EU and UK Consider First Stand-Alone Disparagement Cases

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The development of case law on disparagement has, to date, been driven mainly by the French competition authority, or has been addressed under consumer protection or other national laws. The European Commission's (EC's) and the UK Competition and Markets Authority's (CMA's) ongoing investigations of Vifor Pharma present these agencies' first pure disparagement abuse cases.

These investigations suggest that companies will need to be mindful that both the EC and the CMA may investigate competitor complaints of disparagement if there is a concern that sales of competing pharmaceuticals are materially affected in the EEA or the UK. Also, following the interest of these agencies, competition authorities in member states will likely be encouraged to investigate potential disparagement complaints with a sufficiently relevant local impact.

Vifor recently submitted commitments to address the EC's concerns. If the EC decides to accept the commitments, it will not need to prepare and publish a reasoned infringement decision interpreting the boundaries of the abuse of dominance doctrine in relation to companies pursuing a disparaging strategy. Moreover, European courts will not have the opportunity to confirm or comment on the novel theory of harm — at least beyond the 2018 ruling by the European Court of Justice in *Hoffman-La Roche* that coordination between competing pharmaceutical companies to communicate misleading information (which indicated off-label use of a product was less safe than the on-label use of another product) amounted to a restriction of competition. Reminiscent of the developments relating to allegations of excessive pricing by Aspen Pharmacare, an EC commitment decision may be the ultimate outcome. Whether the CMA, meanwhile, will also opt to consider the matter on the basis of commitments remains to be seen.

Background

In June 2022, the EC opened an investigation of Vifor, a global pharmaceutical company, regarding a suspected anticompetitive disparagement campaign. The EC is investigating allegations that Vifor spread misleading information about the closest competing product in Europe on the market for the treatment of iron deficiency, Pharmacosmos' Monofer, following a complaint by Pharmacosmos. Commenting on the investigation, the EC's commissioner for competition, Margrethe Vestager, said, "The dissemination of misleading information regarding the safety of [the competitor's] iron deficiency treatment […] may have delayed its uptake."

The EC's investigation of Vifor constitutes its first pure disparagement abuse case. While the commission has an ongoing case against pharmaceutical company Teva in relation to similar conduct, in that investigation, the EC is examining both the misuse of the patent system and disparagement of a rival multiple sclerosis medicine in order to hinder competition to Teva's popular medicine Copaxone.

In fact, in the EU, only the French competition authority has an established line of cases on disparagement as a stand-alone abuse of dominance. The French authority has imposed fines on pharmaceutical companies in three separate cases that concern misleading health care professionals and health care authorities about risks related to the safety of prescribing competing generics. The national authority determined the companies' behavior intended to hinder or delay the entry of generics to the market. The French Supreme Court confirmed one of these disparagement decisions, while the French Court of Appeal overturned another.

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In early 2024, the CMA also opened an investigation into Vifor in relation to the same concerns as in the EC's case: The CMA is investigating whether Vifor's misleading claims regarding the safety and effectiveness of Monofer amounted to an abuse of dominant position in the supply of iron deficiency treatments for patients of the National Health Service in the UK. The CMA's case follows several complaints made by Pharmacosmos about Vifor to the UK Prescription Medicines Code of Practice Authority (PMCPA), which administers the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry (a code that sets standards for the promotion of prescription medicines to health professionals and other relevant decision-makers in the UK). The PMCPA panel found in 2016 that Vifor had made disparaging statements about the safety of Monofer, and the panel imposed sanctions for breach of the ABPI code.

Vifor has proposed the following commitments, which would be overseen by a monitoring trustee, to address the EC's concerns over the alleged disparagement:

- Vifor will launch a comprehensive and multichannel communication campaign (via email and mail, in-person, on its website and in leading medical journals) to rectify and undo the effects of the potentially misleading messages the company previously disseminated regarding the safety of Monofer.
- For a period of 10 years, Vifor will not engage in external promotional and medical communications about Monofer's safety profile using information that is neither based on Monofer's Summary of Product Characteristics nor derived from randomised, controlled clinical head-to-head trials.
- Vifor will implement a number of measures and safeguards to ensure compliance with the EC competition regime, including (i) internal mechanisms to ensure that all relevant external promotional and medical communications and internal training materials align with the commitments prior to use of the materials, and (ii) annual internal trainings of staff and a system to certify compliance.

Interested third parties have until mid-May 2024 to share comments with the EC on the proposed commitments. If the commission accepts the commitments, its decision will not reach a final conclusion on whether there has been an infringement but will merely find that there are no longer grounds for action.

Vifor would remain under investigation in a parallel UK case, although Vifor could similarly aim to settle the CMA's case with commitments.

Professional support lawyer **Elizabeth Malik** contributed to this article.