Investment in Possible Future Generic Marketing Excludes Legitimate Basis for Pharma Settlement, Suggests EU Advocate General

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In her opinion issued on June 4, 2020, Advocate General (AG) Juliane Kokott recommended that the European Court of Justice (ECJ) dismiss in its entirety the appeal by Lundbeck A/S and Lundbeck Ltd against the General Court's 2016 ruling upholding the European Commission's (the Commission) 2013 infringement decision in its first "pay-for-delay" case.[1] Rejecting all arguments put forward by the appellants, the AG opined that the General Court correctly upheld the Commission's assessment that, at the time the patent dispute settlement agreements at issue were concluded, there was a potential competitive relationship between Lundbeck and the manufacturers of generic medicinal products and the agreements constituted restrictions of competition by object. The AG also opined that the General Court correctly upheld the fines imposed — both in principle and with regard to their calculation.

Despite useful questions during the oral hearing as to the Commission's ability to draw conclusions about the "by object" nature of the agreements, the AG confirmed the General Court's findings on all points. In its recent ruling in *Generics (UK) and Others (Paroxetine)*,[2] the ECJ provided useful guidance that the Commission must prove that the value transferred was the sole and exclusive reason for the settlement agreements (which the Commission did not actually find in *Lundbeck*) or was sufficiently large to act as an incentive. In *Lundbeck*, the AG seemed to reduce this analysis to a conclusion that it was "apparent from the material in the file that those manufacturers would not have agreed to stay out of the market unilaterally after having taken significant steps and having made significant investments, in the absence of the payments to them from Lundbeck." This seems to substantially exclude a legitimate basis for a settlement agreement that contains any form of value for the generic manufacturer, particularly when the generic manufacturer has made an investment, even preliminary or on a limited basis, in the possible future marketing of the product at issue.

Key Takeaways

AG Kokott made the following key points:

- Based on *Generics (UK) and Others (Paroxetine)*, the existence of a process patent does not mean that a manufacturer of generic medicinal products who has a firm intention and an inherent ability to enter the market cannot be characterised as a "potential competitor" of the originator manufacturer. The process patents that were still held by Lundbeck at the time when the agreements were concluded did not constitute insurmountable barriers to manufacturers of generic medicinal products to enter the market. The fact that a manufacturer of generic medicinal products does not yet have a marketing authorisation for its product in a given member state does not preclude the existence of potential competition.
- The patent settlement agreements at issue were restrictions of competition by object. They went beyond the specific subject matter of Lundbeck's intellectual property rights, which 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.

[1] Case C-591/16P, *H. Lundbeck A/S and Lundbeck Ltd v European Commission* (Citalopram), opinion of Advocate General Juliane Kokott of June 4, 2020.

[2] Case C-307/18, *Generics (UK) and Others v Competition and Markets Authority* (Paroxetine), judgment of the European Court of Justice of January 30, 2020.

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- 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.
- It was not unforeseeable from Lundbeck's perspective that the agreements at issue might be caught by Article 101 of the Treaty on the Functioning of the European Union (TFEU). 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.

AG Kokott's Opinion

Competitive Relationship Between Lundbeck and the Generic Manufacturers

On the Alleged Existence of Legal Barriers to Entry Arising From Lundbeck's Patents

The AG opined that in a situation involving an assessment of the potential competitive relationship between a manufacturer of the originator products holding a process patent for the production of an active substance in the public domain and manufacturers of generic medicinal products who are taking steps to enter the market of the medicinal product containing that active substance, the existence of a patent protecting the manufacturing process of that substance cannot, as such, be regarded as an insurmountable barrier (Para. 47). The existence of such a process patent does not mean that a manufacturer of generic products who has 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." (Para. 48).

She added that uncertainty as to the validity of patents protecting an originator product and as to whether generic versions of that product infringe those patents "is a fundamental characteristic of competitive relationships in the pharmaceutical sector." Disputes and legal proceedings in that context are in fact evidence of a competitive relationship between originator and generic manufacturers (Para. 51). Such disputes and legal proceedings "often form part of the preparations for the market entry of generics." (Para. 54). Consequently, it cannot be argued that an "at risk" entry of a generic product to the market, which may result in patent disputes, does not constitute "a real and concrete possibility" for a generic manufacturer to enter the market where patent rights over the originator product still exist (Para. 55). It is all the more true in disputes relating to process patents because "irrespective of whether or not they are valid – [process patents] do not prevent the generic manufacturers from entering the market with the relevant API manufactured under other processes." (Para. 56).

Further, she considered that it is not for the Commission to make predictions concerning the outcome of patent disputes in order to assess the competitive relationships between the operators for the purpose of applying competition law. Rather, the Commission's assessment must 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" (Para. 59). To that effect, account must be taken of (i) the uncertainty as to the validity of patents as a fundamental characteristic of the pharmaceutical sector; (ii) the fact that the presumption of validity of a patent does not amount to a presumption that a generic version of that product properly placed on the market is illegal; (iii) the fact that a patent does not guarantee protection against actions to contest its validity; and (iv) that such actions, and, in particular, the "at risk" launch of a generic product, and the consequent court proceedings, commonly take place in the period before or immediately after the market entry of such generic product (Para. 60).

On the Evidence Put Forward by the Commission

The AG's opinion said, "It is necessary to determine whether, at the time the agreements at issue were concluded, the generic manufacturer had taken sufficient preparatory steps, in administrative, judicial and commercial terms, to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicinal products." (Para. 78). In addition, account must be taken of the originator manufacturer's "perception of the risk" posed by the generic manufacturers to its commercial interests, "as evidenced in particular by the very conclusion of an agreement" between them (Para. 79).

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On the Absence of Potential Competitive Relationship Between Lundbeck and Each of the Generic Manufacturers

The AG said, "The fact that a generic manufacturer does not yet have an MA for its product in a given State does not preclude the existence of potential competition between that manufacturer and an originator undertaking already active in the relevant geographic area, since potential competition includes inter alia the activities of generic manufacturers seeking to obtain MAs as well as all the administrative and commercial steps required in order to prepare for entry to the market. Although the success of the procedure to obtain an MA is indispensable in order for effective competition to exist, the path to obtaining such an MA, when it is taken by an undertaking which has for a long time been seriously preparing its market entry, constitutes potential competition." (Para. 103).

The opinion further said, "Potential competition does not require the demonstration of certain market entry, but merely the existence of real and concrete possibilities in that respect." Therefore, to establish the existence of potential competition, the Commission does not need to demonstrate with certainty that entry into the market of the generic manufacturers would have taken place in each of the countries concerned by the agreements at issue before the expiry of those agreements. (Para. 104). "Instead, it is necessary to determine whether that manufacturer had, at the relevant time, taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the patent holder. Those steps may include, inter alia, measures taken by the manufacturer to put itself in a position to have, within that period, the required MAs." (Para. 111).

Classification of the Agreement as Restrictions of Competition 'By Object'

The AG opined that challenging the validity of patents, particularly by means of an "at risk" market entry, is part of normal competition in sectors where exclusive rights to technologies exist. The AG said, "A patent dispute settlement agreement is akin to a restriction of competition by object if the value transfer from the patent holder to the generic manufacturer has no explanation other than the common commercial interest of the parties not to engage in competition on the merits." (Para. 128). "If the sole consideration for that transfer is the generic manufacturer's undertaking not to enter the market and challenge 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 patent." (Para. 129). Because the presumption of validity of a patent does not anticipate the outcome of any patent dispute, an agreement that eliminates that uncertainty by means of a value transfer to the generic manufacturer is akin to eliminating potential competition (Para. 130).

The AG said that it must be "apparent" from the analysis of the agreement "that that value transfer has no explanation other than the generic manufacturer's undertaking not to compete with its product during the agreed period." (Para. 132). It must be apparent that the transfer is not justified by legitimate objectives (*e.g.*, compensation for litigation costs, the actual supply of goods or services or the discharge of financial undertakings given by the patent holder). If that is the case, the AG opined, "it is still necessary to determine whether the value transfer to the generic manufacturer was sufficiently large actually to act as an incentive to it to refrain from entering the market concerned." (Para. 132).

The central points of the AG's comments are discussed below.

- The AG observed that Lundbeck did not demonstrate that the value transfers from Lundbeck to the generic manufacturers were made in exchange for any other consideration than not to enter the market. Similarly, Lundbeck did not present evidence that might cast doubt on the General Court's finding that, in this case, "the amounts of the reverse payments provided for in the agreements at issue were sufficiently high to allow the generic manufacturers to accept the limitations on their autonomy and to reduce their incentives to enter the market." It was "apparent from the material in the file that those manufacturers would not have agreed to stay out of the market unilaterally, after having taken significant steps and having made significant investments, in the absence of the payments to them from Lundbeck." (Para. 133).
- The AG further observed that instead of presenting even minimal concrete evidence toward an alternative explanation for those payments, Lundbeck "simply submit[ted] that those payments are ascribable to the asymmetry of risks between Lundbeck and the generic manufacturers." The AG wrote, "Thus, if the generic manufacturers had entered the market in breach of Lundbeck's patents, the damages that Lundbeck could have obtained following successful legal proceedings would never have been sufficient to compensate for the losses sustained, which would explain its readiness to make the payments at issue." (Para. 134).
- Finally, the AG agreed with the General Court that "'asymmetry of risks' ... like possible shortcomings in national patent law, cannot, even if proven, justify agreements whereby an economic operator pays its competitors to stay out of the market." (Para. 135).

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It is not necessary, in order to classify an agreement as a restriction of competition by object, that the same type of agreement has been found unlawful in the past or for that agreement to be *prima facie* or undoubtedly sufficiently harmful to competition, the AG said. It is sufficient that it is established that certain forms of collusion, such as the exclusion of competitors from the market, are in general so likely to have negative effects on competition that it is not necessary to demonstrate that they had such effects in the case at issue (Paras. 156-157 and Para. 201).

Fines

The AG opined that the General Court correctly upheld the fines imposed — both in principle and with regard to their calculation. In particular, with regard to the standard of proof required for the imposition of a fine, she considered that it was not unforeseeable from Lundbeck's perspective that the agreements 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 generic manufacturers for its payments was their delayed entry into the market. 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 (Para. 198). Lundbeck could not infer from the fact that the agreements had been concluded in the form of settlement agreements covering IP rights that their unlawfulness under competition law was completely novel or unforeseeable (Para. 200).

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