GEDİK & ERAKSOY

Turkish Competition Authority Imposes Administrative Fine on Novartis and Roche

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Fine at issue

On 22 January 2021, the Turkish Competition Authority (**TCA**) announced its decision regarding the investigation of anti-competitive practices by Novartis Sağlık Gıda ve Tarım Ürünleri Sanayi ve Ticaret A.Ş. (**Novartis Turkey**) and Roche Müstahzarları Sanayi A.Ş. (**Roche Turkey**). The TCA found the undertakings to be in violation of the Law No. 4054 on the Protection of Competition, due to their practices aimed at maintaining widespread use of the drug Lucentis as opposed to Altuzan (Turkish version of the drug **Avastin**) which is comparably cheaper. The TCA imposed an administrative fine of 165,464,716.48 TL to Novartis Turkey and 112,972,552.65 TL to Roche Turkey. The reasoned decision of the TCA has not been published yet. However, assessments of other competition authorities are available since both undertakings have been previously subject to investigations by the Italian Competition Authority (**ICA**) and the French Competition Authority (**FCA**) regarding the same practices in question.

Background

Avastin and Lucentis are both drugs developed by Genentech, a company belonging to the Roche group. Avastin is used in cancer treatment and Roche holds its license for commercial exploitation. On the other hand, Lucentis is used for the treatment of eye diseases, namely age-related macular degeneration (**AMD**), and its license is held by Novartis. Although Avastin is developed for cancer treatment, in practice it is frequently prescribed for the treatment of eye diseases as well due to its observed positive effects on AMD patients and its lower price. The off-label prescription has significant effects on the sales of the relevant undertakings, particularly affecting Novartis due to the price difference. The claim investigated by the competition authorities is that the undertakings have colluded to reduce the off-label prescription of Avastin in favour of Lucentis.

ICA's decision and the preliminary ruling of ECJ

With its decision in 2014, ICA ruled that Novartis and Roche had entered into a market-sharing agreement through their practices aimed at discrediting Avastin's off-label use. The ICA came to the factual conclusion that Lucentis and Avastin were equally effective in the treatment of AMD, and therefore the activities of the undertakings which tried to establish Avastin as unsafe in eye disease treatment and kept the demand for Lucentis higher, were anti-competitive. The ICA claimed that these practices had significantly increased Italian healthcare service costs, and administered fines to both undertakings, each exceeding 90 million Euros.

The decision of the ICA was appealed before the Italian Council of State and a preliminary ruling was requested from the Grand Chamber of the Court of Justice (**ECJ**). In its ruling, the ECJ stated that off-label prescription is not prohibited under EU regulations, provided that the drug meets certain conditions. According to the ECJ, this assessment must be made by competent authorities. If the off-label prescription is not unlawful, then Lucentis and Avastin may be regarded as being in the same market and therefore as competing products. The ECJ then assessed the acitivites of Roche and Novarties which targeted healthcare professionals in order to reduce the off-label prescription of Avastin. The ECJ noted that disseminating misleading information to healthcare professionals and the general public regarding the adverse results caused by off-label use of Avastin constitutes a restriction of competition.

Decision of the FCA

The FCA ruled that Genentech, Roche and Novartis held a collective dominant position in the market due to their strategic and structural links. Firstly, they were found to be connected by licensing agreements, which allowed them a "highly-organised system of feedback, discussion forums and joint management committees." Secondly they were found to have structural links, such as Roche being the majority shareholder in Genentech and Novartis being a major shareholder in Roche. Therefore, according to the FCA, the undertakings had aligned financial incentives to differentiate the use of Lucentis and Avastin.

The FCA identified two forms of anti-competitive practice:

(i) Novartis led a global and well-organised campaign targeting healthcare professionals as well as the general public, in order to reduce off-label prescription of Avastin for eye disease treatment. This included a biased emphasis on the available scientific data, and the claim that healthcare professionals prescribing Avastin for eye disease treatment could be faced with civil and criminal liability.

(ii) All three undertakings carried out misleading communications with the French public authorities, voicing concerns in order to prevent the usage of Avastin in AMD treatment and trying to prevent Avastin from being recognised as a safe alternative by the health authorities. For example, Roche caused a related comparative trial to be delayed for several months.

Accordingly, the FCA ruled on a total administrative fine of 444 million Euros on the undertakings due to collective abuse of dominance. It is possible for the undertakings to appeal the decision, and it has been reported that Novartis intends to appeal.

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