CPI EU News Presents:

What the *Servier* judgment[1] teaches us about market definition under Article 102 and patent settlement agreements under Article 101

By James Killick, Jérémie Jourdan & Pierre Pêcheux (White & Case)[2]

Edited by Thibault Schrepel, Sam Sadden & Jan Roth (CPI)

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For the first time in many years, the General Court has annulled a European Commission decision finding of abuse of dominance. By highlighting a series of errors in the way the market was defined, the judgment shows that market definition remains a *sine qua non* of Article 102 cases. The Court also confirms that certain patent settlement agreements entered into between patent owners and manufacturers of generics may be restrictive of competition by object – though the Court also concluded that one of the patent settlement agreements was not illegal by object or by effect.

Background

Servier had settled with five manufacturers of generic drugs (Niche, Matrix, Teva, Krka, and Lupin) over litigation regarding the infringement and/or validity of patents held by Servier. The Commission found the settlements unlawful because they included a value transfer to the generics that induced the latter to settle and agree not to enter the market for a certain period of time. The settlements were qualified as restrictions of competition by object and (unusually) effect under Article 101 TFEU.

Regarding the abuse of dominant position, the Commission objected to Servier's acquisition of an early stage but potentially enabling technology for producing perindopril. The Commission found that, together with the settlement agreements, the acquisition amounted to a single overarching infringement of Article 102 TFEU. Servier's dominance was founded on a very narrow market definition: the Commission considered that the relevant market was limited to the molecule perindopril, and accordingly found that Servier was dominant prior to patent expiry in four national markets (where it held nearly 100 percent of that market).

As a result, in 2014, the European Commission adopted a decision finding (i) that Servier and five generic companies infringed Article 101 TFEU; and (ii) that Servier infringed Article 102 TFEU for an overarching abuse consisting in a series of patent settlement agreements and the acquisition of a process technology.

Servier challenged the decision and the fine imposed by the Commission. The General Court heard the parties' arguments at a four-day hearing in June 2017, one of the longest hearings in its history, and rendered a detailed judgment on December 12, 2018.

The GC annuls the market definition: no infringement of Article 102

In its judgment, the Court found that the Commission had mistakenly concluded that Servier held a dominant position. The Commission had made a series of errors in defining the relevant market covering the pharmaceutical product produced by Servier as limited to the molecule perindopril (a medicine used to treat hypertension and heart failure).

Firstly, the Court judged that the Commission had wrongly considered perindopril to be different, in terms of therapeutic use, from the 15 other ACE inhibitors in the same therapeutic class. After a detailed and thorough review of the evidence relied on by the Commission, the Court concluded, based on medical studies, recommendations from international bodies such as the World Health Organization, polls of prescribing

physicians, responses from makers of other ACE inhibitors, and expert evidence submitted by Servier (unrebutted by the Commission), that there were no significant therapeutic differences between ACE inhibitors.

Secondly, the Court found that the Commission reached erroneous conclusions on the propensity of doctors to switch patients treated with perindopril to other medicines. The Commission had wrongly considered that perindopril was in its own market because of "inertia" on the part of prescribing physicians, which meant that patients tended not to be switched to different drugs.

Thirdly, the Court found that the Commission had drawn incorrect conclusions from the evidence relating to the marketing of perindopril. The Court found that the large sums spent by Servier in marketing perindopril and contrasting it to other medicines in the same class was an indicia that perindopril did compete with these other medicines and that the Commission had not adequately taken this element into account.

The Court found that perindopril could be subject to competitive pressure on the basis of factors other than price, notably promotional efforts. The Court found that physicians do not usually make prescription decisions primarily based on the price of drugs, but rather based on their therapeutic differences, the patient's profile, and the physician's past experience. As a result, an analysis of competition between drugs in the pharmaceutical sector should also take due consideration of qualitative, non-price competitive factors. The Court found that the Commission had erred by giving excessive importance to price.

As a result of these errors, the Court annulled the Commission's finding that the relevant market was limited to the molecule perindopril. It then also annulled the finding of abuse and, accordingly, the fine imposed on the basis of Article 102 TFEU.

Patent settlement agreements analyzed under Article 101

The Court confirms the Commission's view that patent settlement agreements could be qualified as restrictions of competition by object when the patent owner pays a generic drug maker (so long as the latter is a potential competitor) in return for an agreement not to challenge the validity of the patent (non-challenge clause) and/or not to commercialize the generic product (non-commercialization clause).

Then, the Court spends several pages explaining under which circumstances a payment may be problematic. It also explains that a side deal linked to the settlement can, in some circumstances, be equivalent to a payment. Without entering into detailed analysis of the findings on each of the agreements, we summarize below the criteria the Court used to reach its findings.

While the Court acknowledged the importance of intellectual property rights and the value of ending litigation by way of settlement, and considered that granted patents are presumed valid, it also found that such presumption of validity does not equate to a presumption of infringement of that same patent by the generic product. The Court noted that, until a generic company has exhausted every means of challenging a patent, the latter cannot be considered as an insurmountable obstacle to entry in the market.

Hence, the Court found that while the existence of a patent is a relevant part of the context, it does not exclude competition from the generic product.

The Court accepted that non-challenge and non-commercialization clauses included in a settlement agreement can be legitimate, even if they are inherently restrictive of competition. Such clauses are needed for the settlement of patent litigation. However, the Court found that when such clauses have been obtained as a result of a financial inducement (and not as a result of the generic company's view of the strength of the patent), then the agreement should be viewed as a market exclusion agreement and qualified as restriction of competition by object.

The Court however identified situations in which a value transfer will not cause the settlement agreement to be anticompetitive.

First, license agreements on market conditions covering the patents in dispute are generally acceptable. This is because the licensing of the litigious patent is normally based on the recognition, by the generic company, of the validity of the patent and therefore is a normal way of settling litigation.

Second, if the payment covers costs that are inherent to the settlement of the litigation, then it cannot be viewed as an incentive to stop competing. An example of such payment could be the generic company's reasonable litigation costs. The Court considered that it was not excluded as a matter of principle that other payments could be seen as inherent to the settlement, such as the cost of stock destruction, or of compensating third party distributors for cancelled contracts, but held that it was the parties' burden to show it.

Third, the Court found that the value transfer has to induce the generic to stay off the market. Hence, payments of insignificant amounts could be acceptable even if they were not inherent to the litigation.

Finally, the Court analyzed "side deals," i.e. commercial agreements linked to the settlement agreement (e.g. because they were signed the same day). The Court considered that such agreements could also be viewed as a value transfer incentivizing the generic company to stop competing if they have not been concluded at market conditions, which the Commission has to show.

The Court upheld the Commission's findings that the settlement agreements concluded with Niche, Matrix, Teva, and Lupin constituted restrictions of competition by object contrary to Article 101 TFEU. The Court found that the generic companies were all potential competitors, and that the settlements included restrictions of their ability to challenge patents held by Servier and to sell their generic products.

By contrast, the Court annulled the finding that the agreement between Servier and Krka constituted a restriction by object or by effect: the Court found that the dispute between Servier and Krka was settled by means of a license and that the Commission had not shown that the license was not concluded at market conditions. As regards the effects of the agreements, the Court found, *inter alia*, that the Commission had failed to show that, absent the agreement, Krka would have entered the market earlier.

Conclusions

The judgment represents continuity with the past when it comes to market definition: it follows a similar approach as the *AstraZeneca* case, where the market was also found to be the class of products. The judgment is helpful in clarifying the factors that need to be considered when analyzing the market, and that it is wrong for antitrust authorities to give too much importance to price when defining markets in this sector.

The real import of the judgment for Article 102 is the Court's ability and willingness to review the facts in detail. The fact that the first reversal of the Commission in a dominance case since the *Hugin* case in the 1970s came in a case like this, involving tens of thousands of pages of evidence, should reassure anyone concerned about "light" judicial review in dominance cases.

When it comes to Article 101, the Court adopts a comparatively strict prohibition of patent settlements involving payments to generic companies higher than costs of the settlement, based on a formal test in which the terms of the agreement are the main element. It will be interesting to see what the Court of Justice will say in the other two cases (*Lundbeck* and *Paroxetine*) relating to the same topic.

Finally, the judgment is also noteworthy as regards the finding of a restriction by effect under Article 101. The principle is that, if an agreement has entered into force, the Commission should not only look at what might potentially happen to competition, judged as of the date of the agreement (*ex ante*). It must also focus on the actual effects (if any) that materialized when the agreement was in force: in other words, the Commission must compare the market situation as it unfolded from the agreement with that which would have likely unfolded without the agreement. This approach maintains consistency with the jurisprudence of the Court of Justice, notably *Mastercard* (C-382/12 P, EU:C:2014:2201).

[1] Judgment of December 12, 2018 T-691/14, Servier SAS, Servier Laboratories Ltd, and Les Laboratoires Servier SAS v. European Commission, (T-691/14, EU:T:2018:922).

[2] James Killick, Partner White & Case; Jérémie Jourdan, Local Partner, Paris and Brussels, White & Case; Pierre Pêcheux, Associate, White & Case. White & Case assisted Servier in this case. The opinions expressed in this note are however those of the authors alone and do not necessarily represent the views of the firm or of its clients.