Court of Justice of European Union Confirms Lundbeck Pay-for-delay Infringement Decision

On 25 March 2021, the Court of Justice of the European Union (***CJEU***) dismissed all appeals against the decision of the European Commission (the ***Commission***) to fine Lundbeck and four generic pharmaceutical companies (Alpharma, Arrow, Merck, and Ranbaxy) for concluding "pay-for-delay" patent settlement agreements in breach of Article 101 TFEU.

- CJEU Judgment
- Press Release

After the expiry of Lundbeck's compound patent on the active ingredient for its blockbuster anti-depressant, citalopram, several generic firms took steps to prepare for market entry (with Merck actually entering the market, albeit only briefly) despite Lundbeck retaining a number of patents protecting its manufacturing processes. In response, Lundbeck launched or threatened to launch patent infringement proceedings, leading ultimately to six patent settlements with the four generic firms, pursuant to which Lundbeck agreed to make various "transfers of value" to the generic firms and these firms agreed to stay out of the market.

In 2013, the Commission concluded that these settlement agreements violated EU competition law (Article 101 TFEU). Following the initial judgment in 2016 by the General Court, the CJEU's new judgment provides final confirmation of the Commission's decision.

Lundbeck and Generic Firms Were At Least Potential Competitors

An agreement can only violate Article 101 TFEU if there is coordination between independent undertakings which actually restricts competition. Therefore, competition needs to exist in the first place if it is to be capable of being restricted – if not actual competition, then at least potential competition.

In the judgment, the CJEU held that, despite Lundbeck's process patents and evidence indicating that the generic firms may have infringed these patents, Lundbeck and the generic firms were at least potential competitors at the time the agreements were concluded. In line with its earlier judgment in *Generics UK - GSK (Paroxetine)*, the CJEU held that potential competition exists if the generic firm has a "firm intention and an inherent ability to enter the market" (*see*, *Van Bael & Bellis Life Sciences News Alert* of 3 February 2020). In turn, this test is satisfied if the generic firm has "taken sufficient preparatory steps to enable it to enter the market", and if the generic firm does not face insurmountable barriers to entry. On this latter point, the CJEU confirmed that a process patent does not constitute an insuperable barrier, and therefore the generic firms, having taken preparatory steps to enter the market, constituted potential competitors.

Agreements At Issue Constitute "By-object" Restrictions of Competition

Whilst the CJEU accepted that not all settlement agreements involving reverse payments (that is, payments from originator to generic firm) necessarily infringe competition law, it held that the settlements at issue should be classified as restricting competition "by object" as the transfers of value from Lundbeck to the generic firms could have no explanation other than to satisfy all parties' commercial interests not to engage in competition on the merits.

The CJEU clarified that a case-by-case analysis should be carried out to assess whether the net gain from the reverse payments is sufficient to incentivise the generic firm to stay out of the market. In the present case, the transfers of value from Lundbeck to the generic firms entailed lump sum payments roughly corresponding to the profits which the generic firms expected to earn should they have entered the market. In some instances, Lundbeck also agreed to purchase the generic firms' stocks in order to have them destroyed. On this basis, the CJEU found that it was primarily the size of the value transfers which induced the generic firms to accept the limitations on their ability to enter the market, and therefore characterised the agreements as restricting competition by object.

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