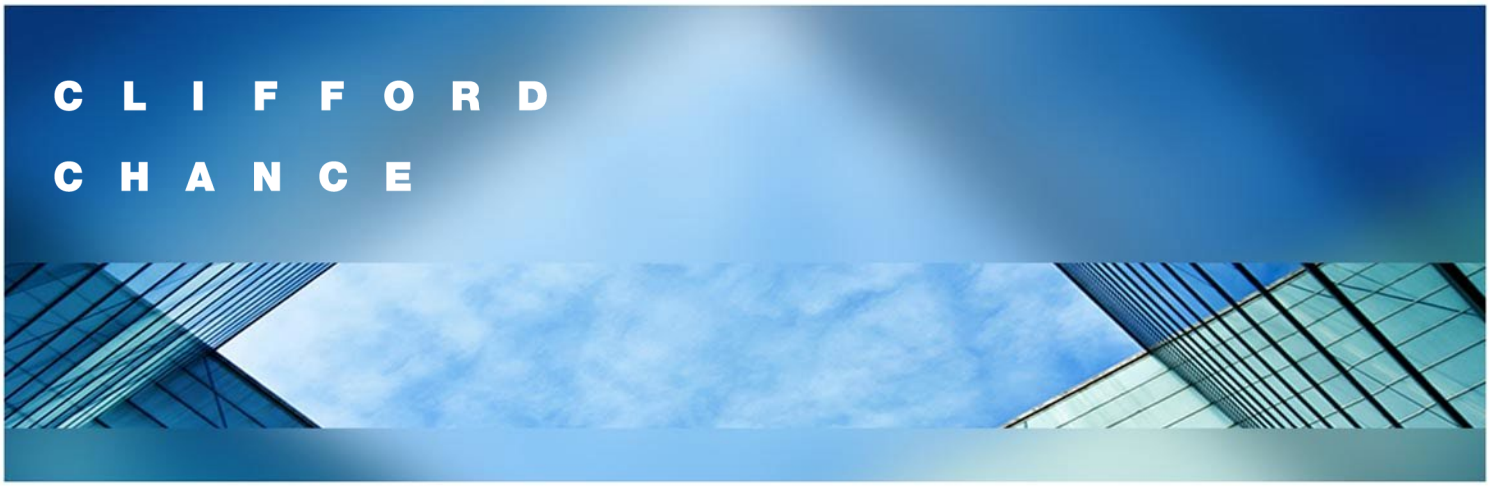

PARIS COURT OF APPEAL OVERTURNS DECISION ON ABUSIVE DISPARAGEMENT IN THE PHARMACEUTICAL SECTOR

In a rare and high-profile defeat for the French Competition Authority (**FCA**), the Paris Court of Appeal (**CoA**) has quashed an FCA decision which found that Novartis, Roche, and Genentech (**Parties**) abused a collective dominant position by disparaging one of their products, which competed with another, more lucrative drug that they also owned. For this alleged breach of Article 102 TFEU and L. 420-2 of the French commercial code, the Parties were fined EUR 444 million.

In its judgment of 16 February 2023 (**Judgment**), the CoA clarified the applicable framework for disparagement under Article 102 TFEU and held that, against that framework, the Parties had not abusively disparaged Avastin (a drug which was used, off-label, for the treatment of age-related macular degeneration (**AMD**)) in communications with healthcare professionals. It also found that the Parties had not unduly interfered with the French healthcare authority (**AFSSAPS**)'s initiatives to encourage the use of Avastin for the treatment of AMD by engaging in obstructive behaviour and disseminating alarmist or misleading information about the use of Avastin.

SUMMARY OF THE FCA'S DECISION

Factual background

At the time of the alleged infringements, Lucentis, a drug developed by Genentech, was the only medicine authorised in France for the treatment of AMD. It was marketed by Novartis, who was granted a licence by Genentech in exchange for royalties on the sales. Roche, as the parent company of Genentech, received profits from sales of Lucentis indirectly through Genentech.

Avastin, which was marketed by Roche pursuant to a separate licence granted by Genentech, was initially developed to counter the vascular development of cancerous tumours. It had been found by doctors to have positive effects on patients with AMD which had led to the development of an 'off-label' use (i.e.,

Key takeaways

- The CoA has quashed the FCA's recent decision n° 20-D-11, in which the FCA found that Novartis, Roche, and Genentech abused a collective dominant position.
- To define the relevant market, the CoA examined whether Lucentis and Avastin (used off-label) are 'substitutable in practice' from the standpoint of prescribing physicians, but also 'legally substitutable' based on the applicable legal and regulatory framework.
- The CoA held that communications which (i) contribute to a public interest debate, (ii) are sufficiently grounded in fact, and (iii) have an objective and neutral tone, do not constitute abusive disparagement under EU competition rules.
- The CoA set a high threshold for communications with healthcare authorities to be 'misleading' under Article 102 TFEU.
- The judgment highlights the difficulties with characterising disparagement as an abuse of dominance and is a clear setback for the FCA. It could also have wider implications for disparagement cases in the EU going forwards.

outside the indication for which it received its Marketing Authorisation (**MA**)) for the treatment of AMD.

The FCA found that, due to the cross-shareholdings[1] and contractual links between them, the Parties collectively held a dominant position in the French market for the treatment of AMD by anti-VEGF (*vascular endothelial growth factor*) drugs. The FCA noted in particular that the three pharmaceutical companies had a shared financial interest in maintaining sales of Lucentis, an expensive drug, rather than encouraging the development of the much cheaper Avastin for AMD treatment.

The FCA's finding of abuse and imposition of an EUR 444 million fine

In its decision n° 20-D-11 of 9 September 2020 (**Decision**), the FCA found that, between April 2008 and November 2013, the Parties abused their collectively dominant position on the market for the treatment of AMD by anti-VEGF by favouring sales of Lucentis over Avastin for the treatment of AMD.

The FCA found that:

(i) Novartis, through a global communication campaign, disparaged Avastin by unjustifiably exaggerating the risks of using it off-label for the treatment of AMD compared with the safety and efficacy of Lucentis (**Disparagement Abuse**).

(ii) All three Parties unduly interfered with initiatives of public agencies to discourage the use of Avastin as an alternative treatment for AMD. In particular, it found that (a) both Roche and Novartis shared biased, alarmist, and misleading communications with the AFSSAPS, (b) Roche unduly refused to provide the AFSSAPS with medical samples of Avastin, and (c) Genentech coordinated the Parties' messaging campaign with the AFSSAPS (**Undue Interference Abuses**).

THE JUDGMENT: KEY TAKEAWAYS

The CoA significantly narrowed the scope of the abuses in terms of duration and market definition

The CoA reduced the possible period of infringement identified in the Decision by almost three years. It found that prescriptions for Avastin should be considered as falling outside the relevant market from 31 December 2011 onwards, as the French 'Bertrand Law' (*loi Bertrand*), which entered into force on that date, effectively prohibited the off-label use of Avastin for the treatment of AMD, given that Lucentis was approved for that indication. Therefore, the CoA found that Avastin and Lucentis, whilst substitutable 'in practice', could no longer be considered 'legally substitutable'.

The CoA also narrowed the scope of relevant market in which the companies were found to be collectively dominant. It noted that, as Avastin is in principle only available in hospitals and not in pharmacies, any potential abuse must be limited to hospital prescriptions.

As a result of these two findings, the CoA dismissed a significant volume of evidence relied upon by the FCA to identify abusive conduct. The CoA then considered the FCA's assessment of the residual evidence as set out below.

[1] According to the Decision, Roche acquired a controlling stake in Genentech in 1990 and acquired the entire share capital of Genentech in March 2009. The Decision also states that Novartis held a non-controlling stake in Roche, owning 6.2% of the share capital of Roche and controlling 33.33% of the voting rights.

Clarity on the legal test for disparagement

The CoA has provided much welcome clarity on the legal tests to be applied to assess potential disparagement and/or undue interference abuses under Article 102 TFEU. In this case, the CoA found that the FCA had failed to meet these legal tests to the requisite standard.

The CoA articulated a three-stage test in relation to the Disparagement Abuse:

1. **Does the communication contribute to a public interest debate?**

   The CoA considered that the off-label use of drugs is in itself a question of general public health interest for several reasons, including the prior regulatory efforts to regulate the off-label use of medicines in France. In this context, the CoA noted that Novartis' communications during the relevant period, which focused on the safety of Avastin used off-label for the treatment of AMD as compared to Lucentis, and which were directed at healthcare professionals, contributed to a general public interest debate.

   The CoA also clarified that it was irrelevant whether the communication campaign was mainly driven by a commercial purpose.

2. **Is the communication sufficiently grounded in fact?**

   The CoA noted that Novartis' communications during the relevant period did not express a link between the differences between the two molecules and the possible adverse effects observed with Avastin as a 'certainty' but as a 'possibility'. Further, Novartis' communications were factually correct and not in contradiction with the results of the studies available at that time.

3. **Is the tone of the communication sufficiently cautious and measured, in light of the relevant public interest debate?**

   The CoA found that Novartis' statements during the relevant period were objective and made in a neutral tone. In particular, it found that the relevant statements were factually accurate – including that Lucentis was indicated for the treatment of AMD and Avastin was not – and referred to adverse events which, based on the studies available, appeared to be specific to Avastin. As a result, the CoA held that Novartis' communications could not be misleading or otherwise liable to exaggerate the risks of the off-label use of Avastin.

   The CoA was clear that the FCA cannot assess in the same way communications concerning (a) differences between a product with an MA and a product without (as in this case), and (b) differences between a generic and originator product, as generic medicines benefit from a regulatory presumption of effectiveness and safety.

   The CoA was less prescriptive regarding the Undue Interference Abuses as the scope of the relevant conduct was significantly reduced (see above). Nevertheless, it is clear from the Judgment that communications to public authorities, as decision makers, must be assessed as a separate abuse to general communications. The CoA emphasised that the AFSSAPS' dedicated internal teams were able to access all articles referred to in the communication to deepen their knowledge and were "*perfectly capable of critically reading the scientific studies under discussion and published*" ultimately concluding that none of the communications during the relevant period were misleading.

   The CoA therefore quashed the EUR 444 million fine imposed by the FCA on Novartis, Roche, and Genentech.

WIDER IMPLICATIONS OF THE JUDGMENT

The FCA's previous pharmaceutical disparagement cases, notably decisions n° 13-D-11 of 14 May 2013 (*Plavix*) and n° 17-D-25 of 20 December 2017 (*Fentanyl*), focused (mainly) on factually inaccurate communications designed to raise doubt as to the safety and efficacy of third-party generic products. The Decision had significantly expanded the scope of this theory of harm by finding that communications could be 'misleading' even if they were factually accurate – for example, if a party provided an unbalanced scientific view or if they employed a selective approach to the scientific studies relied upon in any communication.

Therefore, in overturning the FCA's findings, and by articulating a legal test for disparagement based on the general context, the factual support, and the tone of the communication – with no explicit requirement for communications to be 'balanced' or 'exhaustive' – the CoA may be indicating that the FCA needs to adopt a less expansive interpretation of disparagement going forward. Similarly, from the CoA's treatment of the Undue Interference Abuses, it is clear that the FCA will need to show – to a higher standard – that communications to public authorities are either alarmist or misleading, as such authorities are deemed to be able to cross-check and critically assess submissions.

Taking a step back, the CoA's judgment highlights the challenges in characterising disparagement as an abuse of dominance and could also indicate a broader direction of travel for future cases. For example, in *Hoffmann-La Roche* (C/179/16), the EU Court of Justice confirmed, in response to a request for a preliminary ruling from the Italian competition authority, that Roche and Novartis' communications concerning Avastin could be prosecuted as an Article 101 TFEU infringement. The CoA's rejection of similar underlying conduct as an Article 102 TFEU abuse suggests that competition authorities may generally encounter fewer obstacles when investigating disparagement cases as 'by object' Article 101 TFEU infringements.

The CoA's judgment is, without doubt, a significant development in the evolution of Article 102 TFEU case law for disparagement and undue interference, at a time where the European Commission has opened two separate investigations into alleged disparaging practices in the pharmaceutical sector (Vifor Pharma and Teva). That said, the CoA's Judgment should be treated with a degree of caution. First, it is still open for the FCA to appeal the Judgment to France's highest court (*Cour de Cassation*), though on points of law only. Second, the case law on disparagement in the pharmaceutical sector has largely been developed by the FCA and French courts, the decisions and rulings of which are not binding outside France and have specific French nuances (e.g., the risk aversion of healthcare professionals and hospital prescription practices) which may not be directly applicable to other jurisdictions and/or regulatory environments.

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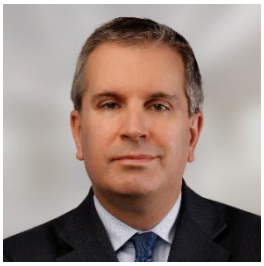

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