Case Comment

Patent settlements under EU competition law: the EU Court of Justice takes a tough stance against value transfers from originators to generics

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Case C176/19 P *European Commission v Servier SAS, Servier Laboratories Ltd, Les Laboratoires Servier SAS*

On 27 June 2024, the Court of Justice of the European Union (CJEU) rendered its two long-awaited judgments in the European Commission's (EC) perindopril case. These judgments by the EU's highest court largely confirm the judgment at first instance by the General Court (GC),[2] but take a more strict approach to what is a permissible patent settlement under EU competition law. The CJEU judgments concern patent settlement agreements between an originator (Servier) and several generic manufacturers (including Krka), in particular:

- The EC's appeal of the GC's ruling that considered Servier's patent settlement agreements with Krka permissible (Case C176/19 P); and[3]
- Servier's appeal of the GC's ruling that considered Servier's patent settlement agreements with several other generic manufacturers impermissible (Case C201/19 P).[4]

The CJEU's judgments have far-reaching implications for the ability of originators and generic drug manufacturers to resolve patent disputes amicably.

Key Points

- The CJEU largely upheld the EC's original decision that Servier's patent settlement agreements with generic drug manufacturers concerning perindopril violated EU competition law, thereby partially overturning the GC's judgment.[5]
- The CJEU found that so-called 'reverse payment' patent settlement agreements may be anticompetitive 'by object' under Article 101 of the Treaty on the Functioning of the EU (TFEU), confirming prior EU case law.[6]
- The CJEU further held that granting a patent licence in some markets in exchange for the licensee agreeing not to enter or challenge patents in other markets should be considered unlawful market-sharing as well, irrespective of the form or legitimate aims pursued by the underlying agreements.
- The GC's criticism of the EC's abuse of dominance allegations was overturned. According to the CJEU, the GC relied on incorrect grounds when it invalidated the EC's market definition for perindopril and thereby the EC's dominance findings. The CJEU referred the matter back to the GC to rule on the abuse of dominance allegations.

This case note focuses on the Krka ruling (Case C176/19 P), which expands the scope of problematic value transfers in the context of patent settlement agreements and cements the CJEU's tough stance on patent settlement agreements under Article 101 TFEU.

Background

Servier's Perindopril

The French pharmaceutical company Servier held a compound patent over blockbuster cardiovascular drug perindopril[7] until its gradual expiry in the late 1990s and early 2000s. Servier applied for supplementary process

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2 Judgment of the General Court of 12 December 2018, Case T691/14 *Servier and Others v Commission.*

3 Judgment of the Court of Justice of 27 June 2024, Case C176/19 P *European Commission v Servier SAS, Servier Laboratories Ltd, Les Laboratoires Servier SAS*.

4 Judgment of the Court of Justice of 27 June 2024, Case C201/19 P *Servier SAS, Servier Laboratories Ltd, Les Laboratoires Servier SAS v European Commission*.

5 Case T691/14, Note 2 above.

6 Judgment of the Court of Justice of 30 January 2020, Case C307/18 *Generics (UK) Ltd and Others v Competition and Markets Authority*; Judgment of the Court of Justice of 25 March 2021, Case C591/16 P *H. Lundbeck A/S and Lundbeck Ltd v European Commission*. These cases concerned so-called 'reverse payment' settlement agreements, which occur when the holder of a patent (normally the originator) agrees to compensate a potential or alleged patent infringer (normally a generic manufacturer) as part of a patent settlement.

7 Perindopril was one of 16 existing angiotensin converting enzyme inhibitors ('the ACE medicinal products') at the time the agreements were concluded. The active ingredient of perindopril takes the form of a salt originally; erbumine.

patent protection in subsequent years, and the validity of those secondary patents was eventually challenged by several generic manufacturers, including Slovenian company Krka, before the European Patent Office and national courts.

Specifically, the process patent over the specific alpha crystalline form of perindopril erbumine used by Servier, and the methods for its manufacture (patent EP1296947, known as the 'alpha patent' or '947 patent'), was the main patent disputed by the generic manufacturers.[8] To resolve the patent disputes, Servier entered into a series of agreements with the generic manufacturers, dealing with their entry into certain EU markets and their ability to challenge Servier's patents.

Krka's Perindopril

In 2003, Krka started developing its own version of perindopril, based on the alpha crystalline form of erbumine covered by the 947 patent. In the years following, Krka obtained a number of marketing authorisations to place the product on the market in several Central and Eastern EU Member States. Concurrently, Krka also started preparing to launch its generic version of perindopril in several other Member States, including France, the Netherlands and the United Kingdom.[9] In 2006, Servier initiated patent infringement claims against Krka for violating the 947 patent in Hungary and in the UK. In late 2006, the proceedings ceased as a result of settlement agreements reached between the parties.[10]

To resolve the patent disputes, Servier and Krka concluded three separate agreements: (i) a settlement agreement; (ii) a licence agreement; (together, 'the October 2006 agreements'); and (iii) an assignment and licence agreement ('the January 2007 agreement'). Under the terms of the October 2006 settlement agreement,[11] Krka agreed to withdraw any validity claim against the 947 patent worldwide and not to challenge it in the future (*non-challenge clause*). In return, Servier agreed to drop the existing patent infringement claims against Krka. Further, Krka and its subsidiaries were not authorised to launch or market a generic version of perindopril which would infringe the 947 patent for the duration of the validity of that patent and in the countries in which it was still valid, unless expressly authorised to do so by Servier (*non-marketing clause*).

Under the licence agreement, Servier granted Krka an exclusive, irrevocable licence to 'use, manufacture, sell, offer for sale, promote and import its own products which contained the alpha crystalline form of erbumine in the Czech Republic, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia.[12] In return, Krka was required to pay Servier 3 per cent royalties on its net sales throughout those territories. Servier retained the right to use the 947 patent directly or indirectly in certain Member States. The arrangement included a non-marketing clause that restricted Krka from launching a competing generic product.

Three months after the conclusion of the settlement and licence agreements, Servier and Krka entered into the January 2007 agreement, an assignment and licence agreement, under which Krka granted two patent applications to Servier, concerning the technology used in the process and preparation of Krka's version of perindopril. In return for that assignment, Servier paid Krka the sum of €30 million.[13]

The EC Decision and Appeal to the General Court

In July 2014, the EC found that the generic manufacturers (including Krka) should be regarded as potential competitors to Servier at the time the settlement agreements were concluded. The EC found these agreements to be anticompetitive under Articles 101 and 102 TFEU, and imposed €427 million in fines on the parties involved. For the arrangement with Krka, Servier was fined almost €37 million. Krka was fined €10 million.

Specifically, the EC considered that the aim of the agreements between Krka and Servier was to partition the market in violation of Article 101 TFEU, in such a way as to create a duopoly (in favour of Servier and Krka) in the seven Central and Eastern EU Member States, and exclude Krka's existing competitive pressure in the remaining 18 Member States, where Krka's generic version of perindopril was slated to be introduced.[14]

Further, in the EC's view, the licence agreement granted by Servier to Krka constituted a significant enough inducement for Krka to accept those restrictions because: (i) it covered the markets on which Krka had traditionally been present in the European Union, where it achieved its highest margins;[15] (ii) it gave Krka the guarantee that Servier would stop initiating patent infringement claims over Krka's use of the 947 patent; and (iii) it established a *de facto* duopoly between Servier and Krka on the seven markets concerned, freeing Krka from the competitive pressure of potential market entry by other generic manufacturers.[16]

Further, the EC found that the January 2007 agreement constituted an additional step in Servier's strategy to delay the entry of other generic manufacturers into the relevant market, where Servier was dominant. The EC therefore concluded that Servier abused its dominance in violation of Article 102 TFEU based on several anti-competitive practices. These included entering into 'pay-for-delay' patent settlement agreements with generic companies, acquiring

8 Note that the 947 patent was eventually invalidated in the UK in 2007 and in the Netherlands in 2008, following claims brought by pharmaceutical company Apotex and its Dutch subsidiary.

9 Case C176/19 P, Note 3 above, at para 10.

10 Ibid., para 16.

11 For completeness, the authors note that other patents held by Servier over the manufacturing process of perindopril were also challenged and subsequently the object of settlement agreements between Servier and Krka. Due to space constraints, this contribution focuses on the 947 patent as the most significant one.

12 Case C176/19 P, Note 3 above, at para 23.

13 Decision of the European Commission of 30 September 2016, Perindopril (Servier), Case AT.39612, paras 1670 to 1679.

14 Ibid. para 1670.

15 Ibid. paras 1673 to 1674.

16 Ibid. para 1677.

competing technologies and related intellectual property rights to prevent generics from producing perindopril, and creating a dense network of patents around perindopril to further delay generic competition. These combined actions were seen as an abuse of Servier's dominant market position, aimed at maintaining its monopoly on perindopril by hindering generic competition.

On first instance appeal in 2018, the GC concluded that most of the agreements covered by the EC decision were contrary to Article 101 TFEU as restrictions of competition 'by object', except for the Krka arrangements. In fact, the GC considered that the non-challenge and non-marketing clauses in the October 2006 agreements were not part of an exclusionary strategy by Servier, but a legitimate means to end the underlying patent disputes, based on Krka's acknowledgment of the validity of the 947 patent. Further, the GC found that the October 2006 licence agreement was pro-competitive, as it *encouraged* Krka's market entry in the seven Central and Eastern EU Member States.[17] As to the EC's abuse of dominance findings, the GC dismissed the EC's claim that Servier had abused its dominant position in violation of Article 102 TFEU, by finding that the EC had defined the perindopril market too narrowly as not including other medicinal products intended for the same therapeutic indication.

The CJEU Judgment

The CJEU cast aside most of the GC's ruling as it pertained to the Krka agreements, in finding, among other points, that the GC had erred in law in not duly considering the body of evidence presented by the EC, which demonstrated Servier's and Krka's intention to unlawfully partition the market for perindopril through the conclusion of the three agreements.

The CJEU emphasised that agreements where significant value is transferred from the originator to the generic manufacturer, effectively paying the latter to delay market entry, are likely to be seen as restricting competition by object. This is because such agreements typically involve the originator compensating the generic manufacturer for not competing, which inherently distorts the competitive process.

The Importance of the Legal and Economic Context

The CJEU relied heavily on the opinion delivered by Advocate General (AG) Kokott. In her opinion, AG Kokott held that: '*the implementation of EU competition law would be seriously jeopardised if the parties to anticompetitive agreements could evade the application of Article 101 TFEU simply by giving such agreements a particular form*'.[18]

In the AG's view, the fact that Krka had not received monetary compensation as part of the settlement agreement with Servier was not a relevant factor. As Krka was the most established competitor to Servier, monetary compensation would not have been a persuasive measure to induce Krka to stay out of the perindopril market. However, market presence permitted by the patent holder would give added value to a generic company.

As the AG pointed out, that added value consisted, specifically, of the '*possibility of distributing its own product and of building up or retaining its customer base, its distribution networks and its brand image*'.[19] AG Kokott further pointed out that such added value is '*especially important on a 'branded generic' market*', since doctors' prescriptions do not refer to the '*international non-proprietary name of a medicinal product*'.

In support of the AG's views, the CJEU noted that the key question to consider was whether the agreements influenced Krka to restrict competition, regardless of the form of the contracts or the parties' subjective views and intent. According to the CJEU, what matters is whether the value transferred via the Krka licence was large enough to induce Krka's abstention from Servier's core markets.[20] Specifically, the CJEU found that the granting of the licensing agreement to Krka constituted an illegitimate *quid pro quo* for the generic manufacturer's commitment not to compete in the national markets not covered by the licence.[21]

Irrelevance of Pro-competitive Effects at the 'By Object' Stage

The CJEU further noted, echoing its recent ruling in *Superleague*,[22] that although the licensing agreement may have been reached in pursuit of a legitimate aim, the parties' intention is not decisive for the purposes applying Article 101(1) TFEU. The CJEU emphasised that a well-intended aim of resolving patent litigation does not justify anticompetitive agreements.[23] It also rejected the notion that granting a licence in some markets (that is, the seven Central and Eastern EU markets) can produce enough pro-competitive effects to justify restrictions on market entry in the remaining markets, noting that such reasoning would disregard: '*the nature of that infringement, consisting not in a simple patent dispute settlement agreement in return for a reverse payment, but of a market-sharing agreement*'.[24] This clarifies recent CJEU case law which left the door open to arguing that pro-competitive effects of a patent settlement agreement can offset any anticompetitive effects.[25]

Market Definition and Dominance Assessment

Finally, the CJEU also disagreed with the GC in finding that the EC relied excessively on price to conclude that the

17 Case T691/14, Note 2 above, at paras 953 to 956.

18 Opinion of Advocate General Kokott, Case C-176/19 P, Note 3 above, at para 270.

19 Ibid. at para 154.

20 Opinion of Advocate-General Kokott, Note 19 above, Case C176/19 P, Note 3 above, at paras 107 and 200.

21 Ibid. at para 469.

22 Judgment of the Court of Justice of 21 December 2023, Case C333/21 *European Superleague Company* at para 167.

23 Case C176/19 P, Note 3 above, at paras 181 and 224.

24 Ibid. at paras 174 to 175.

25 Judgment of the Court of Justice of 30 January 2020, Case C307/18 *Generics (UK) Ltd and Others v Competition and Markets Authority*. The CJEU noted that: '*where the parties to [an] agreement rely on its pro-competitive effects, those effects must, as elements of the context of that agreement, be duly taken into account for the purpose of its characterisation as a "restriction by object"*' (para 103).

relevant market for the dominance assessment consisted only of perindopril.[26]

In its decision, the EC defined the relevant market narrowly, focusing exclusively on perindopril. The EC's approach was based on the pricing dynamics and competitive constraints specific to this drug. According to the EC, perindopril constituted a distinct market because changes in its price did not lead to a significant shift in sales to other medicinal products intended for the same therapeutic indication.

The GC criticised the EC for relying excessively on price in defining the relevant market and emphasised the need to consider other competitive factors. Specifically, the GC found that the EC failed to adequately consider the therapeutic substitutability of ACE inhibitors and concluded that the EC placed excessive importance on price without sufficiently considering other factors such as therapeutic indications and patient preferences.[27]

However, the CJEU departed from the GC's ruling on the definition of the relevant market by reinstating the EC initial approach, and noting that the 'economic substitutability' between medicinal products intended for the same therapeutic indication must be assessed in light of shifts in sales 'brought about by the changes in the relative prices' of those products.[28] Thus, the CJEU supported the EC's original market definition focused on perindopril.

In particular, the CJEU ruled that economic substitutability between products depends on both functional and economic factors, and held that changes in relative prices leading to shifts in sales between products indicate economic substitutability. The CJEU therefore concluded that perindopril forms a distinct market from other ACE inhibitors.

Conclusion

The CJEU's judgment in the *Krka* case provides helpful further guidance on the assessment of patent settlement agreements under EU competition law. It underscores the importance of considering the competitive impact of value transfers, whether monetary payments or other forms of value transfers, in such agreements.

The CJEU rejected the notion that granting a licence in some markets could justify restrictions on market entry in other markets, and emphasised that any pro-competitive effects in licensed markets cannot compensate for anticompetitive restrictions elsewhere. The judgment further[29] limits the scope for pharmaceutical companies to resolve patent disputes amicably if this involves value transfers from the originator to the generic and commitments from the latter not to enter certain markets.

26 Case C176/19 P, Note 3 above, at para 390: '*The General Court could not therefore, without manifestly contradicting itself and disregarding those principles, which it had just rightly set out, hold ... that the relative price inelasticity of demand for perindopril was of little relevance for the purposes of determining the relevant market because it could be explained or justified by the quality of that medicinal product and the importance of its manufacturer's promotional efforts. The General Court therefore erred in law and vitiated by illegality.*'

27 Case T691/14, Note 2 above, at paras 1367 to 1592.

28 Case C176/19 P, Note 3 above, at para 388.

29 As mentioned above, this judgment develops the CJEU's prior case law in Cases C307/18 and Case C591/16 P. Note 6 above.