General Court of the European Union
PRESS RELEASE No 90/16
Luxembourg, 8 September 2016

Judgments in Case T-460/13 Sun Pharmaceutical Industries and Ranbaxy v Commission, T- 467/13 Arrow Group and Arrow Generics v Commission, T-469/13 Generics (UK) v Commission, T-470/13 Merck v Commission, T-471/13 Xellia Pharmaceuticals and Alpharma v Commission and T-472/13 Lundbeck v Commission

Press and Information

The General Court of the European Union confirms the fines of almost €150 million imposed on several undertakings in the context of an infringement intended to delay the marketing of generic versions of the antidepressant citalopram

Lundbeck is a Danish company specialising in researching and marketing new medicinal products, including for the treatment depression. From the late 1970s, Lundbeck developed and patented an antidepressant medicinal product containing the active ingredient 'citalopram'.

After its basic patent for the citalopram molecule had expired, Lundbeck only held a number of patents which provided more limited protection. In particular, Lundbeck had filed a patent relating to a process for the production of citalopram (the salt crystallisation patent). Producers of cheaper, generic versions of citalopram could therefore envisage entering the market.

In 2002, Lundbeck concluded six agreements concerning citalopram with four undertakings active in the production or sale of generic medicinal products, namely Generics (UK),[1] Alpharma, Arrow and Ranbaxy. In return for the generic undertakings' commitment not to enter the citalopram market, Lundbeck paid them substantial amounts and provided other incentives. In particular, Lundbeck paid significant lump sums, purchased stocks of generic products for the sole purpose of destroying them, and offered guaranteed profits in a distribution agreement. Those agreements gave Lundbeck the certainty that the generics undertakings would stay out of the market for the duration of the agreements.

In October 2003, the Commission was informed of the existence of the agreements at issue by the Konkurrence- og Forbrugerstyrelsen (KFST, the Danish authority for competition and consumers). Following its investigation, the Commission, by decision of 19 June 2013,[2] considered that Lundbeck and the generic undertakings were at least potential competitors and that the agreements at issue constituted restrictions of competition by object. The amounts paid by Lundbeck in order to prevent those producers from entering the citalopram market corresponded approximately to the profits that they could have made if they had successfully entered the market. The Commission therefore imposed a total fine of €93.7 million on Lundbeck and €52.2 million on the generic undertakings.

Lundbeck and the generic undertakings brought actions before the General Court of the European Union seeking the annulment of the Commission's decision and the fines imposed on them.

In today's judgments, **the Court** dismisses the actions brought by Lundbeck and the generic undertakings and **confirms the fines** imposed on them by the Commission.

[1] The company Merck, which brought an action in Case T-470/13, was the parent company of Generics (UK) at the relevant time.
[2] 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).

The Court considers first of all, like the Commission, that **Lundbeck and the generic undertakings concerned were indeed potential competitors at the time the agreements at issue were concluded**. It recalls that, in order to establish that an agreement restricts potential competition, it must be shown that, if the agreement had not been concluded, the competitors would have had real concrete possibilities of entering that market. The Court considers that the Commission carried out a careful examination, as regards each of the generic undertakings concerned, of the real concrete possibilities they had of entering the market, relying on objective evidence such as the investments already made, the steps taken in order to obtain a marketing authorisation and the supply contracts concluded with suppliers of active pharmaceutical ingredients. In addition, the Court notes that in general the generic undertakings had several real concrete possibilities of entering the market at the time the agreements at issue were concluded. Those possible routes included, inter alia, launching the generic product with the possibility of having to face infringement proceedings brought by Lundbeck.

The Court also considers that the Commission was entitled to conclude that **the agreements at issue constituted a restriction of competition by object**. [3] In that respect, the Court takes the view that Lundbeck did not demonstrate that the restrictions set out in the agreements at issue were objectively necessary in order to protect its intellectual property rights and, in particular, its crystallisation patent. Lundbeck could have protected those rights by bringing actions before the competent national courts in the event that its patents were infringed.

Furthermore, there were numerous ways of settling a patent dispute without agreeing to restrictions on the market entry of undertakings. Lastly, there was uncertainty as to whether Lundbeck's crystallisation patent would have enabled it to block the market entry of all the generic undertakings; those undertakings thus had real concrete possibilities of entering the market at the time the agreements at issue were concluded. It follows that the Commission was entitled to conclude that there was a restriction of competition by object.

The Court also points out that the Commission was only required to demonstrate that the agreements at issue revealed a sufficient degree of harm to competition, in view of the content of their provisions, the objectives that they were intended to achieve and the economic and legal context of which they formed part. It was not however required to examine the effects of those agreements or the situation that would have arisen if they had not been concluded. According to the Court, what matters is that the generic undertakings had real concrete possibilities of entering the market at the time the agreements at issue were concluded with Lundbeck, with the result that they were exerting competitive pressure on the latter. That competitive pressure was eliminated for the term of the agreements at issue, which constitutes, by itself, a restriction of competition by object.

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months of notification of the decision.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to European Union law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

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[3] Article 101(1) TFEU prohibits agreements that have as their object the restriction of competition.