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When Criticising Competitor Products Becomes an Antitrust Problem: Disparagement in Competition Law


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Introduction

Disparagement in the pharmaceutical sector has in recent years come into the crosshairs of antitrust investigations in Europe. The French *Autorité de la Concurrence* ("**ADC**") was the initial driver, but the European Commission ("**EC**" or "**Commission**") and the UK Competition and Markets Authority ("**CMA**") have also more recently brought their own cases. The recent investigations into Vifor, following complaints by Pharmacosmos, which produces a rival intravenous iron deficiency treatment (by the EC and the CMA),[1,2] and Teva (by the EC)[3] were concerned with the dissemination of allegedly misleading information about competitors' products as an exclusionary strategy (and additionally in the case of Teva, an alleged misuse of the patent system to delay entry by generics) as an abuse of dominance under Article 102 of the Treaty on the Functioning of the European Union ("**TFEU**") (and its UK equivalent).

As a result of these cases, a somewhat clearer path is emerging as to where to draw the line between legitimate behaviour and conduct that raises antitrust risk. On the one hand, communications directed to competent authorities before the granting of a marketing authorisation ("**MA**") appear to be on the lower risk end of the spectrum as it is inherent in the authorities' functions to conduct expert evaluations of scientific evidence and advocacy and to reach a considered decision. On the other hand, the following are likely to be associated with significant antitrust risk: (1) disseminating false or misleading information to healthcare practitioners ("**HCPs**") and/or payers; and (2) communications calling into question the safety, efficacy or therapeutic equivalence of a product confirmed by a competent authority in the absence of new evidence. Moreover, the threshold of when information is false and misleading is low. In addition, determinations of whether regulatory rules, including product advertising rules, have been breached can be used as significant evidence by complainants or the competition authorities when investigating any allegations.

This chapter considers the emerging decisional practice in this area, and how the recent landmark cases *Teva* and *Vifor* fit into the analysis.

The National Cases

Prior to the recent EC investigations into Teva and Vifor, disparagement cases had been largely dealt with by national competition authorities, particularly the ADC, which has a long track record of cases relating to disparagement as an abuse of dominance, a significant proportion of which relate to the pharmaceutical sector.

To determine whether a company has abused its dominance by engaging in disparagement, the ADC used the following criteria: (1) the allegedly disparaging company holds a dominant position; (2) there is negative public communication about the competing product (the disparagement); (3) the disparagement has actual or potential effects; and (4) there is a causal link between the dominant position and the disparagement.

The ADC's earliest decisions on disparagement as an abuse of dominance in the pharmaceutical sector saw Sanofi[4] and Schering-Plough[5] fined €40.6 million and €15.3 million, respectively, for disparaging generic versions of their products Plavix (clopidogrel), an anti-platelet medicine, and Subutex (buprenorphine), an opioid addiction treatment product, in 2013.

Since then, the ADC has also made decisions finding abuses of dominance through disparagement against Janssen-Cilag[6] (in relation to its product Durogesic, an opioid analgesic with active ingredient fentanyl, for which it was ultimately fined €21 million)[7] and collectively Novartis, Roche and Genentech[8] (in relation to Novartis' product Lucentis and Roche's product Avastin, for which the ADC fined the companies €444 million, although this has since been overturned,[9] see below). In the case of Janssen-Cilag, the company had suggested that the MA process for generics would not be sufficient to protect patient health and safety by highlighting the simplified nature of the dossiers which only contain bioequivalence studies, and had also distorted the French Health Products Safety Agency ("**Agency**") warning by emphasising the risk of substituting an originator with a generic product, whereas the Agency warning had mentioned all types of substitution, including from generic to reference product and generic to generic product.[10] Further, although the Agency's warning listed specific risks associated with a change in treatment for some types of patients and mentioned that these risks could be eliminated by medical monitoring, Janssen-Cilag did not clarify the types of patients at risk or that monitoring could be used, instead suggesting that any treatment change could lead to a specific risk.[11] In the communications, Janssen-Cilag also stressed the allegedly unprecedented nature of the Agency's warning; however, this was a recent introduction to the Public Health Code.[12] In both the above cases, there was tension between the concepts of free speech and disparagement. Overturning the ADC's decision against Novartis, Roche and Genentech, the Paris Court of Appeal[13] confirmed that negative public communication will not constitute disparagement where it: (1) relates to a topic of public interest; (2) is sufficiently grounded in fact; and (3) is expressed in a cautious manner, with a neutral and objective tone. The case is currently pending an appeal before the French Supreme Court.[14]

Prior to the French case, the allegations of disparagement in relation to Novartis, Roche and Genentech were first the subject of an Italian competition authority ("**ICA**") decision[15] in 2014, which found that the companies had engaged in concerted practices prohibited under Article 101 TFEU to prevent the off-label use (not approved use) of the cheaper Avastin product for ophthalmological conditions, and had a common interest in increasing sales of the more expensive and later-developed Lucentis product, which had an MA for ophthalmological conditions (both products having been developed by Roche's subsidiary Genentech). On referral of the matter to the CJEU, the Court ruled that:

> "*an arrangement put in place between two undertakings marketing two competing products, which concerns the dissemination, in a context of scientific uncertainty, to the European Medicines Agency, healthcare professionals and the general public of misleading information relating to adverse reactions resulting from the use of one of those medicinal products for the treatment of diseases not covered by the marketing authorisation of that product, with a view to reducing the competitive pressure resulting from such use on the use of the other product, constitutes a restriction of competition 'by object' for the purposes of that provision.*"[16]

The ICA fined Novartis and Roche a combined €182.5 million,[17] noting that the companies had "*put in place a complex collusive strategy, which aimed at engendering among physicians and more in general, the public, fears about the safety of* [Avastin]",[18] including coordination on the modification of the Summary of Product Characteristics ("**SmPC**") of Avastin (which would allow a communication to be sent to healthcare professionals to highlight adverse side effects) and external communications strategy.[19]

Following the Court's decision, the ADC and Belgian competition authority ("**BCA**") issued their decisions finding that Novartis and Roche had abused the dominant position which they held together. The BCA ended up fining the companies €2.78 million,[20] although this is also pending an appeal. The Greek competition authority has also issued a statement of objections against the companies.[21] Outside of the EU, the Turkish competition authority[22] also fined the companies 278.5 million Turkish lira (€30.9 million); however, this was overturned by the Ankara Administrative Court.[23]

Vifor – EC and CMA Decisions

The first EC decision in relation to disparagement was its acceptance of commitments from Vifor Pharma in response to the EC's initial concerns of anticompetitive disparagement.

Following a complaint from Pharmacosmos (both to the EC and the CMA), the EC initiated a formal investigation into potential anticompetitive disparagement of iron medicine in June 2022.[24] Vifor was accused of disseminating misleading information about the safety of Pharmacosmos' treatment, Monofer, in an effort to promote its own product, Ferinject. In particular, the Commission identified two main "messages" that Vifor disseminated as part of its "*communication campaign capable of leading HCPs into believing that administering Monofer entails serious health risks and that Monofer has a worse risk profile compared to Ferinject*":[25]

1) that Monofer was a "dextran", "dextran-derived" or "dextran-based", playing on the association of "*historic negative safety connotations of HMW IV iron dextrans (which are no longer marketed in Europe)*"[26], even though Monofer was in fact based on the chemical composition ferric derisomaltose; and
2) that Monofer had more hypersensitivity reactions than Ferinject, which the Commission found was "*based on inaccurate and/or incomplete information*"[27], as "*Vifor did not rely on sufficiently robust scientific evidence apt to substantiate its claim*".[28] The Commission noted that this message did not demonstrate the relevant healthcare authorities' key findings (especially the European Medicines Authority) as set out in the SmPCs for Monofer and Ferinject.

The Commission pointed out Vifor's misleading communication campaign and, in April 2024, Vifor proposed a series of commitments aimed at addressing these concerns which were accepted by the Commission in July 2024. These included: (i) initiating a clarifying multi-channel communication campaign to reassure healthcare professionals of Monofer's safety; (ii) clearly stating that there is no evidence of increased risk of hypersensitivity reactions compared to Ferinject; (iii) pledging to avoid making promotional claims not based on Monofer's SmPC for the next decade; and (iv) enforcing strict compliance measures, including annual staff training on competition regulations. A monitoring trustee was designated to oversee Vifor's compliance with all the commitments for the next 10 years.

Concurrent with the EC investigation, the UK's CMA initiated in January 2024 its first standalone disparagement investigation under Chapter II of the Competition Act focusing on Vifor's[29] alleged misleading claims about Monofer in the UK, in particular the same claims as outlined above and investigated by the EC.[30] Vifor has also proposed commitments and on 10 December 2024, the CMA published a consultation expressing its intention to accept Vifor's commitments[31] and inviting third-party comments before making a final decision. Apart from an additional payment of £23 million to the National Health Service, the commitments reflected those accepted by the Commission.

The notice of intention to accept the proposed commitments noted that the conduct in question had been "*the subject of a number of adverse findings by the PMCPA and its Appeal Board in the period 2008 to 2024*",[32] referencing decisions by the Prescription Medicines Code of Practice Authority ("**PMCPA**"), which administers the voluntary UK industry code, the ABPI Code of Practice for the Pharmaceutical Industry (ABPI being the Association of the British Pharmaceutical Industry). The notice further noted the ABPI Code requirements that, *inter alia*, "*[i]nformation, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly*" and that promotional material may only use a comparison if it is not misleading.[33] Importantly, underlying PMCPA papers are potentially recoverable by the CMA in an investigation.

The consultation closed in January 2025, with a decision anticipated soon. If the proposed commitments are formally accepted, the CMA will close the investigation without determining whether the suspected conduct violated the Chapter II prohibition and the commitments will become effective upon acceptance.

Teva – EC Decision

On 31 October 2024, the EC issued its decision[34] finding that Teva had abused its dominance in several Member States (Belgium, the Czech Republic, Germany, Italy, the Netherlands, Poland and Spain) in relation to its product Copaxone, whose active ingredient is glatiramer acetate ("**GA**"), and is used to treat multiple sclerosis. The EC found that Teva had engaged in two types of anticompetitive practices:

- a systematic disparagement campaign; and
- a misuse of patent procedures.

The decision is consistent with the draft Article 102 Guidelines[35] and restates that it is legitimate for a dominant company to engage in a strategy to deal with competition from generic products as long as it does not depart from competition on the merits.

While the EC determined that these anticompetitive practices were complementary, it also found that the patent and disparagement abuses were distinct which, in line with the position in *Vifor*, confirms that disparagement can be a free-standing breach of Article 102 TFEU.

The EC fined Teva €462.2 million, which was the first time the EC had imposed a fine for either practice.[36]

Competition on the merits

Consistent with the EC's draft Article 102 Guidelines, both abuses were framed as departing from competition on the merits and being capable of hindering and/or delaying market entry.

The patent abuse is not considered in detail in this chapter focused on disparagement. However, the Commission found that the patent abuse was part of a deliberate strategy to delay generic entry which underlined Teva's objective intent. This was also relevant for the disparagement analysis, but the Commission made it clear that disparagement was a free-standing abuse.

In respect of the disparagement abuse, the Commission found three problematic prongs to the communications which went to questioning the basis for granting the generic MA and the therapeutic equivalence of the generic.

The EC found that Teva's communication campaign included two phases. In the first phase, Teva tried to convince MA bodies to raise the bar for granting an MA to competing GA products. In parallel, Teva was systematically challenging MAs. Both these conducts allegedly resulted in delays to the granting of the MAs. In the second phase, Teva's campaign was market-facing and focused on payers and HCPs. The Commission found that the campaign in the second phase exploited the conservative nature of HCPs, who tend to avoid prescribing medicines surrounded by controversy, and the limited capacity of payers to undertake detailed scientific assessments.

The Commission specifically found that only the conduct of the second, market-facing campaign was abusive. The remaining conduct before the MA bodies was simply "*relevant context*" and which "*may have laid the ground work for making these market players [i.e. HCPs and payers] more receptive to Teva's messages*".

Interestingly, the Commission accepted that it was legitimate for Teva to discuss the automatic substitution (i.e., whether a pharmacist can freely dispense Synthon GA, the generic product, to a patient with a Copaxone prescription, or *vice versa*) but it found that those legitimate discussions did not exonerate the misleading conduct.

The Commission rejected Teva's arguments that its communications were legitimate scientific discourse or protected by freedom of speech. The Commission found that there is no room for scientific debate about essential properties (safety, efficacy, therapeutic equivalence) confirmed by a competent authority issuing an MA, in the absence of new evidence. It also dismissed the comparison to the judgment of the Paris Court of Appeal in *Avastin* on the basis that: (1) in that case the discussion related to off-label use; (2) Teva's communications were not a genuine attempt to engage in scientific discourse; and (3) Teva did not have evidence for its allegations.

Importance of internal documents

Internal documents were an important feature of the decision. The Commission referred to them to conclude that the objective of Teva's conduct was "*apparent*". Indeed, the Commission quoted extensively from contemporaneous documents. The Commission specifically referred to reminders in documents to obtain antitrust advice and found that they echo "*concerns expressed on several other occasions that Teva's conduct involved serious perils and that it should be kept covert*". This is an important reminder of the role of internal documents in antitrust investigations.

Appeal

Teva has appealed the EC's decision,[37] arguing that the EC incorrectly assessed the market definition and therefore incorrectly found that Teva had a dominant position. The appeal also states, *inter alia*, that Teva's patent filings were legitimate, and that the EC had "*misconstrued the relevant legal and factual context of the EPO system*", and further argues that the EC failed to demonstrate that the allegedly disparaging communications contained "*objectively misleading information likely to discredit … competitors*".[38]

Endnotes

1 *Vifor (IV iron products)* (Case AT.40577).

2 Investigation into suspected anti-competitive conduct by Vifor Pharma in relation to intravenous iron treatments (Case number 51377).

3 *Teva Copaxone* (Case AT.40588).

4 Decision 13-D-11 of 14 May 2013 relating to practices implemented in the pharmaceutical sector.

5 Decision 13-D-21 of 18 December 2013 regarding practices implemented on the French market for high-dosage Buprenorphine sold in private practices.

6 Decision 17-D-25 of 20 December 2017 relating to practices implemented in the fentanyl transdermal device sector.

7 Judgment of 11 July 2019 of the Paris Court of Appeal.

8 Decision 20-D-11 of 9 September 2020 relating to practices implemented in the sector of treatment of age-related macular degeneration (AMD).

9 Judgment of the Paris Court of Appeal of 16 February 2023.

10 ADC Press Release, "*L'Autorité de la concurrence sanctionne le laboratoire Janssen-Cilag et sa maison-mère Johnson & Johnson à hauteur de 25 millions d'euros pour avoir empêché puis limité le développement des médicaments génériques de Durogesic, son médicament princeps*", 20 December 2017.

11 *Ibid.*

12 *Ibid.*

13 Judgment of the Paris Court of Appeal of 16 February 2023.

14 Decision 20-D-11 of 9 September 2020 relating to practices implemented in the sector of treatment of age-related macular degeneration (AMD).

15 *Roche/Novartis*, Case I760, 27 February 2014.

16 Judgment of 23 January 2018, *Hoffman-La Roche* C-179/16, ECLI:EU:C:2018:25.

17 Judgment of the Italian Council of State, of 15 July 2019, *Roche/Novartis*, No. 4990/2019.

18 ICA Press Release, I760 – Drugs: Antitrust applies sanctions to Roche and Novartis for a sign that has conditioned sales of main products intended for the care of sight, Avastin and Lucentis. With fines of more than €180 million.

19 Judgement of the Italian Council of State, of 15 July 2019, *Roche/ Novartis*, No. 4990/2019.

20 BCA, n° 23-PK-02, Test Achats c/ Novartis et Roche, 23 January 2023; BCA Press Release, The Belgian Competition Authority imposes a fine of EUR 2,782,808 on Novartis for abuse of dominant position.

21 Greek competition authority press release, 29 August 2024, Statement of Objections concerning the *ex officio* investigation in the markets for the production and supply of pharmaceutical products for the treatment of ophthalmological diseases.

22 Turkish Competition Authority, Decision of 21 January 2021 in Case No. 21-04/52-21.

23 Ankara 13th Administrative Court, Decisions 2022/2274 E and 2022/2912 K, 30 December 2022.

24 *Vifor (IV iron products)* (Case AT.40577).

25 *Vifor (IV iron products)* (Case AT.40577).

26 *Vifor (IV iron products)* (Case AT.40577).

27 *Vifor (IV iron products)* (Case AT.40577).

28 *Vifor (IV iron products)* (Case AT.40577).

29 Investigation into suspected anti-competitive conduct by Vifor Pharma in relation to intravenous iron treatments (Case number 51377).

30 CMA, Notice of intention to accept commitments offered by Vifor in relation to the supply of high-dose intravenous iron (Case number 51377).

31 CMA, Consultation on proposed commitments in respect of Vifor Pharma's supply of intravenous iron (Case number 51377).

32 CMA, Notice of intention to accept commitments offered by Vifor in relation to the supply of high-dose intravenous iron (Case number 51377).

33 CMA, Notice of intention to accept commitments offered by Vifor in relation to the supply of high-dose intravenous iron (Case number 51377); 2021 ABPI Code, Clause 6(1); 2021 ABPI Code, Clause 14.1.

34 Decision C(2024) 7448 of 31 October 202 in Case AT.40588 *Teva Copaxone*.

35 Draft available at: https://competition-policy.ec.europa.eu/public-consultations/2024-article-102-guidelines_en.

36 EC, Press Release of 31 October 2024, Commission fines Teva €462.6 million over misuse of the patent system and disparagement to delay rival multiple sclerosis medicine.

37 Action brought on 15 January 2025 in Case T-19/25 (C/2025/1126), OJ C/2025/1126.

38 Action brought on 15 January 2025 in Case T-19/25 (C/2025/1126), OJ C/2025/1126.

John Schmidt leads the UK Competition team in London. He has over 25 years of experience dealing with competition authorities and courts in the UK and the EU. He regularly advises on complex competition conduct issues, investigations, litigation and merger cases, with a particular sector focus on life sciences, consumer goods and TMT. He is dual-qualified in the UK and Germany with full rights of audience before the European Court of Justice.

John has extensive experience advising pharmaceutical and medical device companies on pricing matters, including a number of reverse payment patent settlement cases both at the EU and UK level, as well as investigations into excessive pricing and restrictive agreements in the pharmaceutical sector. He also advises on parallel trade and supply chain design, as well as challenging public procurement tenders on behalf of his clients.

Within the retail and consumer goods space, John regularly advises clients on pricing and distribution issues as well as online strategies. He has represented retailers and suppliers in UK vertical pricing investigations.

In merger control, John obtains merger clearances from the CMA and the European Commission and coordinates strategy for multijurisdictional merger clearances in the rest of the world. This increasingly also involves obtaining Foreign Direct Investment clearances in the UK, various EU Member States and worldwide.

John has in-depth experience representing clients on complex competition litigation and has also acted in follow-on damages actions before the Competition Appeal Tribunal. He is currently representing the claimants in respect of Heineken's pan-European trucks fleet for damages arising out of the EU trucks cartel as well as other drinks and consumer goods companies in large individual claims in the Dutch and UK courts.

John has been consistently ranked as a leading lawyer by *Chambers UK* ("very knowledgeable, easy to work with and adept at explaining complicated issues"), *Chambers Europe* and *Chambers Global*, as well as *The Legal 500*.

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In the life sciences space, Zeno has taken a leading role in some of the industry's most significant and complex transactions, including representing Pfizer in its $43 billion acquisition of Seagen and Novo Nordisk in its $11 billion acquisition of fill-finish sites from Novo Holdings (as part of the latter's acquisition Catalent). He also regularly acts on significant transactions before the European Commission and the CMA and advises on some of the most complex transactional, regulatory and compliance issues for clients such as Novo Nordisk, Pfizer, Boston Scientific, Bristol Myers Squibb and Curium.

In relation to antitrust litigation, Zeno has experience handling competition damages litigation in various jurisdictions, including England & Wales and the Netherlands.

He maintains an active *pro bono* practice and regularly advises charities and NGOs on a wide range of legal and strategic matters.

Zeno is ranked as a leading lawyer in *The Legal 500* and in 2025 was nominated as a "Rising Star" in the LMG Life Sciences Awards.

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