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Stiff EU Antitrust Fine for 'Misuse' of Patent System Delaying Rival Pharma Entry

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

The 'divisionals game'

This is the first time that the EC identified as an "abuse of a dominant position" a pharma company's "misuse" of European Patent Office (EPO) rules and procedures on divisional patents. The EC referred to Teva's strategy as the "divisionals game".

In short, Teva's basic patent for glatiramer acetate expired in 2015. The company then filed several serial divisional patent applications focused on the manufacturing process and the dosing regimen of glatiramer acetate. The EC found that these created a web of secondary patents, protecting Copaxone, which were challenged by rivals. During the EPO's review of the applications, Teva started enforcing these patents against its rivals to obtain interim injunctions. However, when patents seemed likely to be revoked, Teva withdrew the applications. The EC found that this was done to avoid a formal invalidity ruling, which would have had knock-on effects on the validity of other divisional patents. Eventually though, all of the divisional patents were annulled.

The EC found that Teva's "divisionals game" was illegal and abusive because it allowed Teva to artificially prolong legal uncertainty over its patents. It forced rivals to repeatedly start new lengthy legal challenges and potentially hindered rivals' entry.

Prior EC cases

Although this is the first time that the EC has found that a divisional patent strategy was abusive – and fined the patent applicant – the allegedly illegal conduct bears similarity to practices that the EC has intervened against in the past. Two prior cases are particularly relevant.

Misleading of patent offices

In *AstraZeneca*, the EC fined AstraZeneca 60 million euros (US$65 million) for abusing a dominant position involving its Losec (omeprazole) product, used in the treatment of gastrointestinal acid-related conditions. The EC found that AstraZeneca had provided misleading information to six national patent offices, and thereby gained extended patent protection for Losec through so-called supplementary protection certificates (SPCs). (It also was found to have misused regulatory procedures by selectively deregistering marketing authorizations, with the intent of blocking or delaying generic entry by parallel traders.) In the granting of the SPCs, the patent offices had relied on the information provided by AstraZeneca and had not, as in the case of patent applications, assessed whether new inventions were involved. The SPCs allowed AstraZeneca to block or delay generic omeprazole entrants.

The Court of Justice of the European Union (CJEU) ultimately upheld the EC's finding that the misleading practice involved abusive conduct. The CJEU recalled established case law holding that a dominant firm must not "**eliminate a competitor**" and thereby strengthen its position by using methods other than those which come within the scope of "**competition on the merits**". The CJEU concluded that the company had "**deliberately attempted to mislead the patent offices and judicial authorities in order to keep for as long as possible its monopoly**" by notifying the patent offices of "**highly misleading representations and by a manifest lack of transparency**", and that this conduct "**fell outside the scope of competition on the merits**" (para. 93).

The CJEU also noted that assessment of whether representations made to public authorities for purposes of improperly obtaining exclusive rights are misleading must be made on specific facts and may vary according to the circumstances of each case. It could not be inferred, however, that any patent application made by a dominant firm which is rejected because it does not satisfy the patentability criteria automatically gives rise to antitrust liability.

Misuse of the patent system

In *Almirall/Boehringer*, the EC investigated, as in *AstraZeneca*, whether Boehringer Ingelheim had secured patents by providing misleading information to the EPO. Almirall had been granted patent protection in relation to aclidinium bromide, which is used in the treatment of chronic obstructive pulmonary disease (COPD). Shortly after a conference presentation of pre-clinical work involving aclidinium bromide, Boehringer, the market leader in the treatment of COPD, filed three patent applications related to combination treatments involving aclidinium bromide and other agents, and later also filed several divisional patents. Almirall objected to the applications and brought court challenges, where Boehringer was held to have provided false information regarding one patent application. After Almirall complained to the EC that Boehringer had abused a dominant position by filing for patents about the new treatments that lacked merit, the EC launched an investigation concerning the alleged misuse of the patent system to exclude potential COPD competition.

The EC's investigation was ultimately closed, after the parties – at the EC's recommendation – reached a bilateral settlement agreement. That settlement removed the alleged blocking positions and ended the pending litigation between the parties, so that Almirall was free to launch its own combination medicines after obtaining marketing authorisation from the competent bodies. On that basis, the EC concluded that it no longer needed to pursue the investigation.

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 patent holders, is whether and when a "divisionals game" 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.

Given the inherently exclusionary properties of patents, a critical question for the courts will be to decide whether the practices that the EC, for the first time, found objectional form part of normal competition in the pharmaceutical industry. Patent applications and strategies to extend patent protection certainly are

commonplace – and, under existing case law, seeking patents that are later rejected does not, in itself, attract liability. Companies need not be infallible in their dealings with regulatory authorities. Although there are parallels between the *Teva*, *AstraZeneca* and *Almirall/Boehringer* cases – all three involved strategies to secure extended exclusivity that allegedly raised entry barriers for cheaper rival products – there also are principled differences. AstraZeneca deliberately (and Boehringer apparently) made misleading representations to patent authorities with a view to disadvantaging competitors. Teva used the patent system to its advantage, allegedly with the intent of delaying a rival's entry, but the materials available as of today do not suggest that it acted fraudulently vis-à-vis the EPO.

Thus, the EC's theory of harm in *Teva* appears to extend the potential for antitrust liability beyond the *AstraZeneca* case law. The boundary between normal and illegal conduct will not be clear until the General Court has ruled on Teva's appeal. In the meantime, firms will do well to analyse strategies for patent protection carefully to reduce risk under EC competition law. This is especially important for firms that may hold dominant positions and expect challenges from generic or other entrants with cheaper alternatives.

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