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Misleading info by pharma firms may constitute “by object” infringement

The European Court of Justice recently further developed the definition of “by object” restrictions. The ECJ ruled that an arrangement between two competing pharma companies to spread misleading information regarding the safety of a product, with a view to reducing the competitive pressure on another product, constitutes a restriction of competition “by object”. The ECJ reiterated that “by object” restrictions only apply to arrangements that reveal by their very nature a degree of harm to competition sufficient for there to no longer be a need to assess their effects. The ruling not only shows that companies should think twice about their arrangements with competitors. It also confirms that determining whether an arrangement qualifies as a “by object” restriction is not a mechanical exercise, but needs a detailed analysis of relevant facts and circumstances.

In February 2014, the Italian Competition Authority imposed fines on pharma firms Roche and Novartis for concluding an agreement designed to promote the use of the more expensive drug Lucentis over the cheaper alternative Avastin by spreading misleading information regarding the safety of the off-label use of Avastin. After their appeals were dismissed by the Italian Regional Administrative Court, Roche and Novartis lodged an appeal before the Italian Council of State. The Italian Council of State referred the matter to the ECJ for a preliminary ruling asking, among other things, whether the arrangement constituted a restriction of competition “by object” under Article 101(1) TFEU.

The ECJ reiterated that the concept of a “by object” restriction should be interpreted strictly, and can only be applied to “certain types of coordination between undertakings which reveal a degree of harm to competition that is sufficient for it to be held that there is no need to examine their effects”. The reason for that is that certain forms of coordination “can be regarded, by their very nature, as being harmful to the proper functioning of normal competition”. To establish a “by object” restriction, account must be taken of the content of the arrangement, as well as its objectives and the economic and legal context of which it forms a part. When determining the economic and legal context, it is also necessary to consider the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the markets in question.

When looking at the purpose of the arrangement, the ECJ considered that objectives other than those required under pharmacovigilance were likely being pursued in a situation where two competing pharmaceutical companies spread information on a product marketed by only one of them. As to the nature of the information, the ECJ found that the referring court should assess whether this could be regarded as misleading by examining whether the purpose of that information was to confuse the regulatory authorities of the

adverse reactions of Avastin and to emphasise the public perception of the risks associated with its off-label use. Given the characteristics of the medicinal products market, the dissemination of such information would likely encourage doctors to refrain from prescribing that product, thus resulting in the expected reduction in demand. In this event, the ECJ found that the arrangement should be regarded as being sufficiently harmful to competition to render an examination of its effects superfluous.