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VBB on Competition Law

Issue Highlights

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CJEU sets strict standards for market definition and patent settlements in the pharmaceutical sector

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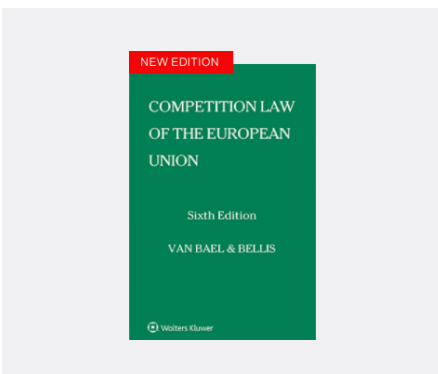
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ABUSE OF DOMINANT POSITION

European Union level

CJEU sets strict standards for market definition and patent settlements in the pharmaceutical sector

On 27 June 2024, the Court of Justice of the EU (“CJEU”) delivered its judgments in the *Servier* case (Cases C-176/19 P et al), siding with the European Commission’s initial decision and setting forth an analysis that will increase the risks that patent settlement agreements can be found to infringe EU competition law. In particular, the CJEU (i) applied principles to market definition in pharmaceutical cases that will often result in very narrow markets (making findings of dominance more likely), (ii) required a broader evaluation of the parties’ contractual relationships to examine the anti-competitive nature of a settlement agreement, and (iii) confirmed that patent settlement agreements among pharma companies can be qualified as “object restrictions” regardless of whether their impact on competition may be benign.

Background of the Case

The dispute originates from a 427 million Euro fine decision imposed by the Commission against pharmaceutical innovator Servier and several manufacturers of generic versions of perindopril for a series of patent settlement agreements and a technology acquisition.

On first instance, the General Court (“GC”) had confirmed the Commission’s finding that most of the settlement agreements constituted a restriction by object in violation of Article 101 TFEU, but annulled the Commission’s decision concerning the agreements concluded with Krka as well as the Commission’s finding of an abuse of dominance (see, [Van Bael & Bellis, Insights & News of 27 December 2018](#)).

In the new judgments, the CJEU largely confirmed the Commission’s original decision. It partially overturned the GC’s judgment insofar as it had annulled the Commission’s abuse of dominance analysis and the evaluation of settlement agreements with Krka and referred these issues back to the GC for further evaluation.

Market Definition & Abuse of Dominance

Defining the relevant market is a necessary pre-requisite in abuse of dominance cases. In its decision, the Commission found a narrow market consisting solely of Servier’s perindopril and its generic equivalents but excluding other ACE inhibitor therapies in the same therapeutic class and with the same therapeutic indications. The Commission’s decision to exclude these other ACE inhibitor therapies was materially based on evidence indicating that, despite significant reductions in the prices of other ACE inhibitors, the price of Servier’s perindopril remained stable and its volumes increased.

The GC annulled the Commission’s narrow market definition because it relied too much on price-based factors and ignored the fact that competition in the pharmaceutical sector also occurs based on non-price “qualitative” factors (e.g., the efficacy and safety profile of a medicine). In the pharmaceutical sector, price-based competition tends to occur primarily in access negotiations with national insurance funds and other payors, while quality-based competition tends to occur in the context of the promotion of medicines to doctors for prescription to individual patients.

The CJEU disagreed with the GC that a distinction should be drawn between price-based and quality-based forms of competition, and held that the assessment of the relevant market should instead focus on whether products are “economically substitutable”, taking into account all price-based and quality-based characteristics. Further, the CJEU specified that, in order to determine whether medicines approved for the same indication are economically substitutable, it was necessary to assess whether changes in the relative prices result in a shift in sales between medicinal products. Absent findings of substitution effects in response to relative price increases, the products belonged to separate different markets. The

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CJEU therefore held that the specific characteristics of the pharmaceutical sector (notably, the role of prescribing doctors and the fact that medicines are covered by national reimbursement systems) would be relevant only insofar as they are reflected in the evolution of the prices and sales of the respective products.

Assessment of Licensing Agreements related to Patent Settlements

In its decision, the Commission decided that Servier's patent settlement and related licence agreements concluded with Krka constituted a restriction of competition by object. The GC annulled this element of the decision on the ground that the Commission had failed to prove that the very low level of royalty payable by Krka to Servier under the license constituted a form of value transfer to the generic competitor in exchange for its commitment to not compete with Servier.

The CJEU disagreed with the GC, holding that the license and settlement agreements should be evaluated "as a whole", and that the GC erred by focusing its analysis solely on the terms of the license agreement. According to the CJEU, these two agreements, evaluated as a whole, constituted a form of a market-sharing agreement, with Servier agreeing to not oppose Krka's marketing in Krka's core market, and with Krka agreeing to not enter Servier's core markets. Applying this holistic approach, an evaluation of the specific level of the royalty rate was not necessary to find the existence of an infringement.

Restrictions of Competition By Object

Relying on its judgments in *Generics* and *Lundbeck* (see, [Van Bael & Bellis, Insights & News of 28 April 2021](#)) the CJEU confirmed that the other patent settlement agreements concluded by Servier and generic manufacturers Lupin, Niche Generics, Unichem Laboratories, Matrix, Teva and Biogaran restricted competition by object as they amounted to market exclusion agreements. The CJEU reversed the GC's position (which opened the door for

a possible analysis of effects also in the context of by object restrictions) that conduct may not be qualified as a by object restriction if the effects of the conduct are either ambiguous or even positive. Instead, consistent with the recent ruling in the *Superleague* case, the CJEU held that, unlike for the establishment of a restriction by effect, competition authorities are not required to carry out any assessment of the effects of a conduct in the context of the analysis of a possible by object restriction.

Key Takeaways

These judgments are important as they provide further clarity on the existing case law applicable to the pharmaceutical sector. In particular, these judgments clarify that any assessment of the relevant market must focus on economic substitutability, rather than individual forms of price or quality-based competition. This will increase the likelihood that pharmaceutical products will be subject to very narrowly defined markets, which in turn will make it easier for competition authority to bring abuse of dominance cases. Further, the judgments increase the likelihood that any "side deals" or other agreements entered in connection with patent settlements will be subject to close scrutiny by competition authorities, limiting opportunities to develop "creative" arrangements to protect patent settlement agreements from competition law scrutiny.

ABUSE OF DOMINANT POSITION

National level

Italian highest administrative court rejects finding of an abuse of dominance by the Italian Equestrian Sports Federation as its regulatory powers were limited to sport issues

On 5 July 2024, the Italian highest administrative court (the “HAC”) handed down its judgement concerning anti-competitive practices in the market for the organisation of amateur equestrian events. The HCA reversed a decision by the Italian Competition Authority (the “ICA”) and held that the ICA had wrongly concluded that the Italian Equestrian Sports Federation (“FISE”) had abused its dominant position on the market for the organisation of equestrian sporting events.

FISE is an association of undertakings which represents, regulates, and organises, various undertakings active on the equestrian market. It is the only equestrian federation to be associated with the Italian National Olympic Committee. Since 2011, FISE’s activities were subject to behavioural commitments which were designed to address concerns of the Italian Competition Authority (the “ICA”) that FISE may have infringed both Articles 101 and 102 TFEU. In 2017, two complaints were made stating that FISE no longer complied with the 2011 commitments, including allegations that FISE was once again sending letters to rivals warning them not to organise events the federation had not authorised. The ICA adopted a decision against FISE, finding that it had breached its commitments and abused its dominant position. This decision was later upheld by the Italian administrative court of first instance.

The HAC annulled the ICA’s decision, as it found that the evidence provided by FISE called into question its dominance on the relevant market for the organisation of horse competitions. ICA’s determination that FISE held a dominant position was based on FISE’s regulatory influence, which limited the possibility of other equestrian event organisers to compete. FISE argued that dominance should instead have been found based on its turnover relative to the organisation of equestrian events, compared to the turnover of other undertakings present on the market. The HAC agreed. It found that

FISE organised few events per year, and that many more events were organised by other undertakings for which FISE only received calendar fees, but no other income, such as for the sale of tickets or the sale of broadcasting rights.

Furthermore, the HAC found that – contrary to the facts in other recent cases in the sports sector, such as *ISU* and *Superleague* (see, [Van Bael & Bellis, News & Insights of 29 January 2024](#)) – FISE did not have any powers to authorise or regulate events which it did not itself organise. FISE also had no influence on the participation of its members in events outside of the federal level. Therefore, the fact that FISE had certain regulatory powers that were not held by other undertakings on the market was not proof of a dominant position.

Additionally, the HAC considered that, if any, FISE’s powers only concerned the sports and technical sides of the activities, and not the economic aspects. Therefore, FISE’s regulatory powers did not allow it to regulate the relevant market. This conclusion affected both the finding of dominance and that of restrictive effects since the HAC considered that – applying the principle stated by the Court of Justice in *Meca Medina* – any such effects merely concerned sports issues, and not the economic side of the organisation of events.

The HAC concluded that the ICA did not carry out a sufficient analysis to determine the reach of the regulatory powers of FISE, and, therefore, annulled the ICA’s finding of an abuse of dominance. The annulment also extended to the ICA’s parallel conclusion that the commitments had been breached. According to the HAC, that conclusion was based on the same facts as the finding of an abusive conduct, and could not therefore be considered autonomously. Without a valid finding of an abuse of a dominant position, the commitments, and the alleged non-compliance, had no legal basis.

CARTELS AND HORIZONTAL AGREEMENTS

National level

German FCO accepts launch of automotive licensee group for jointly negotiating SEP licences for mobile communications technology under certain conditions

The German Federal Cartel Office (“FCO”) announced in June that it will “tolerate” the launch of the *Automotive Licensing Negotiation Group* (“ALNG”), a cooperation between BMW, Mercedes-Benz and VW and automotive component supplier Thyssenkrupp for the purpose of jointly negotiating the terms of licences for standard essential patents (“SEPs”) for mobile communications technology. Car manufacturers and automotive component suppliers need SEP licences for mobile communication standards such as 4G and 5G in order to implement mobile data transmission in cars. The licensors of such SEPs have long entered into joint licensing agreements which pool their SEPs for licensing as a package, which is generally considered compatible with the EU competition rules, as long as the licences are offered on fair, reasonable, and non-discriminatory (“FRAND”) terms.

The FCO has issued a form of “comfort letter” to the parties accepting as compatible with Article 101 TFEU and the corresponding Sections 1 and 2 of the German Competition Act a cooperation on the side of the licensees for the joint negotiation of licences for mobile communication standards such as 4G, 5G, Wi-Fi and H.265, subject to certain conditions.

It is noteworthy that, in its assessment of this cooperation, the FCO has expressly applied the guidance provided by the European Commission’s Horizontal Guidelines on the assessment of joint purchasing agreements and, in particular, the market share thresholds set out therein. The FCO thus determined that the parties’ combined share of demand on the market for SEP licensing for “general mobile communications technologies” is below 15%, as demand for such licences is widespread (including, for example, from smartphone producers) and not limited to the automotive industry. On some of the downstream selling markets, i.e., the relevant vehicle markets where the parties compete, the FCO found that the parties’ combined shares exceed the 15% threshold. However,

the FCO considered that the licensing-in cooperation would not increase the risk of collusion on those markets, as the licence costs for SEPs typically account for less than 1% of a vehicle’s total production cost. The joint purchasing would therefore not result in a high degree of cost commonality for the vehicle producers.

Importantly, however, the FCO pointed out that the parties’ share of demand for SEP licences for “more automotive-specific standards” would be likely to exceed the 15% threshold, so that any future plans of ALNG to extend its joint negotiation activities to SEP licences for other technologies, in particular automotive-specific standards, would not be covered by the comfort letter.

In its letter, the FCO stated that it will not act against the joint SEP licence negotiations of ALNG, provided that no new factual or legal considerations arise and that ALNG fulfils the following conditions:

- The joint SEP licence negotiations must be limited to *general* mobile communication standards such as 4G, 5G, Wi-Fi and H.265 and must not extend to other, more automotive-specific standards.
- Participation in ALNG must also be open to automotive component suppliers, as these might also have a right to obtain SEP licences under the competition rules.
- Negotiation of licensing terms with ALNG must be voluntary for the licensors (i.e., patent owners and patent pools). This means that the licensors must be free to decide whether to enter into joint negotiations or whether to negotiate bilaterally with individual licensees.
- The exchange of information between ALNG members must be limited to the absolute minimum necessary to operate ALNG and the parties must take appropriate organisational measures to safeguard this.

LEGISLATIVE, PROCEDURAL AND POLICY DEVELOPMENTS

European Union level

European Commission imposes first-ever fine for the deletion of social media messages stored on a mobile telephone during an antitrust inspection

On 24 June 2024, the European Commission (“Commission”) imposed a fine of € 15.9 million on International Flavors & Fragrances and IFF France (collectively “IFF”) for obstructing its inspection concerning possible collusion in the fragrance sector. During the inspection, a senior employee intentionally deleted messages exchanged with a competitor via WhatsApp on a mobile phone.

In the view of the Commission, the infringement was of a particularly serious nature given the timing of the data deletion, which occurred after the employee had been informed about the inspection, and the fact that the Commission inspectors were not made aware of the deletion but had to detect it themselves. The deleted messages referred to business-related information. They were recovered with the assistance of IFF, which opted for a cooperation procedure by acknowledging its liability and accepting the maximum penalty.

The fine of € 15.9 million corresponds to 0.15% of IFF’s total turnover, and reflects a 50% reduction from the original amount (0.3% of IFF’s total turnover) on account of the proactive cooperation of the company during and after the dawn raid.

The case serves as a strong reminder for companies to implement and regularly update their internal dawn raid policies and compliance programmes and to alert their employees not to alter or delete any business-related electronic data stored on their mobile phones, including WhatsApp chats and other social media communication, in the event of a Commission inspection.

Companies have the right to receive interest on antitrust fines provisionally paid to the European Commission that are later annulled or reduced

On 11 June 2024, the Court of Justice of the European Union (“CJEU”) handed down a judgment (C-221/22P, *European Commission v Deutsche Telekom*) which re-affirms the obligation of the European Commission (“Commission”) to pay interest when repaying provisionally collected antitrust fines which are later reduced or annulled by the EU Courts.

In October 2014, Deutsche Telekom (“DT”) received a fine of € 31 million from the Commission, for abusing its dominant position on the Slovak telecommunications market. DT provisionally paid this fine in January 2015. In December 2018, the General Court of the European Union (“GC”) reduced the fine imposed on DT by approximately € 12 million. Thereafter, the Commission repaid to DT the amount of the fine reduction but refused to pay interest for the period between the date on which the fine had been provisionally paid and the date on which the Commission had repaid the undue amount.

In response, DT brought an action before the GC to obtain compensation for loss of profit as a result of the loss of use of the principal amount of the undue portion or, alternatively, for the harm suffered because of the Commission’s refusal to pay interest. The GC partly upheld DT’s claims and awarded to it approximately € 1.8 million in damages (see, in detail, [VBB on Competition Law, Volume 2022, No. 1](#)).

On appeal, the CJEU upheld the GC judgment. The CJEU relied upon settled case-law to rule that, in the event of annulment or reduction by the EU Courts of a Commission antitrust fine, the Commission must pay interest for the period of time beginning from the date of the provisional payment of that fine until the date of its repayment. Further, the CJEU determined that the GC was right in adopting as the applicable rate, by analogy, the rate laid down in Article 83 of Delegated Regulation No 1268/2012, i.e., the ECB refinancing rate increased by 3.5 percentage points.

LEGISLATIVE, PROCEDURAL AND POLICY DEVELOPMENTS

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As the CJEU explained, this is not a case of default interest but rather the interest payable by the Commission in such circumstances is intended to compensate the undertaking concerned at a standard rate for the loss of enjoyment of the amount at issue. The obligation to pay interest stems from Article 266 TFEU which requires the institution whose act has been declared void to take the necessary measures to comply with that judgment with retroactive effect. Further, the CJEU ruled that the Commission's refusal to pay appropriate interest is a sufficiently serious breach of EU law capable of giving rise to the EU's non-contractual liability.

The CJEU's judgement departed from the earlier opinion issued by Advocate General Collins, which argued that the Commission was not required to pay default interest, and instead was required to pay interest where necessary to take into account any depreciation in the value of money due to the passage of time between the date of provisional collection of the fine and the date of the 2018 GC judgment.

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