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Press and Information

Advocate General's Opinion in Case C-591/16 P
Lundbeck v Commission

Advocate General Kokott proposes that the Court of Justice should uphold the fine of almost €94 million imposed on the Lundbeck pharmaceutical group in the context of agreements intended to delay the marketing of generic versions of its antidepressant medicinal product citalopram

The Advocate General proposes dismissing the appeal brought by Lundbeck against the judgment of the General Court upholding the Commission's decision imposing that fine

By decision of 19 June 2013,[1] the Commission imposed a fine of almost €94 million on the Danish pharmaceutical group Lundbeck, which had developed an antidepressant medicinal product containing an active ingredient called 'citalopram'. According to the Commission, in 2002, when the patents protecting that active ingredient within the European Economic Area ('EEA') were about to expire and Lundbeck was still the holder of secondary patents protecting certain manufacturing processes of that active ingredient, Lundbeck made payments to four manufacturers of generic medicinal products (Generics UK[2], Alpharma, Arrow and Ranbaxy)[3] in exchange for which those manufacturers agreed to refrain from entering the market.

This constitutes the first application by the Commission of the EU's prohibition on cartels to agreements in settlement of patent disputes entered into by a patent-holding originator undertaking and manufacturers of generic medicinal products. According to the Commission, such settlement agreements are not unlawful per se and may even be in the public interest as a means of conserving resources and encouraging economic development. However, such patent dispute settlements become problematic when they clash with the rules of competition law because their true aim is not to resolve a patent dispute, but to forestall or delay the market entry of potential competitors. The Commission claims that that was the case in relation to the agreements entered into by Lundbeck and the manufacturers of generic medicinal products concerned in this case.

The action brought by Lundbeck against the Commission's decision before the General Court was dismissed by judgment of 8 September 2016.[4] The General Court thus upheld the Commission's decision.[5]

Lundbeck brought an appeal against the judgment of the General Court before the Court of Justice,[6] in which it asked the latter to set aside that judgment and annul the Commission's decision.[7]

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[1] Commission Decision C (2013) 3803 final of 19 June 2013 relating to a proceeding under Article 101 TFEU and Article 53 of the EEA Agreement (Case AT.39226 — Lundbeck).
[2] At the time, that undertaking was controlled by Merck KGaA through Merck Generics Holding GmbH.
[3] Fines totalling over €52 million were also imposed on those manufacturers, see Press Release No. 90/16.
[4] Case T-472/13, Lundbeck v Commission, see also Press Release No. 90/16.
[5] The appeals brought by the manufacturers of generic medicinal products were also dismissed, see Press Release No. 90/16.
[6] At the same time, the manufacturers of generic medicinal products also brought appeals against the judgments of the General Court dismissing their actions against the Commission's decision. In those cases, which are still pending, the Court decided to rule without an Opinion.
[7] In the context of that appeal, Lundbeck is supported by the European Federation of Pharmaceutical Industries and Associations (EFPIA), as it was before the General Court, while the Commission is supported by the United Kingdom.

In today's Opinion Advocate General Juliane Kokott proposes that the Court should dismiss the appeal and uphold the General Court's judgment and the Commission's decision.

First, according to Advocate General Kokott, the General Court did not err when it upheld the Commission's assessment that, at the time the agreements were concluded, **there was a potential competitive relationship between Lundbeck and the manufacturers of generic medicinal products.**

The Advocate General takes the view that the General Court was indeed right to find that the Commission had correctly concluded that **the patents protecting certain processes for the manufacture of citalopram that were still held by Lundbeck at the time when the agreements were concluded did not constitute insurmountable barriers to the entry of the manufacturers of generic medicinal products to the market.**

The Advocate General cites the Court of Justice's recent judgment in Generics (UK) and Others[8] and notes that the existence of a process patent does not mean that a manufacturer of generic medicinal products who has in fact a firm intention and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterised as a 'potential competitor' of the manufacturer of the originator medicinal product concerned.

In that regard, the Advocate General observes that uncertainty surrounding the validity of patents protecting medicinal products is a fundamental characteristic of the pharmaceutical sector. Consequently, actions seeking to contest their validity, 'at risk' launches of generic medicinal products and the resulting court proceedings are common in the period before or immediately after the market entry of a generic medicinal product. It is not for the Commission, by assessing the strength of the patents concerned or whether generic products infringe them, to make predictions concerning the outcome of disputes between patent holders and manufacturers of generic medicinal products, in order to assess the competitive relationships between those operators for the purpose of applying competition law. The Commission's assessment must rather have regard to the question of whether, notwithstanding the existence of patents, the manufacturers of generic medicinal products have real and concrete possibilities of entering the market at the relevant time. It follows that, in this case, the Commission was not required to show that the manufacturers of generic medicinal products were able to enter the market without infringing any of Lundbeck's patent rights.

According to Advocate General Kokott, the General Court was also right in finding that **the fact that a manufacturer of generic medicinal products does not yet have a marketing authorisation for its product in a given State does not preclude the existence of potential competition**.

A refusal to recognise the existence of a potential competitive relationship between the holder of a patent for a medicinal product and the manufacturer of a generic version of that product (which, moreover, has been found to have a firm intention and an inherent ability to enter the market) simply because that manufacturer does not yet have such an authorisation, would amount to precluding any potential competition and thereby prevent competition law from being applied during the preparatory stage of the market entry of generic medicinal products, which includes the steps taken to obtain such an authorisation.

Such an approach would seriously undermine the effectiveness of the EU's prohibition on cartels, since it would mean that the preparations of future market entrants could be halted or delayed by means of exclusion agreements, with the result that the market entry of those operators and actual competition would be prevented or delayed.

[8] Case C-307/18 Generics (UK) and Others, see also Press Release No. 8/20.

Secondly, Advocate General Kokott takes the view that the General Court did not err in finding that **the agreements at issue were restrictions of competition by object**.

In particular, she agrees with the General Court's finding that **those agreements went beyond the specific subject matter of Lundbeck's intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market**.

In that regard, the Advocate General observes that a patent dispute settlement agreement must be classified as a restriction of competition by object if the value transfer from the patent holder to the manufacturer of generic medicinal products has no explanation other than the common commercial interest of the parties not to engage in competition on the merits. If the sole consideration for that transfer is an undertaking from the manufacturer of generic medicinal products not to enter the market and challenge the validity of the patent, this indicates, in the absence of any other plausible explanation, that it is not its perception of the patent's strength but the prospect of the value transfer that prompted it to refrain from entering the market and challenging the validity of the patent.

Lundbeck adduced no evidence capable of demonstrating that its value transfers to the manufacturers of generic medicinal products were made in exchange for any consideration from the latter aside from their undertaking not to enter the market.

Thirdly, Advocate General Kokott rejects Lundbeck's arguments in which it alleges that the General Court erred in law when it upheld the **fines** imposed by the Commission both as a matter of principle and as regards their method of calculation.

In that regard, the Advocate General points out that it was not, inter alia, unforeseeable from Lundbeck's perspective that the agreements at issue, which took the form of patent dispute settlements, might be caught by the EU's prohibition on cartels. As a party to those agreements, Lundbeck could not have been unaware that the only consideration it received from the manufacturers of generic medicinal products for its payments was their undertaking not to enter the market during the agreed periods. A literal reading of Article 101 TFEU makes it quite clear that agreements between competitors aimed at excluding some of them from the market are unlawful. In addition, and in any event, in order for an agreement to be classified as a restriction of competition by object, it is not necessary for the same type of agreement to have been found unlawful in the past or for that agreement to be prima facie or undoubtedly sufficiently harmful to competition, without a detailed examination of its content, its purpose and the legal and economic context in which it occurs.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

NOTE: An appeal, on a point or points of law only, may be brought before the Court of Justice against a judgment or order of the General Court. In principle, the appeal does not have suspensive effect. If the appeal is admissible and well founded, the Court of Justice sets aside the judgment of the General Court. Where the state of the proceedings so permits, the Court of Justice may itself give final judgment in the case. Otherwise, it refers the case back to the General Court, which is bound by the decision given by the Court of Justice on the appeal.

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