

Competition & Regulatory Newsletter

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ECJ finds that arrangement between Hoffmann-La Roche and Novartis may restrict competition “by object”

On 23 January 2018 the European Court of Justice (ECJ) handed down its judgment in [Hoffmann-La Roche and Others v AGCM](#).¹ The ECJ held that it is a restriction of competition “by object” for undertakings marketing competing medical products to disseminate misleading information about one of those products in order to reduce the competitive pressure exerted by that product on the other product. An infringement of Article 101(1) of the Treaty on the Functioning of the European Union (TFEU) can be established in these circumstances without any requirement to examine the anti-competitive effects of an arrangement.

The ECJ declined to rule on whether, on the facts of this case, the information disseminated by the parties was misleading. The Court did, however, set out criteria which, if met, would require the relevant national court to find that the information was misleading.

Background

Avastin and Lucentis are both medicines developed by a subsidiary of Hoffmann-La Roche. The licence to commercially exploit Avastin was retained within the Hoffmann-La Roche group, while Novartis was granted a licence to commercially exploit Lucentis. In January 2005 the European Commission granted Avastin a marketing authorisation (MA) in respect of cancer treatment. Two years later, the Commission granted Lucentis an MA for the treatment of eye diseases. However, Avastin was also used for the treatment of eye diseases on an “off-label” basis, even after the grant of the MA to Lucentis, on account of its lower cost.

On 27 February 2014 the Italian competition authority (AGCM) found that Hoffmann-La Roche and Novartis had put in place an arrangement intended to disseminate information that questioned the safety of using Avastin for ophthalmic purposes in order to discourage the off-label use of Avastin and

For further information on any competition related matter, please contact the [Competition Group](#) or your usual Slaughter and May contact.

¹ Case C-179/16 *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, judgment of 23 January 2018.

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therefore reduce the level of competition to Lucentis. The AGCM concluded that this constituted a breach of Article 101(1) TFEU and imposed fines totalling €182.5 million on the pharmaceutical companies.

Hoffmann-La Roche and Novartis appealed that decision in Italy, ultimately bringing the matter to the Italian Council of State which in turn referred a number of questions to the ECJ for a preliminary ruling. Essentially, the Council of State sought clarification on (i) whether Avastin and Lucentis may be considered competing products in light of the fact that Avastin's use for the treatment of eye diseases was not authorised by an MA; (ii) whether the arrangement between the parties in relation to the dissemination of information could be justified as ancillary to the licensing agreement between Hoffmann-La Roche and Novartis regarding the commercialisation of Lucentis; and (iii) whether the arrangement constituted a restriction of competition "by object."

Judgment

Are Avastin and Lucentis competing products?

The ECJ found that the fact Avastin's MA did not cover its use in the treatment of eye diseases did not preclude classification of Avastin as a product in competition with Lucentis. This is because use of a drug for "off-label" purposes is not *per se* unlawful. It would only have been appropriate for the AGCM to conclude that Avastin was not a competing product with Lucentis if the national courts or competent authorities had designated the "off-label" use of Avastin as unlawful (which they had not).

Could the arrangement in place between Hoffmann-La Roche and Novartis be justified as "ancillary" to the licensing agreement?

The ECJ held that the arrangement could not be justified as "ancillary" to the licensing agreement between Hoffmann-La Roche and Novartis. This is because rather than seeking to "*restrict the commercial autonomy of the parties to the licensing agreement*" in a manner "*objectively necessary for the implementation of the [licensing] agreement*", the dissemination of allegedly misleading information regarding Avastin was actually intended to "*restrict... the conduct of third parties*" with the ultimate aim of making Novartis' exploitation of Lucentis more profitable.² The Court did not consider whether this conclusion would be the same if the information disseminated is found not to be misleading.

Does the arrangement constitute a restriction of competition "by object"?

The ECJ began by noting that the concept of a "by object" restriction of competition must be "*interpreted strictly*" by limiting it to arrangements involving "*a degree of harm to competition that is sufficient for it to be held that there is no need to examine their effects*".³ Arrangements can be considered to be harmful "*by their very nature*".⁴ The Court added that in order to establish whether an arrangement amounts to a "by object" restriction "*regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms part.*"⁵

² Paras. 72-73.

³ Para. 78.

⁴ Para. 78.

⁵ Para. 79.

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The Court then considered the purpose of the arrangement put in place and the nature of the information disseminated by Hoffmann-La Roche and Novartis. It concluded that, should the Council of State find the disseminated information to be misleading, then the arrangement - designed to prevent doctors prescribing Avastin to treat eye diseases, thus reducing competitive pressure on Lucentis - would have to be considered “*sufficiently harmful to competition*” to constitute a “by object” restriction.⁶

It stated that the Council of State must find that the information was misleading if the information was designed to (i) “confuse” the competent authorities, and (ii) heighten “*public perception of the risks associated with*” the off-label use of the Avastin.⁷

Comment

The question of what differentiates a “by object” restriction from a “by effect” restriction has been the focus of a number of decisions of the European courts in recent years. The analysis in this case supports the narrower view of what may constitute a “by object” restriction expressed in the 2014 judgment in the *Cartes Bancaires* case.⁸ It repeats that the pre-requisite for determining that an arrangement represents a restriction “by object” is that it contemplates sufficient harm to competition.

Other developments

Merger control

CMA provisionally finds that Fox/Sky merger raises media plurality concerns

On 23 January 2018 the Competition and Markets Authority (CMA) published its [provisional finding](#) that 21st Century Fox, Inc’s anticipated acquisition of the shares in Sky plc it does not already own is not in the public interest. As reported on in our [previous newsletter](#), the Secretary of State for Digital, Culture, Media and Sport (SoS) referred the case to the CMA in September 2017 for a Phase II review on the public interest grounds of media plurality and commitment to the attainment of broadcasting standards.

The CMA provisionally found that, overall, the parties’ approach to broadcasting standards (including the policies and procedures they have in place), as well as their compliance records, indicate a genuine commitment to meeting UK broadcasting standards. The CMA also took account of evidence relating to wider regulatory compliance and corporate governance failures, but attached less weight to these as they are not directly related to the attainment of broadcasting standards.

In assessing the effects on media plurality, however, the CMA provisionally found that the Murdoch Family Trust (MFT), which is the largest shareholder in Fox and News Corp (whose portfolio includes The Times,

⁶ Para. 94.

⁷ Para. 92.

⁸ Case C-67/13 P *Groupement des cartes bancaires v European Commission*, judgment of 11 September 2014.

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The Sunday Times and The Sun), would exercise significantly increased control over Sky and Sky News following the transaction and that this would materially reduce the plurality of persons with control of media enterprises in the UK. The MFT would have too much control over news providers across all media platforms (television, newspapers, radio and online). It would therefore have too much influence over public opinion and the political agenda and there would be a risk that the diversity of viewpoints available to the public would be significantly reduced. The CMA therefore provisionally found that the transaction may be expected to be against the public interest on this ground.

The CMA provisionally identified three **potential remedies**: (i) prohibition of the deal; (ii) a spin-off or full divestiture of Sky News; or (iii) behavioural remedies to insulate Sky News from the MFT's influence. The CMA also flagged that Fox's agreement in December 2017 to sell certain assets, including its interests in Sky, to The Walt Disney Company may affect any proposed remedies.

The CMA has opened consultations on its preliminary findings and proposed remedies, which are due to close on 13 and 6 February 2018 respectively. The CMA must then provide its final report to the SoS by 1 May 2018 (extended from 6 March 2018). It is for the SoS to make the final decision on the proposed deal.

Antitrust

European Commission fines Qualcomm for exclusivity payments to Apple

On 24 January 2018 the European Commission **announced** that it had adopted an infringement decision and imposed a fine on Qualcomm of €997.4 million for abusing its dominant position in the global market for Long-Term Evolution (LTE) baseband chipsets by entering into an illegal exclusivity agreement with a key customer, which was designed to exclude competitors from the market. This was the first Commission decision on exclusive dealing since the ECJ *Intel* judgment of September 2017 (for more detail, see our previous [client briefing](#) on the topic).

Qualcomm is the world's largest supplier of the chipsets, which are used to deliver cellular mobile connectivity in smartphones and tablets. An agreement between Qualcomm and Apple, made in 2011, committed Qualcomm to making significant payments to Apple, on the condition that Apple would exclusively use Qualcomm LTE baseband chipsets in its iPhones and iPads. If Apple were to launch a device with a chipset supplied by a rival, Qualcomm would stop making payments, and Apple would have to return previous payments made by Qualcomm.

The Commission found that over the period investigated (*circa* five years and six months) Qualcomm held a dominant position in the global market for LTE baseband chipsets. This conclusion was based, in particular, on Qualcomm's market share, which was over 90 per cent for the majority of the period, and the high barriers to entry in the market

The Commission concluded that Qualcomm had abused its dominant position by preventing rivals from competing in the market by entering into an arrangement with Apple that amounted to an exclusivity condition. Seemingly following the guidance of the Court in *Intel*, the Commission also considered the impact of Qualcomm's conduct on consumers and competition. Among other factors, the Commission

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examined the scale of Qualcomm's dominant position, the significance of the amounts paid, the importance of Apple as a customer (given that it accounts for approximately one third of demand for the chipsets), the range of evidence in support of Apple's reduced incentives to switch supplier, and Qualcomm's failure to demonstrate efficiencies. In its press release the Commission also indicated it had assessed and rejected Qualcomm's price cost test, aimed at showing prices were above cost, by which Qualcomm claimed that the exclusivity payments were not having an anti-competitive effect.

The fine imposed represents 4.9 per cent of Qualcomm's turnover in 2017, which is high in comparison to other notable Article 102 TFEU cases, but still below the 10 per cent maximum cap. Qualcomm has **announced** its intention to appeal the decision.

It will be of interest to read in the Commission's decision, once published, its approach to the Court's guidance in *Intel*. Competition Commissioner Vestager has **stated** that "*We have carefully examined the ruling and the evidence in our case file, to make sure our decision fully complies with the guidance given by the Court.*"

Chinese court grants injunction against Samsung for infringement of Huawei's SEPs

On 11 January 2018 the Shenzhen Intermediate People's Court Intellectual Property Court announced its decision in relation to two Standard Essential Patent (SEP) cases filed in May 2016 by Huawei Technologies Co Ltd against various Chinese entities, including companies belonging to the Samsung Group.⁹ This marks the first ruling from this Court, which was established recently on 26 December 2017 out of the Shenzhen Intermediate People's Court, and also the first time a Chinese court has awarded an injunction in a case relating to international SEPs.

The Court found that Samsung had infringed two of Huawei's 4G SEPs and had failed to comply with fair, reasonable and non-discriminatory (FRAND) principles in SEP cross-licensing negotiations with Huawei. The Court therefore awarded an injunction in favour of Huawei and ordered Samsung to cease its infringements of the two SEPs at issue, which included ceasing the manufacture and sale of all relevant devices.

In establishing Samsung's infringement behaviour, the Court found that Huawei and Samsung had been involved in SEP cross-licensing negotiations for more than six years since July 2011, and that although Huawei complied with FRAND principles during the process, Samsung did not do so and was at "obvious fault". For instance, despite Huawei's various attempts to resolve SEP cross-licensing issues with Samsung via different means including negotiation and arbitration (i.e. acting as a willing licensor and licensee), Samsung employed "malicious" delay tactics in contravention of FRAND principles.

The Court's approach in granting the injunction appears to follow that of the Beijing Intellectual Property Court in its March 2017 decision in *Iwncomm v. Sony*, which set out that, in SEP cases, an injunction should be granted in favour of the patentee if the patentee is not at fault in the course of licensing negotiations, but the implementer is.

⁹ (2016) 粤03民初816 and (2016) 粤03民初840.

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No damages were awarded since Huawei did not seek any. The injunction can only be lifted if terms for the cross-licensing are agreed or if Huawei requests for the injunction to be lifted.

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