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A Rising EU Antitrust Enforcement Tide: 'Exclusionary Disparagement' of Pharma Rivals

November 20, 2024

On October 31, 2024, the European Commission (EC) **fined Teva 462.6 million euros (US$503 million)** for abusing its dominant position to delay competition to Copaxone (glatiramer acetate), its blockbuster multiple sclerosis pharmaceutical. This groundbreaking decision confirms that European Union antitrust enforcement in the pharmaceutical sector remains a priority and continues to attract novel theories of harm, and that infringements draw serious financial exposure. It also raises important questions as to the boundary between legitimate and illegal means of competition in the pharma sector.

The abuse of a dominant position that may affect trade within the EU and prevent or restrict competition is prohibited under Article 102 of the Treaty on the Functioning of the European Union. In the *Teva* case, the EC objected to two practices it found had the overall goal of delaying competition and artificially prolonging the exclusivity of Teva's Copaxone, thereby hindering market entry and uptake of rival glatiramer acetate treatments in seven EU Member States.

- First, it found that Teva had "artificially" extended patent protection for Copaxone. We address the elements and context of this practice **in a separate alert**.
- Second, it found that Teva had engaged in exclusionary disparagement of a competing glatiramer acetate. We analyse that practice in this alert.

The fine imposed in this case is the highest yet in the pharmaceutical sector, surpassing the **330.1 million-euro (US$359 million)** penalty levied on Servier 10 years back. Teva confirmed that it will seek an appeal against the decision before the EU's General Court.

Exclusionary disparagement

This is the first time that the EC has held a pharma company liable for "abuse of a dominant position" because it had engaged in an "exclusionary disparagement" campaign targeting a rival.

The EC found that Teva had conducted a disparagement "campaign" targeting rival multiple sclerosis products. The campaign was directed at key stakeholders (e.g., physicians and national decision-makers for pricing and reimbursement of medicines) influencing market access and pricing of medicines, and was designed to cast doubts about the safety, efficacy and therapeutic equivalence – with Copaxone – of a rival glatiramer acetate treatment. That rival product had been assessed for regulatory approval and obtained marketing authorization. The EC found that Teva's objective was to slow down, or block, the entry of its rival.

The rising tide

Antitrust enforcement against allegedly "exclusionary disparagement" is becoming a more common feature at the EC and Member State levels (applying EU antitrust law and national law modelled on EU law), as authorities scrutinise communications by pharmaceutical companies that may discredit competitors and their products. It is now more than a decade since the French Competition Authority fined **Sanofi** (incidentally, following a complaint by Teva) 40.6 million euros (US$44 million) and **Schering-**

Plough 15.3 million euros (US$16 million) on grounds of abuse of dominance consisting of disparagement of generic versions of, in Sanofi's case, Plavix (clopidogrel) and, in the case of Schering-Plough, Subutex (buprenorphine). Decisional practice and case law has evolved since that time, but the distinction between abusive disparagement and healthy debate or marketing practices remains contentious.

Disparagement or free speech?

A series of cases involving Roche, Novartis and Genentec illustrates the thorny nature of disparagement claims. Novartis markets Lucentis (ranibizumab) in the EU, a treatment for wet age-related macular degeneration (wet AMD), that was developed by Roche's Genentec and licensed to Novartis. Roche markets Avastin (bevacizumab), a blockbuster cancer treatment also developed by Genentec, which is not authorized for the treatment of wet AMD but is used off label as a low-cost option to treatments like Lucentis. Notwithstanding that Avastin was not approved for wet AMD, the Italian Competition Authority adopted a decision finding that Roche's and Novartis' Italian subsidiaries had colluded to reduce competition from that product, when used in wet AMD, vis-à-vis Lucentis. They had allegedly conspired to "**artificially**" differentiate the products in external communications around risks associated with the off-label use. The companies were fined 182 million euros (US$198 million) and, after exhausting appeals, the decision was confirmed.

As part of the appeals process, the Italian Council of State requested guidance from the Court of Justice of the European Union (CJEU), specifically on whether an antitrust violation could arise from an arrangement between the two firms concerning communications on adverse reactions resulting from the off-label use of Avastin. The CJEU confirmed (para. 95) that this might indeed be so: "**the dissemination, in a context of scientific uncertainty, to the EMA, healthcare professionals and the general public of misleading [safety] information [concerning off-label use], with a view to reducing the competitive pressure resulting from such use on the use of the other medicinal product**" restricted competition. In that case, the restriction resulted from contacts between two firms communicating "**misleading**" safety information "**in a context of scientific uncertainty**", rather than from one dominant firm acting unilaterally.

However, relying on the CJEU's judgment, the competition authorities of France and Belgium later found that Roche and Novartis collectively held a dominant position, this position had been abused, and fines were imposed – in France 444 million euros (US$482 million), and in Belgium 2.8 million euros (US$3 million). France labelled the conduct a "**disparaging**" practice "**unjustifiably exaggerating the risks associated with the 'off-label' use**", and Belgium noted that ophthalmologists, hospitals and regulators had been "**misled**" by continued warnings "**about the risks of an off-label use of Avastin even after the publication of studies that no longer allowed to do so without qualification or reference to the scientific uncertainty created by these studies**".

The French decision was challenged on appeal, and the Paris Court of Appeal concluded that the communications on safety did not attract antitrust liability. The Paris Court recognised that, at the relevant time, there was scientific uncertainty about the use of off-label Avastin for wet AMD. Communications that were sufficiently grounded in fact and made in an objective and neutral tone did not constitute abusive "disparagement" under antitrust rules, but were an exercise of freedom of speech contributing to a legitimate debate. The Paris Court also noted that communications concerning differences between an authorized originator product and an authorized generic (which are legally presumed to be as safe and efficacious) should not be assessed against the same standard as communications concerning a product authorized for use in an indication and a product used off label in that indication. In recognising the legitimate need for open scientific debate (great minds do not always think alike!), the approach of the Paris Court was different – and more balanced – than the approach in Belgium (appeal pending) and Italy to the communications, even accounting for factual differences in the different countries.

First EC decision

Earlier this year, the EC concluded its investigation into ***Vifor Pharma***, which was resolved by a commitment decision. The EC suspected that Vifor had pursued a disparagement campaign targeting Pharmacosmos' product Monofer (ferric derisomaltose), which was considered the closest competitor of Vifor's intravenous iron deficiency treatment Ferinject (ferric carboxymaltose). Vifor's communications targeted mainly healthcare professionals and were apparently aimed at protecting Ferinject from competition with Monofer. The EC was concerned that it could have unduly hindered the update of Monofer in nine Member States.

The EC did not make a definitive finding on liability in this case and imposed no fine, but its decision imposed binding commitments on Vifor (and Vifor will be liable to pay a fine if the EC finds that it has breached these commitments). There are three elements to the commitments, which remain in effect for 10 years. First, Vifor must launch a "comprehensive and multi-channel" communication campaign to "rectify and undo the effects" of its earlier messages about the safety of Monofer. Second, it must not engage in external promotional and medical communications about Monofer's safety profile using information that is neither based on the product's label nor derived from clinical trials specifically designed to compare Ferinject and Monofer across the entire European Economic Area. Finally, Vifor must take several steps to ensure compliance with the commitments, which also will be monitored by an independent trustee.

Comment

The appeals process against the EC's decision that Teva has said it will launch will last several years (for instance, in the *Servier* case, the **final appeal** was decided 10 years after the EC's decision). That will surely measure whether the EC's assessment of Teva's market position – and specifically, whether it was right to conclude that it holds a "dominant" position – was correct. The principally more important question, especially to other pharma companies, is whether and when "exclusionary disparagement" amounts to abuse of a dominant position.

In this regard, it is important to recall that **case law unambiguously holds that not every exclusionary effect is detrimental to competition**, even those caused by the conduct of a dominant firm. Normal competition may indeed lead to departure from the market or the marginalisation of rivals. To establish that conduct is "abusive", the EC must show that the dominant firm's conduct actually or potentially restricts competition by excluding firms equally efficient to the dominant, or by hindering their growth, **and** that the conduct involves methods other than those which are part of "competition on the merits" – or normal competition – between firms.

The distinction between communications "on the merits" and abusive "disparagement" is often delicately balanced, and, as the overview above illustrates, the consequences of getting the balance wrong can have dire effects. In the Avastin/Lucentis scenario, the Paris Court of Appeal distinguished between the exercise of free speech by measured, sufficiently grounded communications and disparagement designed to exclude a rival. In this regard, the available evidence – and the robustness of that evidence – matters. This explains the distinction, in that case, between comparisons involving authorized medicines and those used off label. The commitments in the Vifor case embody the same idea: Comparisons there would be based on the label of the rival medicine or broad-based clinical trials conducted with a relevant purpose. The cardinal rule, according to the CJEU, is to avoid "**misleading**" communications, directed at decision-makers influencing a product's uptake and designed for reducing competitive pressure from rivals.

The evolving antitrust enforcement against exclusionary disparagement adds yet another layer of considerations that should be weighed when shaping medical communications campaigns in Europe. This includes communications aimed at healthcare professionals, but also professionals involved in reimbursement and pricing – and even the public at large. The enforcement practice discussed in this alert addresses particular circumstances of the pharmaceutical industry, but competition authorities may well, as they have done in other settings, identify similar concerns in other industries.

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