Italian Highest Administrative Court Refers *Avastin/Lucentis* Case for Second Time to Court of Justice of European Union

1. Background of Case

On 18 March 2021, the Italian highest administrative court, the Consiglio di Stato (the ***CS***), decided to refer a case under its review for the second time to the Court of Justice of the European Union (***CJEU***) pursuant to Article 267 TFEU.

The case finds its origin in a decision issued back in 2014 by the Autorità Garante della Concorrenza e del Mercato, the Italian Competition Authority (the ***ICA***), which had established an anticompetitive arrangement in violation of Article 101 TFEU on the part of Hoffmann-La Roche (***Roche***) and Novartis in relation to the sale of eye medication and imposed a fine of EURO 182.5 million. The ICA found that the parties had implemented an unlawful market-sharing agreement aimed at discouraging the off-label use of Roche's Avastin® in favour of the use of a more expensive competing product (Lucentis®, whose marketing authorisation is owned by Novartis). According to the ICA, the arrangement involved the dissemination of misleading information on the safety of the off-label use of Avastin®.

Both parties challenged the ICA's decision before the national administrative courts. In 2016, the CS referred the case for a preliminary ruling to the CJEU which in 2018 held that:

a. the relevant product market may include, in addition to the medicinal products authorised for the treatment of the relevant medical condition, another medicinal product whose marketing authorisation does not cover that treatment, but which physicians use for that purpose and which is thus, from a practical perspective, a substitute for the authorised medicine;

b. an arrangement that provides for the dissemination of misleading information relating to adverse reactions resulting from the off-label use of one of these medicinal products to reduce the competitive pressure on the use of the authorised medicine constitutes a restriction of competition "by object" under Article 101 TFEU (*see*, *Van Bael & Bellis Life Sciences News Alert* of 24 January 2018).

Following the CJEU's 2018 judgment, the case went back to the CS which, in 2019, delivered its judgment extensively citing the CJEU judgment (the ***CS Judgment***).

2. Challenge of CS Judgment and Second CS Referral to CJEU

Novartis and Roche then challenged the CS Judgment, arguing that the CS failed to observe the prescriptions of the CJEU.

First, the parties contended that the position adopted by the Italian health authorities in relation to the unlawfulness of the off-label prescription of Avastin® should have prevented the CS from classifying both Lucentis® and the off-label use of Avastin® in the same product market.

Second, the parties claimed that the CS failed to determine whether the information which they disseminated was actually misleading. In their view, the CJEU held that a restriction by object could only be found to exist if the information that was spread was deceptive, which implies an assessment of the nature of that information. In the parties' view, the CS did not carry out such an evaluation.

The latest procedural step by Novartis and Roche is highly unusual in that judgments delivered by the highest courts (such as the CS) can only be challenged in an application for revision (*ricorso per revocazione*) in case of an egregious error which is uncontroversial and did not form the subject of the court's reasoning.

In a separate judgment of 15 March 2021, the CS had already declared the parties' action to be inadmissible under Italian law.

However, the CS wondered if the parties could challenge its judgment on account of a violation of EU law. As a result, the CS referred the following questions to the CJEU:

1. Whether the national judge may review the correct implementation of principles enunciated by the CJEU in the same judicial proceedings when national law does not permit a further challenge. Alternatively, the CS seeks to know whether it would be for the CJEU to carry out such a review;

2. Whether the CS judgment is in conformity with the judgment delivered by the CJEU;

3. Whether Articles 4(3) and 19(1) TEU, Articles 2(1)-(2) and 267 TFEU, as well as Article 47 of the EU Charter, stand in the way of a national system that does not allow an application for revision to challenge a judgment delivered by the CS on the grounds that it is not in conformity with a CJEU judgment.

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