and
- for deregistering the Losec capsule, in order to delay or make more difficult the marketing and parallel trade of generic versions of Losec.

In 2010, the General Court of the European Union confirmed the main points of the Commission's decision which considered that AstraZeneca had abused its dominant position. AstraZeneca appealed to the CJEU.

The legal issues

The main legal issues raised by the case are the following: (1) whether the General Court correctly assessed the relevant product market²; (2) whether AstraZeneca's submission of misleading representations to patent offices amounted to an abuse of a dominant position; and (3) whether the deregistration of the Losec capsule MAs constituted an abuse of a dominant position.

1. The CJEU agreed with the definition of the relevant product market chosen by the Commission and the General Court which comprises only PPIs, excluding H2 blockers. Despite a substitution trend that characterized the increase in PPIs' sales and the corresponding decrease of H2 blockers' sales, the CJEU found that the General Court was entitled to conclude that H2 blockers did not exercise a significant competitive constraint over PPIs and therefore were deemed to be outside the product market at issue. Even though PPIs and H2 blockers were prescribed to treat the same conditions, emphasis was placed on the different therapeutic uses of PPIs and H2 blockers, i.e. that PPIs were generally administered to treat more severe forms of gastrointestinal conditions. Moreover, the CJEU noted that even in the absence of H2 blockers, the sales of the PPIs could have gradually evolved in the same manner because of the novelty of the product on the market and the related uncertainty regarding its side effects. The CJEU finally noted that the determination of the market definition is the result of an overall appraisal. The Commission and subsequently the General Court were thus right to take into account while defining the market at issue the competitive relationship between PPIs and H2 blockers, the differentiated therapeutic use of these two products and the greater efficacy of PPIs, to mention but three examples.

2. The CJEU upheld the finding that AstraZeneca had abused its dominant position by supplying misleading information to national patent offices. The CJEU referred to its well-established case law that the concept of 'abuse' is an objective concept and that European Competition law prohibits a dominant undertaking from eliminating a competitor using other methods than competition on the merits³ In the case at hand, AstraZeneca misled the patent offices when applying for SPCs by presenting the date of the first pricing decision (which was also incorrect), instead of the date of the first

² See European Commission's notice on the definition of relevant market for the purposes of Community competition law, EC 97/C 372/03 (Commission Notice (97/C 372/03), paragraph 7: "A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use". According to the Commission's notice, "[m]arket definition is a tool to identify and define the boundaries of competition between firms" (paragraph 2).

³ Article 102 TFEU.

MA in the European Economic Community⁴ in order to obtain SPCs for a longer duration for which it was actually entitled and to keep as long as possible its monopoly on the PPI market. The CJEU underlined the General Court's findings about AstraZeneca's intention to mislead the patent offices, its awareness of making incorrect representations concerning the MA's date, its lack of transparency and its failure to disclose all the relevant information. In the CJEU's view, AstraZeneca's behavior was liable to lead the patent offices to grant the exclusive right applied for. While the CJEU concluded that "[AstraZeneca's] consistent and linear conduct [...] fell outside the scope of competition on the merits"⁵, it specified, as the General Court did in its judgment, that dominant companies making objectively wrong representations in their dealings with patent offices do not automatically commit an abuse. On the contrary, "the assessment of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made *in concreto*"⁶.

3. The CJEU upheld the General Court's finding that an undertaking in a dominant position has a special responsibility to the market under Article 102 TFEU and cannot use regulatory procedures to make entry of competitors on the market more difficult without a legitimate reason or an objective justification. In the view of the General Court and the CJEU, the illegality of abusive conduct under Article 102 TFEU is unrelated to its compliance or non-compliance with other legal rules, including the EU regulations governing pharmaceutical matters which confer on the holder of a MA the right to request the withdrawal of that authorization. In the case at hand, the CJEU found that the deregistration of the Losec capsule MAs prevented generic firms from using the abridged procedure - which means that applicants are not required to carry out new pharmacological and toxicological tests and clinical trials - and thus delayed the market entry of generic products and parallel imports. The deregistration constituted therefore an abuse of a dominant position. Although the CJEU recognized that pharmacovigilance obligations to which MA holders are subject can constitute an objective justification for the deregistration of MAs, the CJEU found no objective justification for AstraZeneca's conduct in the present case.

Points of significance

- Regarding the definition of the market, excluding H2 blockers which are still prescribed by doctors to treat similar conditions, narrowed down the definition of the relevant market to assess abuse of dominant position.
- Simple mistakes of undertakings in a dominant position when dealing with the patent offices are not sufficient to amount to an abuse of that position. The situation has to be examined according to the specific features of the case. In this particular case, the deliberate attempt of AstraZeneca to mislead the patent offices, the scale and prolonged nature of these misleading representations amounted to an abuse of a dominant position .
- Undertakings in a dominant position have special responsibilities to the market and cannot use regulatory procedures to make the entry into the market more

⁴ Now the European Union.

⁵ Judgment of the CJEU, paragraph 93.

⁶ *Idem*, paragraph 99.

difficult for its competitors, unless it can be demonstrated that there is a legitimate reason or an objective justification.

- An undertaking has the right to request deregistration of MAs for an approved product, for example to avoid pharmacovigilance obligations. But such request can amount to an abuse of dominance if it has the sole purpose of preventing the authorization of generics.

Key words

Competition law, abuse of a dominant position, special responsibilities, market definition for pharmaceutical products, misleading patent offices, deregistration of the marketing authorizations for a pharmaceutical product, generic competition.

Available at: <http://curia.europa.eu/juris/liste.jsf?num=C-457/10#>