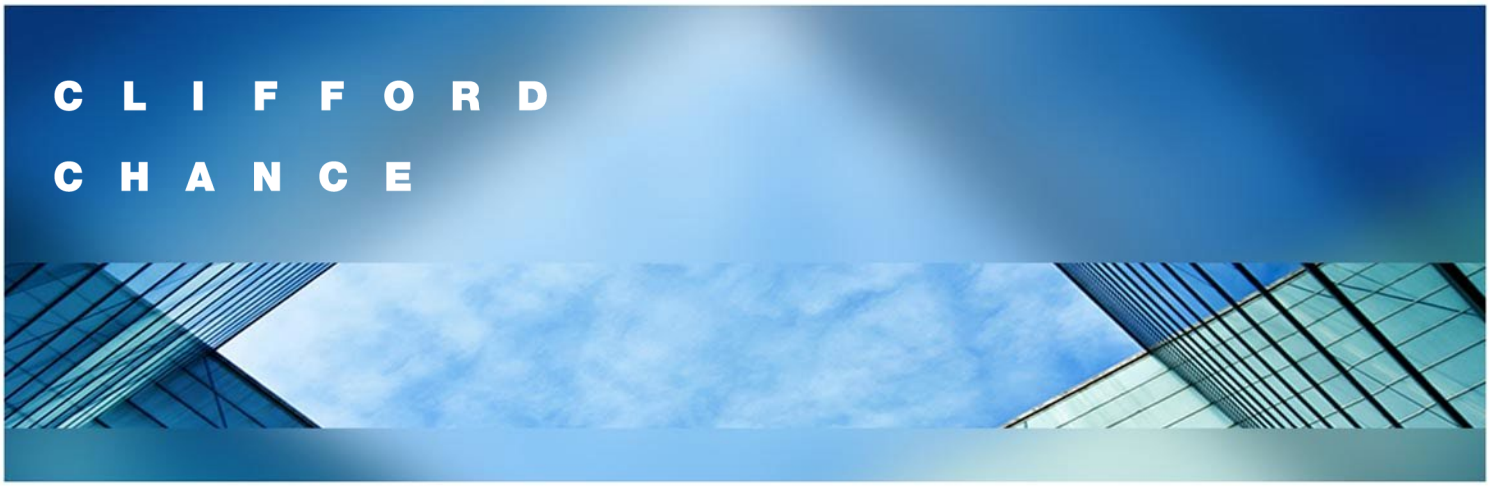

SERVIER SAGA CONTINUES:

The Court of Justice of the European Union clarifies the framework for assessing settlement concluded with licencing agreements and market definition for pharmaceutical products

On 27 June 2024, the Court of Justice of the European Union ("**CJEU**") delivered judgments[1] in the *Servier* case relating to European Commission's ("**EC**") decision from 2014, which fined Servier and several generics manufacturers for concluding a series of agreements, aimed at delaying market entry of generic medicines ("**Decision**"). The EC's Decision was partially annulled by the General Court ("**GC**") in 2018. The EC, Servier and generics manufacturers appealed the GC's rulings.

On appeal, the CJEU set aside certain of the GC's findings. Unlike the GC, the CJEU considered that a combination of a patent dispute settlement agreement that included a non-compete obligation covering certain geographic markets, and a licence agreement relating to that patent covering other geographic markets, constituted a *by object* infringement of Article 101(1) TFEU as an unlawful market sharing agreement. The CJEU also overturned the GC's findings in relation to the market definition, focusing on price-centric assessment of demand substitutability in the pharmaceutical sector.

Key issues

- The combination of a patent dispute settlement agreement and a licence agreement can be classified as unlawful market sharing which restricts competition by object.
- Market-sharing does not require a 'hermetic' division to be characterized as a restriction of competition by object.
- Immediate entry into certain geographic markets can be viewed as out-of-market efficiencies and irrelevant for determining the existence of an infringement on other geographic markets covered by the settlement agreement.
- Substitutability of two pharmaceutical products should not be limited to assessing their functional characteristics but requires assessing whether the demand would shift to substitutes products in case of a small but permanent price increase.

BACKGROUND

Servier held a number of patents in relation to the active ingredient of perindopril (erbumine), a treatment for hypertension. The validity of Servier's "947 patent" was contested by several generics manufacturers before the national courts in various EU Member States. Servier eventually concluded settlement agreements with these manufacturers, who agreed not to challenge the validity of the patent and refrain from entering the perindopril market, in return for what the EC considered value transfers. On that basis, the EC held that all settlement infringements infringed Article 101(1) TFEU by object.

The GC upheld the EC Decision regarding all settlement agreements between Servier and generics manufacturers, except the one between Servier and Krka. Servier and Krka had agreed that Krka would not enter certain EU markets (Servier's core markets) and, concomitantly, the two parties concluded a licensing agreement, under which Krka was allowed to enter other EU markets (which were Krka's core markets). It is the combination of the settlement and licencing agreement, which according to the EC Decision resulted in market sharing, that was at issue in the present case.

1 See in particular, Case C-176/19 P, *Commission v Servier;* C-151/19 P, *Commission v Krka*.

A combination of settlement and licensing agreements can restrict competition by object: It is the context, and not the form of the agreement that matters

The CJEU recalled that linking a patent dispute settlement agreement to a licence agreement concerning that patent does not, in itself, constitute a conduct restricting competition. They can be concluded with a legitimate aim and entirely lawfully based on the parties' recognition of the validity of the patent in question.

However, the CJEU held that the fact that licensing agreements generally pursue a legitimate objective in abstract and that their wording does not reveal an anticompetitive intent, cannot exclude that they can form part of a restriction of competition by object, depending on their origin, legal and economic context and specific characteristics of the market in which they occur.

Licence agreements concluded at arm's length can still form part of a restriction of competition. The GC considered that, if there is a genuine dispute relating to a patent, a settlement agreement including clauses restrictive of competition (e.g., non-marketing and non-challenge clauses), associated with a licence agreement is in principle legitimate. It can therefore only be qualified as a restriction of competition by object if the EC demonstrates that the license agreement was not concluded at arm's length and thus masks a reverse payment.

The CJEU disagreed. It held that the GC disregarded the actual nature of the infringement, which pursued a market-sharing objective. According to the CJEU, the GC wrongly focused its analysis merely on the form and legal characteristics of those agreements, rather than examining their actual relationship with competition.

Granting of licence as an inducement to share markets. The CJEU considered that, as the settlement and licence agreements were economically connected, they should have been examined together. It found that the licence granted to Krka on its core markets was a prerequisite for Krka agreeing to not enter Servier's markets pursuant to the settlement agreement. The CJEU agreed with the EC that the licence agreement acted as a significant economic incentive for Krka to accept the restrictions and constituted a transfer of value from Servier to Krka. Consistent with its previous case-law, the CJEU also verified that this substantial transfer of value could not have any other explanation but the mutual interest not to engage in competition on the merits.

Market sharing does not require a 'hermetic' geographic division. The CJEU also explained that market sharing exists even if the division of territories is not hermetic. It is not necessary that markets are exclusively reserved for a certain party. Therefore, the fact that Servier was not excluded from Krka's core markets does not preclude the characterisation of market sharing.

Pro-competitive effects, particularly "out-of-market" efficiencies, are irrelevant to characterize a by-object restriction. The CJEU clarified that potential pro-competitive effects are not necessarily relevant when determining whether an agreement presents a sufficient degree of harm to be restrictive of competition by object under Article 101(1) TFEU. In particular, the parties cannot rely on positive effects that arise in markets which are not covered by the infringement.

The CJEU considered that even if the licensing agreement had some positive effects on competition due to Krka being allowed to launch its generic drug immediately in its core markets, without running the risk of patent infringement, these positive effects could not be taken into account for the purpose of determining the existence of the infringement, which was only limited to Servier's core markets.

Settlement agreement as a "strong indication" of potential competition. An agreement can restrict competition only if companies are at least potential competitors. Potential competition exists if, notwithstanding the existence of patents, there are "*real and concrete possibilities*" to enter the market. In particular, the authorities should assess whether a generics manufacturer took sufficient preparatory steps and that there are no insurmountable barriers to that entry. The CJEU also recalled that an agreement between a generics manufacturer which is not yet present on the market and originator is "*a strong indication*" that they are competitors.

In relation to probatory value of evidence, the CJEU makes clear that not all internal documents hold the same value. For example, the views of operational R&D units, indicating that they do not intend to compete with the originator, do not necessarily reflect the strategic decision of the management, when evidence also shows that generics manufacturer continued to produce generics despite suffering setbacks in patent litigation.

The CJEU makes clear that assessment of all relevant elements pertaining to potential competition, which the GC failed to carry out, is *always* necessary when there are still pending disputes on patents. Only if patent's validity has been definitely established in all courts before which the question has been brought would the situation of potential competition be inconceivable.

For companies who are negotiating settlement agreements, *Servier* case acts as a useful reminder to consider all aspects of agreements holistically, avoiding any transfers of values which would induce their (potential or actual) competitors to refrain from entering the market. In particular, settlement agreements containing deferred entry for different EU markets may attract scrutiny. Companies should also be alert to potentially different positions across its organisation in relation to the strength of patents and statements made in internal documents.

Market definition: The CJEU confirms the EC's narrow market definition, with a price-centric view of demand substitutability

In its Decision, the EC considered that the relevant market, on which Servier was dominant, was the market for medicinal products containing perindopril. According to the EC, perindopril was not substitutable with other angiotensin converting enzyme inhibitors ("**ACE inhibitors**"), as the fall in prices of these ACE inhibitors did not result in a transfer of demand from perindopril to those ACE inhibitors, and perindopril price has remained stable.

The GC annulled that finding, claiming that the EC has made an error in the assessment of substitutability, attaching excessive importance to the price. It considered that, in the context of pharmaceuticals, price competition is less relevant. Demand essentially comes from physicians, who generally focus on product characteristics instead of prices, as neither they nor the patients pay for the drugs due to health insurance mechanisms. According to the GC, the starting point to determine the relevant market is whether two products are therapeutically interchangeable, from a physician's perspective. The GC found

that perindopril and ACE inhibitors were indeed interchangeable. According to the GC, ACE inhibitors exerted qualitative, non-price competitive pressure, which should have been taken into account.

The CJEU disagreed. Despite specific characteristics of the pharmaceutical sector, in which price is significantly less relevant, the CJEU considered that the substitutability of two products should not be limited to assessing their functional characteristics, but requires assessment whether they are "economically substitutable" – *i.e.*, it requires analysing whether the demand between two products would shift in case of a small but permanent price increase. If it does not, this reveals the existence of separate markets.

The CJEU's judgment therefore reveals a very price-centric view of demand substitutability, which is somewhat surprising given that, on pharmaceutical markets, competition is not exclusively price driven. The statement of the CJEU according to which the lack of shifts in sales following a price decrease excludes substitutability is particularly puzzling, considering that the demand is largely not price sensitive. Also, this position contrasts somewhat with the EC's updated Market Notice, which specifically recognises that in certain cases non-price parameters, such as functionalities and intended use, are particularly relevant for the assessment of substitution. It seems that in markets in which price is still an element of competition (as opposed to "zero price" markets), the CJEU considers that market boundaries should therefore be assessed from the perspective of cross-price elasticity.

The case does not, however, end with the CJEU's judgment. Having annulled the GC's abuse of dominance analysis and the evaluation of settlement agreements with Krka, the CJEU referred these issues back to the GC for further evaluation for the next stage in this long saga.

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