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EU Court of Justice Advocate General Saugmandsgaard Øe indicates that providing misleading information aimed at undermining the reputation of one drug to the benefit of another drug might constitute a restriction by object *(Hoffmann-La Roche)*

Unilateral Practices, Italy, Relevant market, Pharmaceutical, Healthcare, Licensing agreement, Concerted practices (notion), European Union, Preliminary ruling (Art. 267 TFEU)

Opinion of Advocate General Saugmandsgaard Øe, F. Hoffmann-La Roche LTD and Others v. Autorità Garante della Concorrenza e del Mercato (AGCM), 21 September 2017, C-179/16

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On 21 September 2017 Advocate General Saugmandsgaard Øe ('AG') issued his opinion in *F. Hoffmann-La Roche vs Autorità Garante della Concurrenza e del Mercato (AGCM)*. In his opinion the AG provides guidance to the Court of Justice of the European Union ('CJEU') on the various questions raised by the Italian *Consiglio di Stato* ('CdS'). The CdS raised these questions in the context of an appeal against a decision of the Italian Competition Authority ('ICA'), which found that Roche and Novartis concluded an illegal market sharing agreement in the market for eye condition drugs. These questions related to market definition in the pharma sector; the impact of a licensing agreement on the application of Article 101; and the treatment under Article 101 of a concerted practice involving dissemination of potentially misleading information regarding the safety and efficacy of competing products.

I. The Parties Involved

F. Hoffmann-La Roche ('Roche'), a Swiss multinational healthcare company founded in 1896, through its Italian subsidiary Roche SpA ('Roche Italia').

Novartis AG, a Swiss multinational pharmaceutical company founded in 1996, through its Italian subsidiary Novartis Farma SpA ('Novartis Italia'). It is important to stress that Novartis holds a 33% shareholding in Roche.

II. The facts

Genentech Inc., a biotechnology subsidiary of Roche, developed two drugs: Avastin and Lucentis. Both drugs are obtained from the same antibody and have the same therapeutic mechanism but nevertheless the drugs are based on different active ingredients: bevacizumab and ranibizumab, respectively. Given the specific characteristics of each active ingredient, Genentech considered each drug was suited for the treatment of different conditions: cancer and certain eye conditions [**1**], respectively. Consequently, Genentech applied for a different marketing authorisation ('MA') for Avastin and Lucentis. Avastin received an MA for the treatment of cancer and Lucentis received an MA for the treatment of certain eye diseases.

Genentech, which is commercially only active in the US, granted a licence to exploit Avastin to its parent company Roche and, given that Roche is not active in the field of the concerned eye conditions, granted Novartis a licence to exploit Lucentis.

Avastin obtained a MA and was approved for reimbursement in 2005. The MA for Lucentis was only granted in 2007 and reimbursement was only approved in December 2008. Prior to the introduction of Lucentis, doctors had started prescribing Avastin to patients who suffered certain eye conditions, notwithstanding that Avastin had not been intended nor approved for such treatment. Such off-label use is reimbursable under Italian legislation. Given the lower cost of Avastin, off-label prescriptions continued even after Lucentis was introduced on the market.

In 2014, the ICA fined Roche (EUR 90.5 million) and Novartis (EUR 92 million) for agreeing to discourage the off-label use of Avastin. According to the ICA's findings, their agreement was designed to create an artificial differentiation between Avastin and Lucentis by manipulating the perception of the risks associated with the use of Avastin for certain eye conditions. The ICA concluded that the parties' strategy was designed to move customers towards the more expensive Lucentis by communicating to pharmaceutical regulatory authorities, medical professionals and the general public that Avastin when used off-label was less safe than Lucentis. The ICA concluded "*that the arrangement constituted an unlawful market-sharing agreement and therefore constituted a restriction of competition* **by object***, within the meaning of Article 101(1) TFEU.*" (emphasis added). The ICA's decision was confirmed on appeal by the *Tribunale Administrativo Regionale del Lazio*.

Roche and Norvatis further appealed to the CdS. In this context, the CdS asked the CJEU guidance on the following points.

- **Market definition in the pharma sector.** Role of MAs and which products should be included in the relevant market?
- **Impact licensing agreement.** Are the parties to a license agreement competitors? If not, how does this impact the application of Article 101?
- **Dissemination of allegations of lesser safety and efficacy - By object restriction?** Should the dissemination of allegations of the lesser safety and efficacy of one drug by comparison to another drug, aimed at undermining the reputation of the former to the benefit of the latter, be considered as a 'by object' restriction?

III. Opinion AG Saugmandsgaard Øe

Market definition in the pharma sector.

In essence, the CdS asked the CJEU: (i) whether the relevant product market can be defined independently of the scope of an MA; and (ii) whether the relevant product market can contain drugs used off-label.

The AG preliminary indicates that according to existing case-law a relevant product market comprises all those products which are regarded as interchangeable or substitutable by the consumer, taking into account their characteristics, their prices and their intended use. [**2**] Whether products can be considered interchangeable will depend on what is actually happening on the market rather than on legislative rules that may make interchangeability more difficult.

(i) On basis of the above, the AG holds that the content of an MA may influence the market definition but is not decisive. The fact that a drug is not authorised for a particular use, does not prevent customers from using it for such use. When a drug is used outside its MA, it can become interchangeable with, or substitutable for, a drug that is authorised for that specific use.

(ii) Furthermore, the AG considers that the uncertainty concerning the lawfulness of prescribing and marketing drugs for off-label use does not necessarily mean that these drugs are not interchangeable and do not belong to the same product market as authorised drugs. In other words, the mere fact that a drug ought not to be prescribed or marketed for off-label use does not, in itself, preclude that drug from being part of the relevant market.

Conclusion. The use of a drug off-label and a drug authorised for a specific treatment may fall within the same relevant market, "*provided that [the former] is actually used interchangeably with medicinal products whose marketing authorisation covers those indications*" (paragraph 187).

Impact licensing agreement.

The licencing agreement between Genentech and Novartis relating to Lucentis is a technology transfer agreement. According to the Technology Transfer Regulation [**3**], Genentech (Roche) and Novartis cannot be considered competitors. Parties to a licensing agreement are not regarded as competing undertakings when the licensee operates on the relevant market only by virtue of the agreement. In the absence of the licensing agreement, the licensee would have been neither an actual competitor nor a potential competitor of the licensor.

However, the purpose of the restrictive agreement at hand - concluded several years after the licensing agreement itself - was to influence third parties so that they would limit their use of Avastin (Roche), which does not incorporate the technology licensed to Novartis, and turn to the more profitable drug: Lucentis (Novartis). Consequently, that agreement cannot be considered ancillary to the implementation of the licensing agreement.

Conclusion. Restrictions relating to the exploitation of licensed technology by a licensor may fall outside the scope of Article 101 if they are objectively necessary for the conclusion of a licensing agreement. However, such reasoning does not apply to restrictions on the exploitation of a different technology, in particular, if the restrictions were not agreed upon in the licensing agreement but under a concerted practice post-dating the conclusion of the licensing agreement.

Dissemination of allegations of lesser safety and efficacy - By object restriction?

The AG starts by recalling that the concept of restriction 'by object' refers to these restrictions *"which, in themselves, reveal a 'sufficient degree of harm' to competition to render the examination of their effects on competition superfluous" [**4**]*.

The AG then distinguishes two types of 'dissemination of information': (i) dissemination of misleading information and (ii) dissemination of precise and objective information.

(i) On the basis of the national court's reference, the AG understood that *in casu* the parties presented incomplete and selective information, downplaying the value of scientific evidence to the contrary. Consequently, the allegations of Avastin's lesser safety by comparison with Lucentis were lacking in

objectivity and hence had a misleading character. Such concerted communication of misleading allegations of the lesser safety of one drug compared to another is, by its very nature, harmful to the proper functioning of normal competition, to the extent that an examination of its effects on competition is not necessary. [**5**]

Paragraph 163 of the AG's reasoning is essential in this regard: provided that the disseminated information is deemed misleading, the purpose of the practice is necessarily anti-competitive. In such context, there is no other plausible alternative explanation than an anti-competitive one. [**6**]

(ii) If the allegations are not misleading, but are precise and objective, collusive communication of such claims are not to be considered a restriction of competition.

IV. Comment

The AG's opinion provides useful guidance on how product markets in the pharma context should be defined and how one should apply EU competition law to licensing agreements. In addition, the AG further clarifies the distinction between 'by object' and 'by effect' infringements.

Article 101 prohibits agreements that have as their object to restrict competition or have restrictive effects on competition. The distinction between anti-competitive agreements that are infringements 'by object' and those that are infringements 'by effect' is key for the allocation of the burden of proof between authorities and the concerned parties. [7] The 'object' doctrine is valuable for a competition authority - once an agreement or concerted practice is qualified to be restrictive 'by object', there is no need to undertake a detailed analysis of the agreement's effect(s) on the market (*i.e.*, restriction on competition is assumed; however, no presumption exists). For companies, however, the 'by object' qualification of their conduct means that the burden is shifted onto them to prove that the agreement nevertheless meets the conditions for individual exemption under Article 101(3). On the contrary, when an agreement or concerted practice is categorized as restrictive 'by effect', the acting competition authority bears the burden to prove the actual or potential negative effects on competition, without having the possibility to fall back on assumptions.

Should the CJEU uphold the AG's opinion, it would confirm our view - shared with various competition law authors - [**8**] on when a 'by object' qualification is appropriate: if an undertaking cannot refer to a plausible - pro-competitive - purpose of an anti-competitive practice, chances are high that a 'by object' qualification will follow. The AG shares these authors' view that such an approach is already followed by the CJEU, although the CJEU never endorsed it explicitly. The AG substantiates his findings by referring to the *Cartes Bancaires [**9**]* Judgment, indicating that in that Judgment "*the* **Court held, in substance**, *that an instance of collusion was* **not a restriction of competition by object because**, *in light of the context and, in particular, the structure of and operating conditions in the market in question,* **its true aim was not anticompetitive**." (emphasis added). [**10**]

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[1] Age-related macular degeneration (an ophthalmologic condition).

[2] C-475/99, *Ambulanz Glöckner*, 25 October 2001, paragraph 33 ; C-1/12, O*rdem dos Técnicos Oficiais de Contas*, 28 February 2013, paragraph 77.

[3] Regulation No 772/2004.

[4] C-56/65, *LTM*, 30 June 1966, p. 249; C-67/13, *CB v. Commission*, 11 September 2014, paragraph 49, 53 and 57; C-469/15, *FSL and Others v. Commission*, 27 April 2017, paragraph 103.

[5] Please note that the distribution of false information can also infringe Article 102 TFEU and its national counterparts. See for example: Simon Troch, Emmelien Rientjes, "The Belgian Competition Authority fines the country's largest yeast producer for resale price maintenance and abuse of dominance (Algist Bruggeman)*"*, 22 March 2017, *e-Competitions Bulletin* March 2017, Art. N° 84450.

[6] Paragraph 163 of the AG's opinion: "*the* **objective** *of the concerted dissemination of misleading allegations of the lesser safety of one medicinal product by comparison with another* **is necessarily the exclusion of the first medicine to the advantage of the second, or at the very least a reduction in the demand for the first medicine. Given the misleading nature of such allegations, there can be no plausible alternative explanation for such collusion***, in particular, one relating to the pursuit of legitimate aims concerning the transparency of the information available in the market and the protection of public health*" (emphasis added).

[7] See also Simon Troch, Cecilia Sbrolli, "The EU Court of Justice rules on limited exclusivity restriction in lease agreements and concludes that it is not a restriction by object (Maxima Latvija)*"*, 26 November 2015, *e-Competitions Bulletin* November 2015, Art. N° 78000.

[8] See for example Ibañez Colomo, P., and Lamadrid, A., 'On the notion of restriction of competition: what we know and what we don't know we know', *The Notion of Restriction of Competition*, edited by Gerard, D., Merola, M. and Meyring, B., *Bruylant*, Brussels, 2017, pp. 353 to 358.

[9] C-67/13, *CB v. Commission*, 11 September 2014, paragraphs 74, 75 and 86. In addition, the AG refers to C-403/08 and C-429/08, *Football Association Premier League and Others*, 4 October 2011, paragraph 143 and the opinion of AG Trstenjak in C-209/07, *Beef Industry Development Society and Barry Brothers*, paragraphs 51-53.

[10] Footnote 96 of the AG's opinion