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French Competition Law Newsletter

Highlights

— The Paris Court of Appeals quashes the French Competition Authority decision fining three pharmaceutical companies for alleged collective dominance practices

— The French *Conseil Constitutionnel* decides in favour of constitutional right of appeal of French Competition Authority's decisions rejecting commitments during antitrust proceedings

— The French Competition Authority introduces the first network visualization tool to explore its publications

The Paris Court of Appeals quashes the French Competition Authority decision fining three pharmaceutical companies for alleged collective dominance practices

On February 16, 2023, the Paris Court of Appeals overturned the French Competition Authority (the "**FCA**") decision which had fined Novartis, Roche and its subsidiary Genentech €444 million in 2020, ruling that, contrary to French Competition Authority's findings, the pharmaceutical companies had not abused their collective dominance on the market for the treatment of age-related macular degeneration ("**AMD**") by discouraging "off-label" prescriptions (i.e. prescriptions for use outside of the market authorization of a medication).[1]

Background

On September 9, 2020, FCA fined Novartis, Roche and Genentech for abuse of collective dominance position as it considered that the three pharmaceutical companies constituted a single entity because of Novartis' shareholding in Roche, Roche's shareholding in Genentech and the licensing agreements between (i) Genentech and Roche for the distribution of Avastin ex-US and (ii) Genentech and Novartis for the distribution of Lucentis ex-US.

[1] Paris Court of Appeals ruling of February 16, 2023 (No. 20/14632).

The FCA first found that Novartis unduly disparaged Roche's Avastin medication – a cancer treatment drug also administered off-label by a number of doctors to treat AMD – in order to favor the use of its own medication, Lucentis, which was about 30 times more expensive than Avastin.[2] Second, the FCA held that the three pharmaceutical companies implemented blocking tactics, including spreading false information about the safety risks of prescribing Avastin off-label and, regarding Roche, failing to seek market authorization for the use of Avastin to treat AMD in order to prevent the entry of this cheaper treatment into the French market for the treatment of AMD.[3]

The three pharmaceutical companies appealed the FCA decision before the Paris Court of Appeals. On February 16, 2023, the Court of Appeals upheld the companies arguments, finding that they had not infringed competition law and thereby quashed the FCA decision in its entirety.

Product scope and timeframe of the alleged practices

Before analyzing the merits of the case, the Court first clarified that while Novartis' Lucentis is used both in hospitals and pharmacies, Roche's Avastin can only be found in hospitals. The Court therefore limited the relevant market scope to AMD hospital prescriptions.

Second, following the Mediator healthcare scandal and the entry into force of a new legislation in 2011 (the so-called "Bertrand law"), the use of off-label drugs was heavily restricted in France.[4] In particular, off-label treatments could only be prescribed if there were no authorized alternatives available for a given pathology. Consequently, as of December 2011, Avastin could no longer be used for the treatment of AMD. Conversely, Novartis' Lucentis had all the necessary authorizations to be used as an AMD treatment. The Court thus found that Avastin (Roche) and Lucentis (Novartis) could not be regarded as competing products on the relevant market (i.e. the French market for the treatment of AMD through hospital prescriptions) as of December 2011.

Lack of disparagement and anticompetitive effects

On the merits, the Court of Appeals found that Roche and Novartis' communications with healthcare professionals and agencies regarding the benefits of their respective drugs to treat AMD did not amount to anticompetitive disparaging as they were based on accurate knowledge at the time of the alleged practices. In light of the objective differences between Avastin and Lucentis, the respective safety and efficacy of both drugs for AMD treatment were the topic of national and foreign scientific debate at the time, and the risks associated with off-label use of Avastin were unknown. The Court found that the drugmakers had thus legitimately cautioned against the prescription of any off-label drugs, including Avastin, due to lack of scientific studies and proven results.

Regarding Roche, its statements regarding Avastin were considered neither alarmist nor misleading by the Court of Appeals as there was still a great deal of scientific uncertainty and worrying reports regarding the use of off-label Avastin for AMD treatment at the time. Also, as the drugs could not be substituted for one another under the Bertrand Law, the Court considered irrelevant whether Roche had caused delays to further studies or additional authorizations for Avastin, as these factors would not have resulted in any anticompetitive effects.

Regarding Novartis, the Court considered that by highlighting *probable* – as opposed to *definite* – links between Avastin and negative effects on health it had merely exercised its freedom of speech to contribute to the legitimate debate on the substitutability of Avastin for Lucentis.

[2] FCA Decision 20-D-11 of September 9, 2020 regarding practices implemented in the treatment of AMD.

[3] For further details, see the French Competition Law Newsletter, October 2020 edition, available at: https://www.clearygottlieb.com/-/media/files/french-competition-reports/french-competition-newsletter-october-2020.pdf.

[4] Law No.2011-2012 of December 29, 2011 aimed at reinforcing the safety of medicines and health products.

Novartis. This was considered sufficiently moderate in tone and neither misleading nor wrongful by the Court of Appeals.

Hence, the FCA failed to prove, to the requisite standard, that the pharmaceutical companies disparaged the use of Lucentis, and the Court of Appeals annulled the €444 million fine and ordered the FCA to publish an acknowledgment of its ruling on its website, clarifying, in particular, that the three pharmaceutical companies did not commit any anticompetitive infringement.

An appeal of the FCA is currently pending before the French Supreme Court (*Cour de cassation*).

Main takeaways

The FCA decision raised a number of critical questions regarding the definition of a collective dominant position and the nature of the abuse. In particular, the standard of proof applied by the FCA to establish the abuse was low, as it relied almost entirely on one party's (Novartis) disparagement tactics against Avastin to demonstrate a collective scheme of practices. Although, as one may expect, the Court of Appeals' ruling falls short of providing any further guidance on the definition of collective abuse, it makes clear that the FCA shall take account of the multi-factorial environment companies operate in and therefore cannot substitute its competition assessment for that of other – in the present case, health – authorities.

The French *Conseil Constitutionnel* decides in favour of constitutional right of appeal of French Competition Authority's decisions rejecting commitments during antitrust proceedings

On February 10, 2023, the French Constitutional Council ("***Conseil constitutionnel***") considered that the second sentence of Article L. 464-2, I, paragraph 1 of the French Commercial Code, which provides that the French Competition Authority ("**FCA**") may accept commitments in the context of antitrust litigation proceedings, but says nothing about its power to refuse them, complies with the French Constitution and, on this occasion, confirmed that companies can lodge appeals again French Competition Authority decisions rejecting suggested commitments.[5]

Background

In October 2016, the FCA launched an investigation into Sony interactive entertainment France and Sony interactive entertainment Europe limited (together "**Sony**")'s practices following a complaint from an accessory manufacturer alleging that Sony had abused its dominant position in the market for next-gen gaming consoles.

As part of its preliminary assessment, the FCA's investigation services found that Sony had implemented two anti-competitive practices. First, Sony had updated the PlayStation 4 operating system which allegedly resulted in the alteration of the functioning of certain third-party controllers.[6] Second, Sony had implemented an allegedly ambiguous and opaque licensing policy for companies seeking to sell controllers compatible with the PlayStation 4.

In response to these competition concerns and in order to put an end to the proceedings, Sony offered a number of commitments (in particular, to make its licensing policy for

[5] Conseil Constitutionnel decision No. 2022-1035, February 10, 2023, , *Sony interactive entertainment France e.a.*

[6] Three types of controllers are compatible with the PlayStation 4: (i) Sony controllers, (ii) third-party controllers manufactured under Sony licence and (iii) other third-party controllers which do not benefit from a Sony licence.

PlayStation 4 controllers more transparent and non-discriminatory). On October 23, 2020, the FCA rejected Sony's latest set of commitments and sent the case back for further investigation on the merits.[7] Sony brought the case before the Paris Court of Appeals requesting the annulment of the FCA decision rejecting its commitments offer. The Court of Appeals considered the appeal was inadmissible as it found that there was no clear case law or legislation showing that Sony had the right to appeal. According to the Court, an FCA decision rejecting commitments could not be appealed separately from the final FCA decision on the merits.[8]

Referral of Sony's claims before the *Conseil Constitutionnel*

Sony further challenged the Court of Appeals ruling before the French judicial Supreme Court ("***Cour de cassation***").[9] Sony notably claimed before the *Cour de cassation*, which then referred the matter to the *Conseil Constitutionnel* on December 7, 2022,[10] that the provision (*i.e.* the second sentence of Article L. 464-2, I, paragraph 1 of the French Commercial Code mentioned above[11]) – which enables the FCA to use the same adjudicators for both its commitment and sanction procedures, in the same case, is unconstitutional. Sony claimed that said provision (i) violates constitutional principles of independence and impartiality by not precluding the members of the FCA case team having rejecting commitments in a given case to later rule on the sanctions to be imposed in the same case and (ii) breaches companies' rights of defence and to an effective judicial remedy by preventing companies from appealing against a decision to reject commitments.

A constitutional right of appeal of decisions rejecting commitments

The *Conseil Constitutionnel* first held that the FCA's power to review commitments and its power to fine a company for breach of antitrust rules have separate objectives. Their outcome does not impact one another and the principles of independence and impartiality are thus not violated by allowing the same adjudicators review commitments and impose fines in the same case.

The *Conseil Constitutionnel* then held that companies should however be granted the right to appeal against FCA commitments rejections even if this right is not explicitly mentioned under Article L. 464-2, paragraph 1, second sentence. In legal terms, the *Conseil Constitutionnel* held that a decision rejecting commitments should be treated as one of the decisions listed as subject to appeal under Article L. 464-8 of the French Commercial Code.

The case has now been referred back to the *Cour de cassation* who may decide to overturn the Court of Appeals' ruling on inadmissibility, thereby giving Sony the chance to argue the merits of its appeal against the enforcer's commitments rejection decision.

In sum, FCA decisions rejecting remedies can thus always be subject to judicial review, which means that, in future cases, the FCA has to provide robust reasons for rejecting remedy proposals. The *Conseil Constitutionnel* decision thereby increases the rights of the parties before the FCA and, subsequently, before the Paris Court of Appeals which would have to reassess the effect of commitments the FCA initially rejected in case of appeal.

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[7] FCA decision No. 20-S-01 of October 23, 2020.

[8] Paris Court of Appeals, April 21, 2022, *Sony Interactive Entertainment France e.a.*, n° 20/16953.

[9] For sake of completeness, Sony had also brought the case before France's highest administrative court ("***Conseil d'Etat***") requesting the annulment of the FCA decision rejecting its commitments offer on the grounds of excess of power. On July 1, 2022, the *Conseil d'Etat* ruled that Sony's appeal of the FCA decision rejecting its commitments could not be heard since the Conseil d'Etat had no jurisdiction to rule over such case. The *Conseil d'Etat* held that a decision of the FCA to reject commitments was not capable in itself of producing legal effects. Consequently, such decision could not be considered as unrelated and severable from the underlying FCA proceedings and could not be appealed.

[10] *Cour de Cassation*, December 7, 2022, *Sony Interactive Entertainment France* and *Sony Interactive Entertainment Europe Limited*, n° 22-16.616.

[11] Article L. 464-2, I, paragraph 1 of the French Commercial Code, second sentence (free translation) : "*The Competition Authority may order the parties concerned to put an end to the anti-competitive practices within a specified period or impose specific conditions. It may also accept commitments proposed by the undertakings or bodies and likely to put an end to its competition concerns that may constitute prohibited practices pursuant to Articles L. 420-1 to L. 420-2-2 and L. 420-5 or contrary to the measures adopted pursuant to Article L. 410-3.*"

The French Competition Authority introduces the first network visualization tool to explore its publications

On January 31, 2023, the French Competition Authority presented an interactive network graph tool on its website that identifies references made in French Competition Authority antitrust publications (such as decisions, opinions and interim measures published between 2009 2021) to its other publications. The visualization tool (available at: https://sen-codex.dev/) represents these references in the form of a graph interconnecting French Competition Authority's publications with one another.

The purpose of this visualization tool is to help users identify important French antitrust publications based on their impact on newer publications (number of citations) and the size of their online audience. Through various filters, users can set the tool so that the graph allows to first identify publications by their industry (*e.g.*, "Bank/ Insurance"), time period (between 2009 and 2021), or reference number (*e.g.*, "14-A-11"). To date, the database for this visualization tool includes 350 decisions, 276 opinions and 9 interim measures published by the FCA between 2009[12] and 2021. FCA merger control decisions are not included in the current dataset. Developed by the FCA's Digital Economy Unit[13] in partnership with CodeX "Computational Antitrust"[14] the tool is publicly accessible in open data on the FCA's GitHub, a code hosting platform.

In the future, the FCA Digital Economy Unit plans to further fine-tune the tool, for example by identifying other types of citations, including cases from the European Commission, and monitoring similar visualization tools which are or may become available in other jurisdictions. The network analysis could also include merger control publications, with the main objective of identifying the decisions that define new relevant markets.[15]

This visualization tool, as well as the regular infographics and videos presenting FCA investigations results published on the FCA's website, are part of the FCA's ongoing effort to raise awareness regarding its large scope of intervention and/or provide interactive tools to help grasp the cross-cutting nature of competition law and the benefits for all market stakeholders, notably end customers.

[12] 2009 is the first full year of the FCA's existence under its current governing structure.

[13] This specialized unit was created in September 2020 and is responsible for collecting in-depth knowledge on all aspects of the digital environment and collaborating with the FCA's inspections units to examine anticompetitive practices.

[14] The initiative is supported by the Stanford University Codex Center and aims at investigating how legal informatics can help automate antitrust proceedings and further improve antitrust analyses.

[15] *See* Y. Guthmann, A. Frumence, C. Hoogterp, *Deploying Network Analysis in Antitrust Law*, Stanford Computational Antitrust, volume 3, available at: https://www.autoritedelaconcurrence.fr/sites/default/files/2023-01/Stanford-Computational-Antitrust-en.pdf.

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