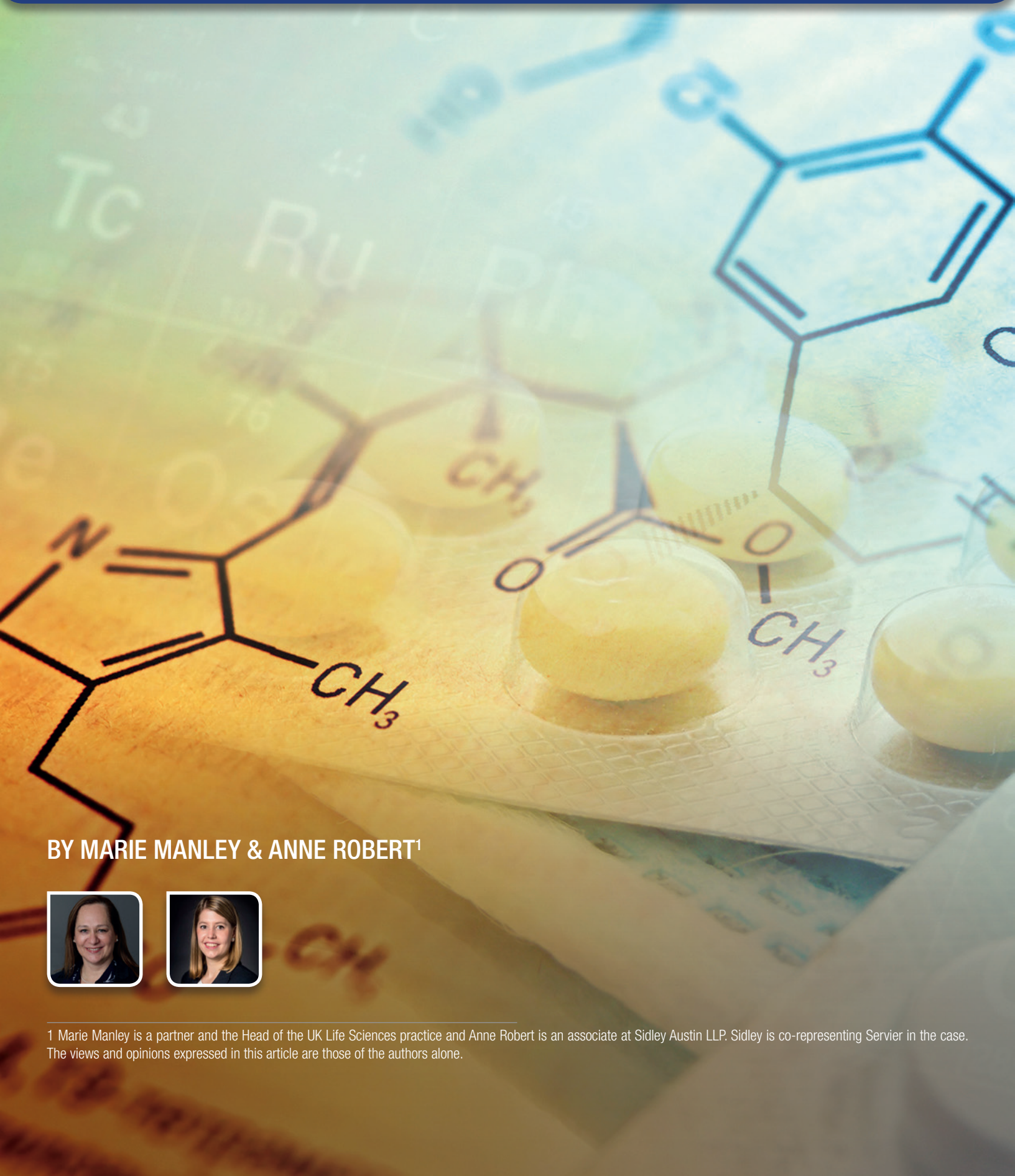
TO SETTLE OR NOT TO SETTLE? AN ANALYSIS OF THE *SERVIER* PATENT SETTLEMENT CASE AND ITS PRACTICAL IMPLICATIONS



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I. INTRODUCTION

Investigations into patent settlement agreements are still fairly new in the European Union. The European Commission ("Commission") adopted the Final Report of its inquiry into the pharmaceutical sector in July 2009. Since then, it has published eight reports on the monitoring of patent settlement agreements, and has adopted two infringement decisions (with a third investigation still ongoing). Each of the decisions was appealed and led to a judgment by the General Court ("GC").

The most recent development is the GC's judgment in the *Servier* case.[2] This case is particularly noteworthy because (i) the GC refuted the Commission's assessment of the product market definition and hence the dominance abuse under Article 102 of the Treaty on the Functioning of the European Union ("TFEU"), which marks the first annulment in many years;[3] and (ii) the Commission's finding that the settlement agreement between Servier and the generic company, Krka, infringed Article 101 TFEU. On the other hand, the GC agreed with the Commission that the agreements between Servier and the other generic companies each restricted competition "by object". The GC's analysis in that context raises fundamental questions about the interplay between competition law and intellectual property rights ("IPRs").

This article reviews the key takeaways from, and the possible implications of, the *Servier* case for the pharmaceutical industry. It focuses in particular on some of the key issues from an IP and regulatory perspective. The GC's ruling is not final yet as the Commission and all the parties have appealed the findings to the Court of Justice ("CJEU").[4] Two other cases are currently pending before the CJEU: the *Lundbeck* case[5] and a referral from the UK Competition Appeal Tribunal in the *Paroxetine* case.[6] Although they all involve patent settlement agreements concluded between originator and generic companies, each of these cases presents its own specificities, and parallels can only be drawn to a limited extent.

2 Case T-691/14, *Servier and Others v. Commission*, EU:T:2018:922.

3 The last full annulment of an Article 102 TFEU decision on the merits was 15 years ago in the *Atlantic Container* collective dominance case: Joined Cases T-191/98 and T-212/98 to T-214/98, EU:T:2003:245.

4 Cases C-201/19 P, *Servier and Others v. Commission*; C-176/19 P, *Commission v. Servier and Others*; C-198/19 P, *Teva UK and Others v. Commission*; C-151/19 P, *Commission v. Krka*; C-144/19 P, *Lupin v. Commission*; C-164/19 P, *Niche Generics v. Commission;* C-166/19 P, *Unichem Laboratories v. Commission*; C-197/19 P, *Mylan Laboratories and Mylan v. Commission*.

5 Case C-591/16 P, *Lundbeck v. Commission*.

6 Case C-307/18, *Generics (UK) and Others*.

II. THE FACTUAL BACKGROUND AND CONTEXT OF THE *SERVIER* CASE

On July 9, 2014, the Commission fined Servier and five generic companies (Niche, Matrix, Teva, Krka, and Lupin) for having entered into patent settlement agreements that allegedly violated Article 101 TFEU.[7] According to the Commission, each of the agreements restricted competition "by object" because they included a value transfer from Servier to the generic company, which allegedly induced the generic companies to settle and refrain from entering the market for a determined period. The Commission also found that the settlement agreements restricted competition "by effect". The agreements related to perindopril, Servier's angiotensin-converting-enzyme ("ACE") inhibitor, used to treat hypertension and heart failure.

In addition, the Commission held that Servier abused a dominant position in violation of Article 102 TFEU through the combination of the patent settlements and the acquisition of an upstream process technology to produce the active pharmaceutical ingredient ("API") for perindopril, which according to the Commission was non-infringing.

The Commission alleged that Servier put in place an overall strategy that was aimed at excluding its generic competitors and/or delaying their entry into the market. The Commission defined the relevant product market downstream very narrowly, limiting it to the perindopril molecule despite the fact that the therapeutic class of ACE inhibitors included 16 similar molecules, all treating the same therapeutic indication. As a result, it found that Servier was dominant on that market. The Commission also found Servier dominant on the upstream market for the process technology.

Servier (and each of the generic companies) appealed the Commission's decision ("Decision") in its entirety. On 12 December 2018, the GC upheld the Decision as to the illegality of the patent settlement agreements, except for the agreement between Servier and Krka, where the GC ruled that it did not restrict competition "by object" and "by effect." It annulled the Decision in so far as it relates to the product market definition and dominance finding. Servier's total fine was reduced from €331 million to €228 million.

III. THE COMPETITION LAW ASSESSMENT OF PATENT SETTLEMENT AGREEMENTS

A. The Legal Test

The GC confirmed the Commission's overall test pursuant to which a patent settlement agreement will restrict competition "by object" if (i) it is concluded between an originator and a generic company that qualifies as a potential competitor; (ii) the originator company makes a value transfer (generally a payment) to the generic company; and (iii) that transfer is made in return for the latter's commitment not to challenge the validity of the underlying patent (non-challenge clause) and/or not to commercialize the generic product (non-commercialization clause).[8]

B. The Role of IPRs

The *Servier* case took place within a particular factual context. The compound patent for perindopril had been filed with the European Patent Office ("EPO") in 1981 and, following the grant of supplementary protection certificates in most Member States, patent protection expired in 2003. However, at the time of the agreements, several process patents were still in place, including patent EP1296947 ("947 patent"), which was at the heart of the dispute and concerned the alpha crystalline form of the perindopril erbumine salt and the process for its preparation.

7 Case AT.39612, *Perindopril (Servier)*.

8 It is interesting to note that in the *Lundbeck* case, the GC took a number of "additional factors" into account, including: the fact that the value transfer by Lundbeck to the generic companies was allegedly based upon each generic company's expected profit had it entered the market; the fact that none of the agreements contained a commitment by Lundbeck to refrain from infringement proceedings against any of the generic companies after the agreements had expired; and that the agreements did not in fact settle any patent dispute. The GC also held that the commitments by the generic companies went beyond the scope of the contested process patents and thus beyond what Lundbeck could have obtained by successfully litigating.

In a context where the compound patent has expired but several other patents (e.g. process, formulation, *etc.*) remain in place, generic companies that would like to enter the market have several options. They can seek a declaration of non-infringement, file an action of invalidity, or enter "at risk," i.e. launch the product without "clearing the way".[9] If the originator company brings an infringement action, the generic company can also counterclaim the invalidity of the patent(s). It should be noted that the burden of establishing the invalidity of a patent is not easy. The originator company, on the other hand, can obtain an injunction if there is a sufficiently serious threat that the generic company will enter the market with an infringing product. In the *Servier* case, litigation was ongoing with each of the generic companies, involving the 947 patent but also several of Servier's other process patents. At the time the agreements were concluded, none of the cases had resulted in a final ruling on the merits by a national court; Servier's 947 patent was, however, successfully upheld by the EPO in the first instance. In addition, Servier was successful in a summary invalidity action brought by one of the generic companies (Krka) and was also granted a number of preliminary injunctions against generic companies by the English Patent Court.

The GC acknowledged the importance of IPRs and the value of settlements. It also recognized the presumption of validity of granted patents. However, the GC appears to have taken the position that competition law rules should prevail over IPRs, in this case patent rights. Neither the CJEU jurisprudence nor any rule of law requires that such a preference be given to one set of rules over the other. On the contrary, the CJEU has consistently emphasized the importance of protecting IPRs[10] and the crucial importance to balance competition law and IPRs. This balance is particularly relevant as both serve a common goal, namely promoting consumer welfare.

C. What is Meant by "Potential Competition"

The GC considered that, in order to establish that the generic companies qualified as potential competitors, the Commission had to show that the generic companies had "real and concrete possibilities" to enter the market. In the GC's view, it was sufficient for that purpose that the Commission showed that the generic companies had taken steps and invested in the development, manufacturing, and commercialization of a generic form of perindopril. To rebut the Commission's case, the GC said that the innovative company (i.e. Servier) had to demonstrate that the generic companies were faced with "insurmountable obstacles," preventing them from entering the market.

The GC's analysis is problematic for several reasons, some of which are developed below.

First, the GC imposes an impossible task on the innovative company given that e.g. the generic application for a marketing authorization is not a public document which can be accessed by third parties and it is therefore impossible for a third party, such as Servier in this case, to know the details of the difficulties faced by a generic company in the application process.

Further, the GC considered that the mere existence of a patent was not an "insurmountable obstacle" to entry because the generic companies could have entered "at risk". The GC disregards the scope of patent protection, which provides the patent owner the right to stop any infringing product falling within the scope of the patent from being commercialized in the protected jurisdiction (see e.g. the Agreement on Trade-Related Aspects of Intellectual Property Rights and Directive 2004/48/EC on the enforcement of IPRs).

The GC also disregarded the value to originator companies of obtaining a preliminary injunction or judgment at first instance upholding the validity of the patent. According to the GC, an injunction is temporary and first instance judgments can be overruled on appeal and are therefore not final. Neither one of them therefore rules out generic competition. However, an injunction or a judgment at first instance should be sufficient evidence that the patent concerned is an obstacle to entry for generic companies. Injunctions are a fundamental part of the patent enforcement system. By not recognizing their value, the GC seems to suggest that damages should be the only appropriate remedy for patent infringements. Moreover, if only a final judgment on the merits can rule out generic competition, this would put an impossible burden of proof on the companies given that the whole purpose of a settlement is to end a dispute before a final ruling is issued.

In the *Servier* case, the GC also agreed with the Commission that the technical, regulatory and/or financial barriers to entry that the generic companies were facing did not prevent them from being potential competitors of Servier. The perceptions of the generic companies on the likely outcome of the litigation were only an indication of their intention, not their ability, to enter the market.

9 Which consists in resolving any patent issues before entering the market either by applying for a revocation of the patents concerned or seeking a declaration of non-infringement regarding the product the generic company intends to launch.

10 See e.g. Case C-170/13, *Huaweï v. ZTE*, EU:C:2014:2391.

D. On the Restriction of Competition "by object"

The GC recognized that non-challenge and non-commercialization clauses included in a settlement agreement can be justified. This is good news, as such clauses are indispensable for the settlement of any patent dispute. Indeed, no company would consider settling a dispute regarding the validity/infringement of a patent if the day after the settlement one party could re-commence legal proceedings invoking the same claims and counterclaims of invalidity/infringement as were settled.

According to the GC, a settlement agreement becomes problematic if it includes a reverse payment inducing the generic company to accept such clauses and limit its efforts to enter the market. It is in that case the inducement, rather than the recognition by the generic company of the validity of the litigious patent, that constitutes the real reason for the restrictions in the agreement. A patent settlement agreement that fulfils these criteria will qualify as a market exclusion agreement, and thereby a "by object" restriction of competition.

On that basis, the GC found that the agreements concluded between Servier and the generic companies (except Krka) infringed Article 101 TFEU. The GC considered that it did not have to examine whether the agreements also restricted competition "by effect".

The GC's qualification of the agreements in the *Servier* case as "by object" restrictions also raises a number of concerns. This article will not cover them all, but focuses on a few IP and regulatory aspects.

First, as underlined by Advocate General Nils Wahl in the *Cartes bancaires* case,[11] only conduct whose harmful nature is proven and easily identifiable, in the light of experience and economics, should be regarded as a restriction of competition "by object," and not agreements which, having regard to their context, have ambivalent effects on the market. Patent settlement agreements have no such harmful nature and are fundamentally different from market sharing agreements concluded e.g. in the *BIDS* case,[12] which did not concern IPRs. Although, as previously explained, the GC recognized the presumption of validity of the patents, it did not seem to recognize the value of such patents and the specific context for each of the agreements. Patent settlements, however, are inherently complex and cannot be analyzed in the same way as cartel agreements. The CJEU has explicitly clarified that restrictions "by object" should be reserved to agreements that are inherently harmful to competition.[13] Out-of-court settlements of patent disputes, which should generally be encouraged, are not inherently anticompetitive and should therefore be subject to a "by effects" analysis.

Second, the GC did not recognize the importance for the generic companies of being among the first wave of entrants on the market on the one hand, and the consequences of generic entry for the patent holder on the other. For the generic, it is important to be the first in this situation, or among the first wave of those entering the market, in order to secure a large slice of the initial profit. If the generic company is not within the first wave of entrants (e.g. because it faces regulatory issues), there is little value for it in entering the market afterwards, as competition will have driven prices to the lowest figure capable of covering costs, and thus to a low profit. As a result, the possibility of a "super profit", available to the generic companies that are part of the first wave of market entries, will be gone. A patent settlement agreement between an originator and a generic company cannot be assessed without taking these factors into account. For example, a generic company that realizes that, for some reason e.g. regulatory difficulties, it will not be able to enter the market on time (namely with the "first wave" of generics), may be inclined to settle rather than continue litigation. It seems odd to prevent such company, once it has decided to settle for its own reasons, from negotiating the best deal possible with the originator (e.g. by negotiating the best possible payment).

Third, other factors such as bifurcation, which exists in many EU Member States and pursuant to which the infringement/invalidity claims of a patent can be subject to different procedures, creating a risk that litigation lasts for a long time and occurs simultaneously in various jurisdictions; or the cost of having to pursue proceedings against several parties and/or across different jurisdictions and the uncertainty of their outcome, have to be taken into account when assessing the context of, and rationale behind, patent settlements.

Fourth, the settlement of one litigation proceeding may have little effect on competition if several parallel litigations are ongoing. For example, if a settlement results neither in delaying generic entry nor in delaying the resolution of the legal proceedings challenging the validity of the patent, it seems rather excessive to characterize it as restriction "by object" simply because it includes a payment. In other words, the context matters as much as the terms of the settlement.

11 See Opinion of Advocate General Wahl delivered on March 27, 2014 in Case C-67/13 P *CB v. Commission*, EU:C:2014:1958.

12 See Case C-209/07, *Beef Industry Development and Barry Brothers*, EU:C:2008:643.

13 *See* Case C-67/13 P, *CB v. Commission*, EU:C:2014:2204.

E. The Value Transfer

Despite the above, not all patent settlement agreements including a payment will necessarily be problematic. Indeed, patent settlements *per se* are not an issue, and the GC highlighted that value transfers need to be looked at carefully. According to the GC, a value transfer that covers costs inherent to the litigation is unlikely to be considered an incentive to delay market entry. The GC also clarified that other payments could be legitimate, although it will be up to the parties to show that such costs were inherent to the settlement of the litigation and justify the amounts in question. Although we cannot enter into the specificities of the *Servier* case in this article as the case is under appeal, in assessing whether a value transfer is justified one should look at many factors, including the commercial context surrounding the settlement agreement. For example, considerations such as the desire to avoid costly and time-consuming litigation in multiple jurisdictions, or the purchase of patents, or even to secure a generic distributor in a particular jurisdiction should be considered. The determination of the impact of the value transfer should thus be made on a case by case basis, taking into account all relevant elements which could justify its amount.

Moreover, an amount that is insignificant will not give rise to an inducement not to enter the market and will likely be acceptable, even if not inherent to the litigation.

F. The Krka Agreement

The GC considered that certain agreements will not give rise to a suspicion of a restriction of competition "by object". This is the case for example where a settlement agreement is accompanied by a license agreement concluded at market conditions and is based on the recognition, by the generic company, of the validity of the patent. Such an agreement will likely escape competition law scrutiny.

On that basis, the GC found that the agreement between Servier and Krka, pursuant to which Krka received a license on the litigious patent in seven European countries, could not be characterized as an illegal market sharing agreement restricting competition "by object". The GC found that the royalty paid by Krka under the license agreement was consistent with market value and therefore did not consist in a reverse payment. Further, the settlement agreement with Krka was concluded after the EPO had upheld the validity of the relevant patent and the granting of an injunction against Krka by the High Court in the UK. The GC found that this context was a key consideration for Krka to decide to settle, i.e. that the settlement was reached on the basis of the strength of the patent.

The agreement with Krka is also the only one that was subject to a "by effects" analysis by the GC. In its analysis, the GC found that the Commission did not prove that Krka would likely have entered the market earlier with its own generic product, in absence of the agreement. The GC's test is consistent with previous case law.[14]

The GC rejected the Commission's theory that the fact that Krka was removed as a competitive threat was in itself sufficient to establish appreciable effects on competition, absent any proof of effects on parameter of competition such as price, quantities, quality, and innovation. It was moreover not established by the Commission that Krka's continuation of the proceedings against the 947 patent would probably, or plausibly, have allowed a faster or more complete invalidation of the patent, given that the challenge of the 947 patent was continued in the UK by Apotex and before the EPO by several other challengers.

IV. THE ANALYSIS OF RELEVANT PRODUCT MARKET UNDER ARTICLE 102 TFEU

The GC considered that the Commission's definition of the relevant market contained several errors. Most notably, when analyzing the competitive constraints on perindopril, the Commission did not sufficiently assess the substitutability of perindopril and other ACE inhibitors in terms of their therapeutic use, underestimated the propensity of patients treated with perindopril to be switched to another ACE inhibitor, and gave too much importance to the price factor.

A. The Importance of Therapeutic Substitutability

The GC disagreed with the Commission's emphasis on price analysis. The Commission concluded that the market should be defined narrowly, and be limited to perindopril in its originator and generic versions, because the different ACE inhibitors did not impact the price of perindopril.

14 Case C-382/12 P, *MasterCard v. Commission*, EU:C:2014:2201.

According to the Commission, because sales of perindopril were more significantly affected by the entry of the perindopril generic than by the entry of generics of other ACE inhibitors, other ACE inhibitors did not exercise competitive pressure on perindopril.

The GC, on the other hand, considered that all the ACE inhibitors belonging to the same class were substitutable; and that perindopril was subject to competitive pressure from "qualitative" factors other than price, e.g. the promotional efforts by manufacturers of other ACE inhibitors; or the fact that doctors do not usually make prescription decisions primarily based on price but based on therapeutic differences, as well as the patient's profile. The GC's analysis is in line with previous case law.[15]

The GC emphasized that when analyzing competition between medicinal products in the pharmaceutical sector it is crucial to take qualitative, i.e. non-price competitive factors, in particular therapeutic effectiveness, into account. Markets must thus be defined following a global analysis, including price and non-price factors.

B. Doctors' Prescribing Behavior

The GC considered that the Commission erred when assessing doctors' tendency to switch patients treated with perindopril to other medicines.

The Commission had found that perindopril was in a market of its own because of doctors' reluctance to switch patients to different medicines. The GC disagreed and held, based on the evidence before it, that such a theory was not established and that the Commission's assessment of the evidence relating to the marketing of perindopril was erroneous. Moreover, the GC considered that the fact that Servier made substantial investments to market perindopril and tried to differentiate it from other ACE inhibitors was a relevant factor showing that perindopril did compete with these other medicines.

In addition, according to the GC, the medical studies, recommendations from international organizations (e.g. the World Health Organisation), surveys of prescribing physicians, responses from producers of other ACE inhibitors, and expert statements, did not prove that there were significant therapeutic differences between ACE inhibitors.

The GC annulled the Commission's product market definition which limited the relevant market to the perindopril molecule only. As a result, it also annulled the Commission's finding that Servier was dominant on the product market as defined in France, the Netherlands, Poland and the UK. The definition of the relevant API technology market (which was based on the product market) was also annulled, and so was the part of the fine imposed on Servier relating to the infringement of Article 102 TFEU.

It is noteworthy in this context that the GC carried out a detailed and thorough review of the vast evidence before it. In the end, it conducted a full judicial review of the Commission's market definition and dominance assessment. This shows the importance of internal documents and evidence in proceedings before the GC. Whereas the Commission is increasingly requesting large amounts of documents from companies during investigations and heavily relies on internal company documents to establish its theories of harm, the *Servier* case shows that such documents and scientific evidence are equally important for companies' defense.

V. CONCLUSION

With appeals pending before the CJEU, the final word has not been spoken just yet. In particular, it will be interesting to see how the CJEU, which has always been the protector of IPRs, will strike the balance between such rights and competition law. In addition to the CJEU's judgment in the *Servier* case, the rulings in the *Lundbeck* and *Paroxetine* cases may also provide further clarifications. During the hearing in the *Lundbeck* case on 24 January 2019, it was clear that the CJEU is carefully considering how to assess patent settlement agreements and where to draw the line between legal and illegal agreements.

15 E.g. Case T-321/05, *AstraZeneca v. Commission*, EU:T:2010:266.

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