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QUICK LINKS

European Commission fines Teva €462.6 million over patent system misuse and competitor disparagement

On 31 October 2024, the European Commission announced that it had fined Teva €462.6 million for abusing its dominant position to delay the market entry of rival medicines to treat multiple sclerosis. This is the first ever fine imposed by the Commission in relation to divisional patent applications and competitor disparagement practices.

Background

Teva is a global pharmaceutical company and is best known for developing and marketing Copaxone, a prescription medicine widely used for the treatment of relapsing multiple sclerosis. Copaxone contains the active pharmaceutical ingredient glatiramer acetate, over which Teva held a basic patent until 2015.

In October 2019 and January 2020, the Commission carried out unannounced inspections at the premises of several Teva subsidiaries in the EU. In March 2021, the Commission launched a formal abuse of dominance investigation against Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals Europe BV, before issuing its Statement of Objections in October 2022.

The Commission's findings

The Commission found Teva guilty of abusing a dominant position in the markets for glatiramer acetate in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain. In the Commission's view, Teva engaged in two types of abusive conduct: a patent strategy aimed at artificially extending the legal protection of its Copaxone medicine and a "*systematic disparagement campaign*" against a competing product.

Misused patent procedures

According to the Commission, Teva's conduct involved a misuse of the European Patent Office's (EPO) rules and procedures through the strategic filing and withdrawing of divisional patents. Divisional patents derive from an earlier 'parent' patent application and share similar content but may focus on different aspects of the same invention.

The Commission found that Teva filed multiple divisional patent applications in a staggered way, creating a web of secondary patents around Copaxone focusing on the manufacturing process and dosing schedule of the medicine. According to the Commission, when these patents were challenged by Teva's competitors and pending the EPO's review, Teva enforced these patents against its competitors by obtaining interim injunctions. The Commission took issue with the fact that, when the patents seemed likely to be revoked, Teva then "*strategically withdrew them, to avoid a formal invalidity ruling, which would*

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have set a precedent threating other divisional patents to fall like dominos". The Commission concluded that such actions placed a significant burden on competitors, who had to repeatedly start new lengthy legal challenges, thus allowing Teva to prolong legal uncertainty over its patents and to potentially hinder the entry of competing medicines to the market. All pending divisional patents have since been annulled.

Disparagement campaign

The Commission also concluded that Teva had deployed a "*systematic disparagement campaign*" against a competing, cheaper glatiramer acetate medicine for the treatment of relapsing multiple sclerosis. The Commission found that Teva spread misleading information about the rival medicine's safety, efficacy and therapeutic equivalence with Copaxone, despite the fact that the rival product had been approved by the relevant health authorities, who had previously confirmed its safety and efficacy. The Commission considered that Teva's disparagement campaign targeted doctors and national decision-makers for pricing and reimbursement of medicines, with the objective of slowing down or blocking the entry of the rival product in several Member States.

The Commission concluded that, taken together, Teva's patent system misuse and competitor disparagement had the overall objective of delaying competition and artificially prolonging the exclusivity of Copaxone by hindering the market entry and uptake of competing medicines. According to the Commission, both abuses "*were complementary and together amounted to a single and continuous infringement of Article 102*".

Comment

On the same day as the decision was announced, Teva released a statement asserting that it would "*vigorously defend its position on appeal*" and describing the Commission's theories of harm as "*extreme, untested and factually unsupported*".

This is the second time the Commission has looked into disparagement campaigns, following the Commission's acceptance of commitments by Vifor in July 2024, including to rectify comments previously made about the safety of a competitor's product. Commenting on the decision, Margrethe Vestager, outgoing Executive Vice-President in charge of competition policy, stated that "*[w]ith these consecutive actions, we send a clear message to dominant pharmaceutical companies that we will not tolerate the use of disparagement campaigns to foreclose competing medicines*". The Teva case is the first time, however, that the Commission has formally concluded that such conduct is illegal under competition law – matched with a high fine on Teva "*to achieve deterrence*". The non-confidential version of the decision, once available, should shed some light on how the Commission has drawn the line when analysing these novel types of abuses.

It is also noteworthy that the Commission has emphasised its reliance on evidence found in internal documents from Teva's in-house lawyers, which had been collected during the Commission's unannounced inspections. The Commission and EU courts have long refused to recognise in-house lawyer communications as privileged in the context of EU antitrust investigations. This case serves as a reminder of the importance of structuring the procurement of legal advice so as to preserve legal privilege in the EU, particularly given the resurgence of unannounced inspections in recent years.

Earlier this year, the Commission published a report providing an overview of the enforcement of EU antitrust and merger rules in the pharmaceutical sector between 2018 and 2022. The Commission found that active antitrust enforcement plays an important role in ensuring access to a wide choice of affordable and innovative medicines. It remains to be seen how the future EU Commissioner for the competition portfolio will address competition concerns in the pharmaceutical industry and abuse of dominance cases more broadly. The Commissioner-designate to the post, Teresa Ribera Rodriguez, awaits confirmation following her European Parliament hearing last week.

For more information on Ribera's nomination and the future of EU competition law policy, refer to our previous newsletter. We also covered the Commission's recent draft guidelines on exclusionary abuses in a previous client briefing.

OTHER DEVELOPMENTS

MERGER CONTROL

General Court upholds Commission decision authorising Vodafone's acquisition of certain Liberty Global assets

On 13 November 2024, the European General Court (GC) upheld the Commission's 2019 decision authorising Vodafone's acquisition of Liberty Global's telecommunications activities in Germany, the Czech Republic, Hungary and Romania.

The Commission had conditionally approved the acquisition on 18 July 2019, following an in-depth Phase 2 investigation. The Commission had identified two competition concerns, both in Germany. The first was the parties' overlap in the market for the retail supply of fixed broadband services and the second was that the merger would increase the merged entity's market power in the market for the wholesale supply of signal for the transmission of TV channels. To address these concerns Vodafone offered a package of commitments. The Commission was satisfied that the commitments addressed its concerns and cleared the transaction on this basis (see our previous newsletter for more detail).

Deutsche Telekom, Tele Columbus, and NetCologne challenged the 2019 decision, claiming that the Commission had made manifest errors of assessment regarding the effects of the transaction on competition in the markets for the retail supply of TV signal transmission services in Germany.

The GC dismissed each of the actions, holding that the Commission did not make a manifest error of assessment in finding that the merging parties were not, prior to the transaction, either actual competitors (directly or indirectly) or potential competitors in the markets for the retail supply of TV signal transmission services to customers living in multi-dwelling units or in single-dwelling units in Germany. The GC found that the Commission was therefore correct to conclude that the transaction would not eliminate any competitive relationship between those parties and would not give rise to a significant impediment to effective competition (SIEC) on the relevant markets. The GC also remarked that only concentrations that would significantly impede effective competition in the internal market (or a substantial part of it) are to be blocked. When a concentration would create or strengthen a dominant position, this dominance is not, in itself, sufficient for the transaction to be incompatible with the internal market.

ANTITRUST

SAMR publishes new antitrust guidelines for Standard Essential Patents

On 8 November 2024, the Chinese State Administration for Market Regulation (SAMR) published its Anti-Monopoly Guidelines for Standard Essential Patents (SEPs) (the Guidelines), following public consultation in June 2023.

This is China's first specific set of antitrust guidance on SEPs, which emphasises *ex ante* supervision and ongoing compliance by the relevant stakeholders (such as standards-setting organisations and SEP holders). While the Guidelines do not preclude SAMR's power to investigate antitrust violations in connection with SEPs, they prioritise a soft intervention approach in the form of 'reminder letters' and 'regulatory talks', with a view to encouraging non-compliant businesses to take corrective measures.

Other key provisions of the Guidelines include:

- **Stipulation of 'good practice'**: SEP holders are encouraged to disclose information to standards-setting organisations in a timely and sufficient manner, to adopt fair, reasonable, and non-discriminatory (FRAND) licensing principles, and to engage in good faith negotiation with standards implementors. The basic principles for such 'good practice' are also explained in the Guidelines.

- **Factors for determining anti-competitive conduct**: The Guidelines set out certain factors that are relevant to the assessment of whether a SEP-related practice constitutes a monopoly agreement or an abuse of dominant market position under the Anti-Monopoly Law. Notably, while non-compliance with 'good practice' is not an infringement *per se*, it is an important factor that is likely to be taken into consideration.

- **Merger control implications**: A SEP-related transaction may be subject to merger review in certain circumstances. The relevant factors include: (a) whether the products or services covered by the SEP constitute an independent business or generate independent and calculable turnover, and (b) the form and duration of the relevant licence(s). Businesses should therefore assess if a transaction involving a licence for SEPs is notifiable under the merger control regime before implementing the transaction, in order to avoid the risk of 'gun-jumping'.

The Guidelines mark China's continuous effort in developing its antitrust framework in the field of intellectual property to bring it in line with international standards, and offer practical guidance for businesses to evaluate and improve their SEP practices in a manner that promotes fair market competition.

GENERAL COMPETITION

UK Government orders FTDI Holding to unwind acquisition of stake in semiconductor business on national security grounds

On 5 November 2024, the UK Government, following a national security assessment, issued a final order under section 26 of the National Security and Investment Act 2021. The order requires Future Technology Devices International Holding Limited (FTDI Holding), a China-registered holding company, to divest its 80.2% stake in Scottish chip firm Future Technology Devices International (FTDI), and to do so within a specified period and by following a specified process.

FTDI Holding acquired control of FTDI on 7 December 2021, when it increased its ownership from less than 75% to over 80%. The Government deemed this acquisition a 'trigger event' under Section 8(2)(c) of the National Security and Investment Act, warranting a full review. The Chancellor's final order outlined specific concerns such as the potential misuse of UK-developed semiconductor technology and intellectual property in ways that could undermine national security, as well as the risk posed by FTDI's technology to critical UK infrastructure.

The final order, led by the Chancellor of the Duchy of Lancaster, marks the first deal blocked on national security grounds under the new UK Government, highlighting a continuation of the UK's firm stance on protecting critical infrastructure and technology from foreign influence. It is the sixth transaction to be prevented on national security grounds since the UK foreign investment regime came into force in January 2022. Previous transactions blocked are L1T/FM Holdings UK LTD (order of 19 December 2022), SiLight (Shanghai) Semiconductor Limited/HiLight Research Limited (order of 19 December 2022), Nexperia BV/Nexperia Newport Limited (formerly Newport Wafer Fab) (order of 16 November 2022), Super Orange HK Holding/Pulsic (order of 17 August 2022); and the acquisition of certain IP by Beijing Infinite Vision Technology Company Ltd from the University of Manchester (order of 20 July 2022). For further details on the first three of these decisions, see our previous newsletter and briefing here and here.

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