October 2020

French Competition Law Newsletter

Highlights

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The French Competition Authority fines three pharmaceutical companies for abuse of collective dominance

On September 9, 2020, the French Competition Authority ("**FCA**") fined Novartis, Roche and its subsidiary Genentech €444 million for abusing their collective dominance on the market for AMD treatment. The FCA found that the parties disparaged the off-label use of Roche's Avastin drug and spread an alarmist discourse before the public authorities in order to preserve the dominant position and high price of Novartis' Lucentis drug.

Background

In the late 1990ies, US pharmaceutical company Genentech developed a revolutionary active ingredient called bevacizumab[1] (later sold under the brand name Avastin) to treat certain types of cancer. Bevacizumab was licensed to its parent company Roche for distribution outside of the United States, and was granted a market authorization by the European Commission in 2005. In parallel, having found that Avastin could also help treat age-related macular degeneration ("**AMD**"), Genentech developed and started selling ranibizumab, a specific molecule (sold under the name of Lucentis) that it considered more appropriate for treating AMD. Lucentis was licensed to Novartis for distribution outside of the United States, and was granted an EU market authorization in 2007. Novartis, already at that time, was one of Roche's shareholders with a 33,33% share of the voting rights. Roche, in turn, held a majority stake in Genentech, and acquired all of its outstanding shares in 2009.

[1] The so-called "anti-VEGF" principle, which aims at blocking the "VEGF" ("*vascular endothelial growth factor A*") protein, which contributes to the development of blood vessels and may contribute to the vascularization of cancerous tumors.

As Avastin was about 30 times cheaper that Lucentis, some doctors administered Avastin "off-label" for AMD treatment, on their own responsibility, where, on the basis of an assessment of individual patients, they concluded that it was necessary to do so to meet a patient's specific needs. Roche, however, never applied for an authorization to market Avastin for AMD treatment. In light of the objective differences between the two molecules, a scientific debate arose on the respective safety and efficacy of Avastin and Lucentis for AMD treatment. Between 2010 and 2013, a number of international and French scientific studies were conducted on the topic.

In parallel, the French regulatory framework (which, in particular following the Mediator healthcare scandal, heavily restricted the use and possibility to reimburse drugs used "off-label") evolved and in December 2014, the French Government adopted a decree making it easier to use a drug "off-label" even when an authorized alternative was available.[2] As a result, the *Agence nationale de sécurité du médicament et des produits de santé* ("**ANSM**") issued a "Temporary Recommendation for Use" for the use of Avastin in the treatment for AMD.

The FCA decision

In 2014, the Italian Competition Authority fined Novartis and Roche under Article 101(1) TFEU for anti-competitively agreeing to spread misleading information on the use of Avastin in ophthalmology in order to encourage the use of Lucentis for AMD treatment. Shortly thereafter, the FCA initiated *ex officio* proceedings. Unlike its Italian counterpart, the FCA did not rely on Article 101(1) TFEU and instead alleged that Novartis, Roche and Genentech engaged into abuses of collective dominance infringing Article 102 TFUE and Article L. 420-2 of the French Commercial Code. On September 9, 2020, further to a five year-investigation, the FCA fined the three companies a total amount of €444 million for abusing their collective dominance between March/April 2008 and November 2013.

The alleged collective dominant position of Novartis, Roche and Genentech

The FCA found that the three companies, together, held a collective dominant position on the market for the treatment of AMD. The FCA considered that Novartis, Roche and Genentech constituted a single entity because of Novartis' shareholding in Roche, Roche's shareholding in Genentech, and the contractual links between Genentech and Roche, and Genentech and Novartis respectively, through the licencing agreements. The FCA considered that this single entity held a dominant position on the market for the treatment of AMD where the parties' combined market shares exceeded 90%, until Bayer's entry in 2013.

The alleged practices

The FCA found that (i) Novartis had allegedly disparaged Avastin before patient associations, health professionals, and the general public; and (ii) the three companies had allegedly implemented blocking tactics to delay the public authorities' initiatives to regulate the use of Avastin in the treatment of AMD.

The first infringement. The FCA held that pharmaceutical companies have the duty to communicate in an objective, comprehensive and reliable way to doctors, public authorities, and the public in general.[3] The FCA considered, in this case, that Novartis had disseminated selective and biased data comparing Avastin and Lucentis, unduly insisting on the risks related to the use of Avastin for AMD treatment.

The FCA found that these practices reduced the "off-label" use of Avastin in ophthalmology, which in turn unduly preserved Novartis' quasi-monopolistic position on the market and helped sustain Lucentis' high price. As a side effect, according to the FCA, the practices unduly increased the pricing of Bayer's drug Eylea, since Eylea's price was set taking into account Lucentis' (but not Avastin's) price.

[2] Decree No. 2014-1703 of 30 December 2014.

[3] *See* Decision 20-D-11 regarding practices implemented in the treatment of Age-related macular degeneration (AMD) sector, paras. 764-767.

Novartis was fined €253.9 million for the first infringement.

The second infringement. The FCA found that Roche and Novartis, aided by Genentech, had intervened in an abusive way before the French public authorities. The practice allegedly aimed at delaying the public authorities' initiatives to promote the use of Avastin for AMD treatment.

The FCA relied on (i) Roche's initial temporary refusal to supply samples of Avastin to the *Agence française de sécurité sanitaire et des produits de santé* ("**AFSSAPS**")[4] for the purpose of a stability assessment and (ii) Roche's communications to the AFSSAPS, at the latter's request. It found that Roche had unduly emphasized the side effects of Avastin's use in ophthalmology. As for Novartis, the FCA found that it had spread a worrying discourse among public authorities based on incomplete studies presented out of context. According to the FCA, these practices had a negative impact on the evolution of health care spending, and also contributed to preventing Avastin from being used in comparative tests that could have enabled the *Comité économique des produits de santé* ("**CEPS**") to substantially lower the price of Lucentis.[5]

Although Genentech did not directly intervene in Novartis' and Roche's interactions with French authorities, the FCA considered that it had helped the two other companies coordinate their message so that it remained consistent and based on the same scientific data. The FCA notably supported its conclusion by citing a number of e-mails exchanged between Genentech and the two other laboratories.

Novartis was fined €131.2 million for the second objection, while Roche and Genentech were jointly ordered to pay a €59.7 million fine.

Conclusion

The FCA decision is one of the rare cases, to date, where the FCA found a collective dominant position. It raises a number of critical questions about the definition of a collective dominant position in the context of a contractual licensing relationship, with one of the players involved holding, on its own, a quasi-monopolistic market position (Novartis). The nature of the abuse in such circumstances may also be discussed. The decision, moreover, sets a particularly low standard of proof to establish the abuse, as it almost entirely relies on one of the parties' behaviour (Novartis) to demonstrate a collective scheme of practices. Finally, the decision also raises serious questions regarding the FCA's jurisdiction to interpret scientific studies and assess the legitimacy of laboratories' concerns over the use of medicines. Novartis has publicly announced its intention to appeal the decision.

The French *Cour de cassation* upholds the Paris Court of Appeals' judgment in the TDF abuse of dominance case

On September 16, 2020, the French *Cour de cassation* upheld the Paris Court of Appeals' judgment, which had largely confirmed the French Competition Authority's (the "**FCA**") decision in the TDF case.

Background

In June 2016, the FCA fined TDF €20.6 million for abusing its dominant position on the wholesale market for terrestrial broadcasting services between 2006 and 2010.

[4] AFSSAPS is the former name of ANSM.

[5] The CEPS set the price of medicines reimbursed by the French social security system by looking at the price of other medicines used for the same treatment (also called "comparators"). To qualify as a comparator, a medicine must benefit from certain authorizations or recommendations of use, or be frequently prescribed "off-label". Therefore, in this case, as Avastin was only granted a Temporary Recommendation for Use in 2014, the CEPS did not take its price into account when setting the price for Lucentis.

The FCA found that TDF, a former state monopoly, held a dominant position on both the upstream and downstream wholesale markets for terrestrial broadcasting services.

— On the upstream market, broadcasting operators that own tower sites offer hosting services to broadcasting operators that do not own such infrastructure. Local authorities must authorize them to build pylon sites capable of hosting broadcasting equipment.

— On the downstream market, broadcasting operators offer broadcasting services to television channels, grouped in multiplexes ("**MUX**").

Following a complaint by a competitor, the FCA found that TDF had (i) offered *per se* anticompetitive exclusivity rebates to MUX and (ii) engaged in denigrating conduct by warning municipalities that the installation of competing broadcasting towers could interfere with TDF's existing broadcasting services. TDF appealed.

In 2017, the Paris Court of Appeals largely confirmed the FCA's decision. However, it (i) rejected the FCA's qualification of TDF's rebate scheme as *per se* illegal[6] and (ii) annulled the objection relating to denigrating practices, which led to a reduction of TDF's fine to €17.2 million. Both the FCA and TDF appealed.

On September 16, 2020, the *Cour de cassation* upheld the Paris Court of Appeals judgment in its entirety.

Rebate scheme

The *Cour de cassation* confirmed the Paris Court of Appeals' finding that the rebate scheme implemented by TDF was not *per se* illegal. TDF's exclusivity rebate scheme was indeed based on a different geographic scope than that of the dominated market. Eligibility for rebates was assessed at a local level, whereas TDF was considered dominant on the *national* market for downstream wholesale broadcasting services. The *Cour de cassation* thus considered that the rebate scheme did not fall within the scope of the *per se* illegal exclusivity rebate concept, as defined by the European Court of Justice, and could therefore not be presumed to be anticompetitive.[7]

It nevertheless confirmed that the rebate scheme was anticompetitive due to its effects. Though the relevant market was defined nationally, the Paris Court of Appeals analyzed TDF's position at a local level because the effects of the rebate scheme were local in scope. It concluded that TDF was dominant in each local area of the rebate scheme,[8] and that the rebate scheme had the effect of inciting customers to contract exclusively with TDF in each area.[9]

Denigration

The *Cour de cassation* confirmed that denigration could not be established. It considered that the litigious emails merely presented a risk to municipalities that the construction of a broadcasting tower in close proximity to an existing tower could lead to interference, without explicitly citing any competitors. It acknowledged that the information provided in the emails was incomplete, and therefore misleading,[10] but considered that this was not enough to constitute denigration,[11] despite the fact that the identity of TDF's competitors was obvious given existing market concentration.

[6] Paris Court of Appeals, December 21, 2017, case no. 16/15499, para. 212.

[7] Paris Court of Appeals, December 21, 2017, case no. 16/15499, paras. 202-204, on the basis of the judgment of February 13, 1979, *Hoffmann-La Roche v. Commission*, C-85/76, ECLI:EU:C:1979:36, and the judgment of September 6, 2017, *Intel v. Commission*, C-413/14P, ECLI:EU:C:2017:632. In these cases, eligibility for rebates was assessed on the same market as the market on which the undertakings were dominant, the community-wide vitamins A, B2, B6, C, E, and H markets in *Hoffmann-La Roche*, and the worldwide x86 CPUs market in *Intel*. The exclusivity rebates in these cases were presumed to be anticompetitive.

[8] French *Cour de cassation*, September 16, 2020, Judgment n° 18-11.034 , para. 10.

[9] French *Cour de cassation*, September 16, 2020, Judgment n° 18-11.034 , para. 8.

[10] Paris Court of Appeals, December 21, 2017, case n° 16/15499, para. 133. For instance, the interference would in practice have been easily resolved and service disruption limited.

[11] French *Cour de cassation*, September 16, 2020, Judgment n° 18-11.034 , para. 25.

Key Takeaway

With regard to loyalty rebates, in line with EU precedents,[12] the *Cour de cassation* has considered that for a rebate to be *per se* anticompetitive, the eligibility of the rebate must have the same geographic scope as the dominated market. When that is not the case, a case-by-case assessment must be carried out. In the case of local rebate schemes, the customer's behavior in one local area does not affect eligibility for the rebate in another area, and therefore dominance must be assessed in each local area before reaching a conclusion as to the abusive nature of the rebate.

As for denigration, while the FCA has been at the forefront of developing theories of harm as a result of denigration in pharmaceutical abuse of dominance cases,[13] the ruling shows that the precise contours of denigration abuses are yet to be defined, in particular in non-pharmaceutical cases.

The *Cour de cassation* quashes the Paris Court of Appeals' decision in the SFR/Orange case on the fixed telephony market for secondary homes for the second time

On September 16, 2020, the French *Cour de cassation* annulled a judgment of the Paris Court of Appeals for the second time in the saga between SFR and Orange. While the *Cour de cassation* confirmed the existence of a relevant market for fixed telephony for secondary homes, on which Orange is dominant, it ruled that the Paris Court of Appeals had failed to properly assess Orange's allegedly abusive conduct.

Background

As the historical telecom operator, Orange offers annual access to telephony services ("**ATS**") to its competitors, including SFR. Competitors pay for this access on a monthly basis. The telecom regulator (the "**ARCEP**") controls the monthly fees in order to ensure that they are transparent and non-discriminatory.

In 2000, Orange launched a secondary residence offer ("**SRO**"). The SRO allows owners to suspend the telephone line in their secondary residence when it is unoccupied (the "**Suspension Option**") in exchange for a marginal fee.

In 2010, SFR sought to launch an offer competing with Orange's SRO. It realized, however, that such an offer would not be commercially viable: while SFR would offer the possibility for customers to suspend their line for a marginal fee, SFR would have to continue to pay for Orange's ATS for the entire year. SFR asked Orange to suspend the ATS monthly fees, but Orange refused. SFR therefore brought a damage claim against Orange for abusing its dominant position on a so-called market for secondary residence telephony services. It alleged that Orange had abused that position by refusing to suspend the payment of the ATS monthly fees, thereby preventing it from replicating Orange's SRO.

In 2014, the Paris Commercial Court found Orange liable for abuse of dominant position and ordered it to pay €51.38 million in damages to SFR. The Paris Court of Appeals overturned the judgment ruling that there was no separate market for fixed telephony for secondary homes and, therefore, that Orange did not hold a dominant position on the alleged market.

[12] Judgment of February 13, 1979, *Hoffmann-La Roche v. Commission*, C-85/76, ECLI:EU:C:1979:36, and judgment of September 6, 2017, *Intel v. Commission*, C-413/14P, ECLI:EU:C:2017:632.

[13] See *inter alia* FCA decision No. 13-D-11 relating to practices implemented in the pharmaceutical sector (*Sanofi-Aventis*); and FCA decision No. 17-D-25 of December 20, 2017, relating to practices implemented in the transdermal fentanyl products sector (*Janssen-Cilag*).

In 2016, the *Cour de cassation* annulled the 2014 judgment, criticizing the market analysis carried out by the Paris Court of Appeals, and remanded the case to the same court.

In its 2018 ruling, the Paris Court of Appeals identified a relevant market for fixed telephony for secondary homes, qualified the abuse, and imposed a fine of €52.95 million on Orange. Orange appealed in cassation.

Court ruling

Orange challenged both the market definition and the qualification of the abuse. While the *Cour de cassation* rejected Orange's arguments on the market definition, it overturned the Paris Court of Appeal's finding that Orange had abused its dominant position on this market.

Orange argued that the ATS monthly fees reflected the cost incurred to maintain the network. Therefore, suspending the monthly fees would have had to have been compensated by increased monthly fees for the months when these were paid. At the time, SFR contacted the ARCEP to carry out an analysis of the replicability of Orange's SRO, following which the ARCEP confirmed that the quantum of the monthly ATS fees would have to increase in order to cover Orange's loss. However, when the ARCEP enquired whether ATS subscribers would agree to an increase in the ATS monthly fees in exchange for the right to suspend the ATS monthly payments, all subscribers, including SFR, refused.

The *Cour de cassation* accepted Orange's argument, ruling that the Paris Court of Appeals should have taken into account SFR's refusal to increase ATS monthly fees in its analysis. The *Cour de cassation* annulled the Paris Court of Appeals' judgment and sent the parties back before the Paris Court of Appeals for a third round of arguments.

Key takeaway

The ruling is an example of a complex situation intertwining antitrust and sectoral regulation. A sectoral regulation does not exonerate an undertaking from complying with competition law. In the present case, interestingly, the regulator's intervention—and in particular SFR's refusal to accept the ARCEP's proposal to find a solution—was considered decisive in the qualification of the abuse.

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