Kluwer Competition Law Blog

The One that Almost Got Away – The CJEU's Judgments in Servier

Stijn Huijts (Geradin Partners) · Wednesday, August 28th, 2024

On 27 June 2024, the EU Court of Justice ("CJEU") issued its judgments in the *Perindopril (Servier)* case. The judgments follow a European Commission ("EC") decision of 9 July 2014, and a series of General Court ("GC") judgments of 12 December 2018 in relation to appeals against that EC decision. The case started with a dawn raid in November 2008, and – spoiler alert – elements have been remitted by the CJEU to the GC for further consideration, so at 16 years and counting, the saga is still not completed.

Of the "pay-for-delay" cases brought by the Commission in the late 2000s and early 2010s, Servier is the only one where the parties secured partial victory at the GC. The case deals with important questions around core concepts of EU competition law, including the concepts of "agreement", "restriction by object", and market definition in pharmaceutical markets.

In this blog post, I first discuss the background to the case, after which I focus on three key arguments raised in the CJEU appeal: (i) Servier and the generic manufacturers' arguments against the GC's judgment insofar as it upheld the EC's findings that their agreements restricted competition by object; (ii) the EC's appeal against the GC's judgment insofar as it annulled the EC's decision that Servier's agreement with Krka restricted competition by object; and (iii) the EC's appeal against the GC's annulment of its decision that Servier had abused its dominant position.

Background

In January 2008, the EC launched a sector inquiry into pharmaceutical markets. One of the key concerns it identified was the issue of "pay for delay" or "reverse payments" made in the context of patent settlement agreements relating to drugs that were coming up to the expiry of their patents. The theory of harm is that these agreements artificially prolong the exclusivity period of the patents by "buying off" potential competitors who would otherwise have launched generic versions in competition with the patent holder's product around the expiry of the patents.

Shortly after issuing its final report in the sector inquiry, the EC formally initiated three antitrust investigations into this type of agreement: *Lundbeck*, *Fentanyl* and *Perindopril (Servier)* finding, in each case, that there had been anti-competitive coordination between the patent holder (known as

the "originator") and potential entrants agreeing to delay the launch of generic versions of the relevant drug as soon as it came off patent (known as "generic manufacturers"). The UK competition authority (CMA) started its own case, known as *Paroxetine*. Later, the EC also launched an investigation in the *Cephalon* case.

The EC's *Fentanyl* decision was not challenged, but all other cases led to appeals and ultimately ended up at the CJEU (in the CMA's case via a preliminary reference). The CJEU ruled on the CMA's case first, in its *Generics UK* preliminary ruling, which confirmed that "pay for delay" agreements were restrictions of competition "by object", so long as they (i) are between at least *potential* competitors; (ii) involve a payment from the originator to its potential competitor; and (iii) in return, the potential competitor delays its entry into the market. Following this, the CJEU also upheld the GC's judgment which had, in turn, upheld the EC's decision in *Lundbeck*. Later, the GC also upheld the EC's decision in. Complex and slow as they may have been, these cases were a success story for the EC and CMA (although note that the appeal against the GC's judgment in *Cephalon* is still pending before the CJEU).

But the *Servier* case was different. The case featured some arguably "conventional" pay for delay agreements between Servier as the originator of perindopril, a drug that treats hypertension and heart failure, and several generic manufacturers. However, the EC also characterised a complex three-contract arrangement between Servier and generic manufacturer Krka as a restriction of competition by object and by effect. In addition, the EC found that Servier had pursued an abusive strategy which also infringed Article 102 TFEU. At the subsequent GC appeal, the GC upheld the Commission's decision on the "conventional" pay for delay agreements. However, it annulled the finding of infringement of Article 102, as well as the findings relating to the agreements with Krka, making it the only pay-for-delay case where the parties were (partially) successful at challenging the EC's findings.

The GC's judgments were appealed by six generic manufacturers, Servier, and the EC. The CJEU has now released its judgments in these appeals:

- Seven judgments dismissing the appeals by Servier and the generic manufacturers against the GC's judgment upholding the EC's findings that each of their agreements represented a restriction of competition by object (although Servier secured a reduction in the penalty imposed for its agreement with Lupin from EUR 37 million to EUR 34 million);
- Two judgments upholding the appeals by the EC against:
    - the GC's annulment of its finding that the agreements between Servier and Krka represented restrictions of competition by object and by effect; and
    - the GC's annulment of its decision under Article 102 TFEU, on the basis that the EC had erred in defining the relevant market.

Below, we discuss (i) the dismissal of the appeals by Servier and the generics, (ii) the successful EC appeal on the Servier/Krka agreements, and (iii) the successful EC appeal on market definition.

The appeals by Servier and the generic manufacturers

Servier and the generic manufacturers faced the difficult task of convincing the CJEU after *Generics UK* and *Lundbeck* that their situation was different and the agreements at issue should not have been found to be restrictions of competition by object. In this blog post, I focus on Servier's

appeal (Case C-209/19 P).

The appeal took issue with the EC's findings, upheld by the GC, that Servier and the generic manufacturers were at least potential competitors, and that Servier had made payments to those manufacturers that were sufficiently significant to induce those manufacturers to refrain, even if only temporarily, from entering the perindopril market.

Potential competition is a key aspect of pay for delay cases because, in most cases, the party with which the originator has entered into the agreement is not yet active on the relevant market. The theory of harm is the delay of that competition: the originator is accused of having "bought off" the generic manufacturer, who postpones its entry in return for the payment it receives. However, not just any undertaking is a potential competitor. In the pharmaceutical sector there are many arms-length commercial arrangements between companies that are each other's competitors for certain products, but enter into licensing, contract manufacturing or distribution contracts relating to a different product. Such agreements will often be on the basis of exclusivity, which may be harmless if the contracting party does not realistically exert any competitive pressure on the originator for that product.

Any valid patents are also relevant to the question of whether a generic manufacturer is a potential competitor to an originator, as they may restrict a generic manufacturer from launching a rival product that may infringe the originator's valid patent. In *Generics UK* and *Lundbeck*, the CJEU confirmed that patents are part of the economic and legal context in which agreements are to be assessed. However, the assessment of a patent must not consist in a review of the strength of the patent or of the probability of a court finding that the patent is valid and has been infringed. Rather, the assessment must focus on whether, notwithstanding the patent, the generic manufacturer has real and concrete possibilities of entering the market at the relevant time. Additional factors, such as the conclusion of an agreement between the parties when the generic manufacturer was not present on the market, or the existence of transfers of value to that manufacturer in exchange for the postponement of its market entry, can also be relevant. Therefore, as is often the case, competition law focuses on the economic reality.

Among Servier's arguments on potential competition, one stands out. It relates to whether the GC had failed to have due regard to the subjective perceptions of the generic manufacturers of the strength of Servier's patents. In particular, if there was not yet a formal decision on infringement and validity, a generic manufacturer could *perceive* the patent as being sufficiently strong to deter it from entering the market, so that it would not be a potential competitor. However, the CJEU held that the GC had been right to dismiss this argument. Although perception may be relevant to whether the generic manufacturer had an intention to enter the market, it has no role to play in determining that manufacturer's ability to enter. The perception of the strength of a patent, which is by nature subjective, is not relevant for the purpose of assessing the inherent ability of the generic manufacturer actually to enter the market, nor is it relevant for assessing the objective existence of insurmountable barriers to entry.

Servier also took issue with the GC's findings relating to the anticompetitive object of the agreements between it and the generics. According to Servier, the characterisation of an "anticompetitive object" is reserved for agreements the harmful nature of which is proven and easily identifiable. This characterisation is not appropriate for agreements in respect of which the potential effects are ambivalent.

However, the CJEU finds that it is in no way necessary that the same type of agreement has already been censured by the EC for such agreements to be considered to be restrictive of competition by object. All that matters are the specific characteristics of such agreements, from which any particular harmfulness for competition can be inferred, where necessary as a result of a detailed analysis of those agreements, their objectives and the economic and legal context of which they form part.

The judgment also contains a little nugget for those who have been following the CJEU's judgments in *Superleague*, *International Skating Union* and *Royal Antwerp* (for an analysis of these cases on this blog, see here). In those cases, the CJEU held that the defence of "objective necessity" to achieve a legitimate objective, a defence recognised in cases like *Meca-Medina* and *Wouters*, cannot be raised in cases involving restrictions of competition by object (for more details on the Wouters case-law and how it had been refined by the CJEU in the sports judgments last year, see this blog post and the further criticism of that development here). It was unclear whether that CJEU ruling also applied to ancillary restrictions, where the language of "objectively necessary" is also used. However, the CJEU in the *Servier* judgment does not dismiss Servier's argument on the basis that the agreements restricted competition by object. Instead, it assesses the agreements between Servier and the generic manufacturers against the ancillary restrictions doctrine and holds that the object restrictions contained therein were not ancillary. This, in essence, confirms that object restrictions can still be ancillary (although Servier did not succeed in proving this), even if they cannot be objectively justified for achieving a legitimate objective.

The EC's appeal relating to the agreements between Servier and Krka

The EC, in turn, appealed the GC's annulment of its decision relating to the agreements between Servier and one generic manufacturer, the Slovenian company Krka (Cases C-176/19 P and C-151/19 P). Servier and Krka concluded three agreements between October 2006 and January 2007:

- The October 2006 settlement agreement, under which Krka agreed to withdraw any claim against certain relevant Servier patents, and not to challenge those patents. Moreover, Krka was not authorised to launch a generic version of perindopril which would infringe one of the patents for the duration of its validity, unless expressly authorised by Servier. In return, Servier would withdraw its actions against Krka for infringement of the patents.
- The November 2006 licence agreement, pursuant to which Servier granted Krka a licence on its patent in the Czech Republic, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia ("Krka's core markets"). In return, Krka would pay Servier 3% royalties on its net sales in those territories.
- The January 2007 assignment and licence agreement, under which Krka assigned two patent applications to Servier relating to a process for the synthesis of perindopril and to the preparation of formulations of perindopril. In return for that assignment, Servier paid Krka EUR 30 million.

The EC found that those agreements constituted a single and continuous infringement the object of which was to split the EU into Krka's core markets and Servier's core markets, by authorising Krka to launch a generic version of perindopril in its core markets as a "*quid pro quo*" for Krka's commitment not to compete in Servier's core markets. In other words, the *licence* agreement formed the payment from Servier to Krka, for Krka to accept the restrictions agreed in the

settlement agreement.

The EC also found that the EUR 30 million paid by Servier to Krka under the January 2007 assignment and licence agreement was unconnected with the income that Servier could expect from the exploitation of the technology transferred by Krka. Therefore, the 30 million was viewed by the EC as a sharing of the revenues resulting from the reinforcement of market allocation between Servier and Krka.

However, on appeal, the GC considered that if there is a genuine patent dispute that is settled through a settlement agreement, the fact that there is a connected licence agreement does not in and of itself constitute a strong indication that there was a reverse payment. According to the GC, the EC had to go further and prove that the licence agreement "masks" a reverse payment by showing that the royalty paid by the generic manufacturer under the licence agreement is "*abnormally low*" and therefore was not an arm's length transaction. The GC therefore found that the settlement and licence agreements did not reveal a sufficient degree of harm to competition that the EC could conclude that they constituted a restriction by object.

On appeal the CJEU found significant errors in this analysis by the GC. According to the CJEU, the GC should have examined the infringement found by the EC taken as a whole, rather than focussing on whether the EC had proven that the royalty rate was abnormally low. The GC had ignored the essential elements of the infringement and failed to examine, in the light of the parties' reciprocal commitments and incentives, whether the licence agreement might have induced Krka to refrain from competing with Servier.

By only relying on the fact that the royalty rate was not abnormally low, the GC missed the fact that the legal and economic context gave rise to a sharing of markets. The GC should have analysed the value transfer that resulted from the fact that the licence agreement allowed Krka to market its products on its core markets without risk of infringement. The GC should also have assessed whether that value transfer was sufficiently large to induce Krka not to enter (or postpone entry into) Servier's core markets.

Thus, the GC had too quickly dismissed the EC's analysis on the basis that the licence agreement appeared to be "at arms' length", and therefore could not be an inducement to Krka to refrain from entering Servier's core markets. The premiss that a licence agreement concluded at arm's length cannot constitute an inducement to conclude a dispute settlement agreement containing competition-restricting clauses was not correct, said the CJEU. Therefore, the GC had failed properly to assess the EC's analysis of all the arrangements that were in place between Krka and Servier.

The EC's appeal relating to market definition

The EC also appealed the GC's annulment of the EC's findings under Article 102 (Case C-176/19 P). In this respect, the EC had found that Servier had pursued a single and continuous strategy aimed at delaying the market entry of generic versions of perindopril by combining the acquisition of technology relating to perindopril's active ingredient with patent settlement agreements in return for reverse payment.

On appeal at the GC, the EC's case fell at the first hurdle of market definition. Defining the correct

relevant market is an essential element of Article 102 cases. The EC had defined the relevant market as being the perindopril market, to the exclusion of other angiotensin-converting enzyme ("ACE") inhibitors. The EC's reasons were twofold: (i) perindopril had certain special characteristics; and (ii) the sharp fall in the prices of other ACE products following the arrival of generic versions had not led to a decrease in the prices of perindopril, while the volumes of perindopril sold actually increased.

The EC's killer argument had been that despite the sharp fall in the prices of ACE inhibitors for the same therapeutic use as perindopril, the price of perindopril had remained stable and its sales volumes had increased. However, the GC found that this "*does not support the conclusion that there was an absence of qualitative and non-price competitive pressure*" because in the pharmaceutical sector, competition is based not only on price, but also on quality. The EC had attached excessive importance to prices when determining the relevant market.

However, the CJEU annulled the GC's judgment on market definition. In particular, the CJEU held that substitutability of two products (here: perindopril and the other ACE inhibitors) does not only depend on whether those products are functionally capable of satisfying the same need. It also depends on whether, from an economic point of view, those products are in fact substitutable. Economic substitutability between two products exists where changes in their relative prices lead to a shift in the sales of one to the other.

The price and quantity sold of a product are not the expression of a distinct type of competition that can be contrasted with competition on quality. Economic substitutability instead reflects **all** the characteristics of the product in question, including quality and the promotional activities undertaken by its supplier. The economic substitutability between pharmaceutical products must be assessed in light of the shifts in sales between products intended for the same therapeutic indication, brought about by the changes in the relative prices of those products. A finding that there is no such substitutability reveals the existence of a distinct market, whatever the reasons for that finding, whether it be the intrinsic quality of the product falling within that market or the promotional activities undertaken by its supplier.

The GC was therefore wrong to hold that the EC had placed excessive reliance on price. Instead, the fact that other ACE inhibitors were available for the same therapeutic indication at a lower price, but Servier was able to continue to charge higher prices and maintain (and even increase) its volumes sold, was indicative of perindopril forming a market distinct from those other ACE inhibitors. The CJEU therefore set aside the GC's findings on market definition.

What comes next

This is the end of the road for the appeals by Servier and the six generic manufacturers in relation to the more "conventional" pay-for-delay agreements. As for the CJEU's judgments on the Krka agreements and market definition, the CJEU has ruled as follows:

- It gave final judgment in relation to several of the pleas that Krka and Servier had raised at first instance, upholding that Krka was a potential competitor, that the three agreements could be characterised as sharing the market between Krka's core markets and Servier's core markets, that the agreements had anti-competitive effects, and that the agreements cannot benefit from individual exemption under Article 101(3).

- It could not yet give final judgment in relation to the EC's finding that the agreements restricted competition by object, because the GC had not ruled on certain pleas by Servier and Krka relating to that characterisation. This has therefore been remitted to the GC.
- It could also not yet give final judgment in relation to the infringement of Article 102, so this has also remitted this back to the GC.

Comment

Many debates were had about pay for delay that were no longer hotly contested by the time of these judgments. For example, when the EC first issued its decision, commentators took issue with the idea that a generic manufacturer could be a potential competitor if there were still potentially valid patents in place, and several arguments were raised as to the inability of specific generic manufacturers to enter the market. The legitimacy of settling litigation was also called upon as an argument against findings of infringement. These debates had already been put to rest by the time the CJEU considered the appeals of Servier and the six generic manufacturers. The judgments contain no surprises in this respect.

However, there are some key points in the Court's judgments that risk being snowed under due to the length of the judgments. The first is that complexity is no obstacle to a finding that an agreement restricts competition by object. The CJEU dismissed Servier's argument that the characterisation of an "anticompetitive object" is reserved for agreements the harmful nature of which is proven and easily identifiable. This is a clear statement from the CJEU that (i) it is not necessary that the same type of agreement has already been found to be a restriction by object; and (ii) detailed analysis of agreements, their objectives, and the legal and economic context of which they form part may be necessary to establish that they are a restriction by object. Object restrictions are therefore not only those restrictions that are unlawful on a "cursory look".

This is exemplified by the CJEU's analysis of the three agreements between Servier and Krka. It took an analysis of all aspects of those agreements to find that they in fact gave rise to a sharing of markets between Servier and Krka who are, in the legal and economic context, potential competitors. Although it is now for the GC to decide on the object of the agreements, the CJEU has left the door wide open for such a finding in relation to a complex three-contract arrangement.

The second key point relates to the flexibility of the concept of "agreement" in competition law. As the CJEU's analysis of the three Servier/Krka agreements shows, the anti-competitive agreement is not always identical to the written contract(s). Of course, this is not new. In other contexts, the anti-competitive agreement can be a single clause in a larger contract (such as a non-compete). Where the relevant clause is not ancillary to the wider arrangement, it must be assessed in isolation, so the anti-competitive agreement is actually smaller than the written contract as a whole (a good example is the non-compete in the *Portugal Telecom* case).

Here, the anti-competitive agreement is *larger* than each of the three written agreements between Servier and Krka. The GC was wrong to start its review by looking only at the settlement agreement, and then at the question of whether the licence agreement somehow formed a payment for the restrictions that Krka accepted in the settlement agreement. Instead, it should have taken a holistic view of the three agreements that together formed the infringement of competition law. The concept of agreement is flexible and it stretches in both directions.

The final key point is, of course, the market definition for pharmaceutical products. Here, the CJEU makes a clear choice between functional substitutability and economic substitutability and picks the latter as determinative for market definition. Two products may be functionally substitutable, i.e., they may each be effective in treating the same therapeutic indication, but if there are relative differences in price that do not lead to significant shifts from one product to the other, then this is indicative of there being separate relevant product markets. What matters, at the end of the day, is the economic reality.

**The author was previously a Legal Director at the CMA, where he worked on various cases in the pharmaceutical sector. At Geradin Partners, the author advises companies on competition law issues, including in the pharmaceutical sector. The author was not involved in any of the cases discussed in this blog post.*

This entry was posted on Wednesday, August 28th, 2024 at 11:46 am and is filed under Source: OECD“>Abuse of dominance, European Court of Justice, European Union, Source: OECD“>Market definition, Patent settlements, Pharmaceuticals
You can follow any responses to this entry through the Comments (RSS) feed. You can leave a response, or trackback from your own site.