Servier v. Commission (Case T 691/14): 5 crucial points of the second “pay-for-delay” decision of the EU General Court

Kluwer Competition Law Blog
December 18, 2018

Amalia Athanasiadou

Please refer to this post as: Amalia Athanasiadou, ‘Servier v. Commission (Case T 691/14): 5 crucial points of the second “pay-for-delay” decision of the EU General Court’, Kluwer Competition Law Blog, December 18 2018, http://competitionlawblog.kluwercompetitionlaw.com/2018/12/18/servier-v-commission-case-t-69114-5-crucial-points-of-the-second-pay-for-delay-decision-of-the-eu-general-court/

Introduction

Servier v. Commission (Case T-691/14) is the second decision of the General Court of the European Union on “pay-for-delay” patent settlements in the pharmaceutical industry,[1] following the 2016 decision of the Court on *Lundbeck v. Commission* (Case T-472/13).[2] In 2014, the European Commission imposed fines totalling €427.7 million for violations of European competition laws to the originator Servier (Servier S.A.S., Laboratoires Servier SAS and Servier Laboratories Ltd) and the generic manufacturers Niche Generics Ltd (“Niche”)/Unichem Laboratories Ltd (“Unichem”), Matrix Laboratories Ltd (“Matrix”), Teva (Teva Pharmaceuticals Ltd, Teva UK Limited, Teva Pharmaceuticals Europe B.V.), Krka Tovarna Zdravil d.d. (“Krka”), and Lupin Ltd (“Lupin”) which have concluded patent settlement agreements between 2005-2007, related to Servier’s blockbuster antihypertensive drug perindopril.[3] Perindopril was Servier’s best-selling product in 2006 and 2007, accounting at that time for 30% of the company’s total turnover.[4] Servier and the settling generic manufacturers filed actions against the decision of the EU Commission before the General Court; the hearings took place on June 2017 and lasted four consecutive days.

On December 12, 2018 the General Court rendered its much awaited judgment on *Servier v. Commission*, upholding the Commission’s findings of the restriction of competition by object under Article 101 TFEU for the settlements between Servier and Niche, Matrix, Teva and Lupin. However, the Court disagreed with the Commission’s finding that the settlement between Servier and Krka constituted a restriction of competition either by object or effect and annulled the Commission’s decision for that part. With regard to the fines imposed by the Commission on Servier, the Court confirmed the fines imposed for the Niche, Teva and Lupin settlements, but reduced the amount of the fine imposed to Servier for the Matrix settlement by 30%, while it annulled the fine imposed for the Krka settlement. Additionally, the Court did not uphold the EU Commission’s finding of an abuse of dominant position by Servier under Article 102 TFEU and found that the Commission did not properly establish that the relevant product market was limited to Servier’s drug perindopril, so as a result failed to establish the dominant position of Servier in the relevant market; thus the Court reversed the respective part of the Commission decision and annulled the relevant fine.

Outline

It is extremely difficult to provide a short and useful summary of the overly detailed decision of the General Court that is 1968 paragraphs long and available only in French at the moment of this writing. Instead of attempting the impossible, this note will focus on a short outline of 5 points of the *Servier* decision that are crucial in the author’s view:

- **The 3 criteria upheld by the Court in order to determine whether the patent settlements at issue constitute restrictions of competition by object**
- **Potential competition vis-à-vis the presumption of patent validity**
- **Reverse payments & costs inherent to patent settlements**
- **Side deals concealing value transfers vs. the Krka licensing and assignment agreements**
- **The importance of the definition of the relevant market in pharmaceutical cases**

Analysis

I. The 3 criteria upheld by the Court in order to determine whether the patent settlements at issue constitute restrictions of competition by object

In broad lines, the Court upheld the three criteria used by the Commission in order to determine if the patent settlements at issue constituted restrictions of competition by object within the meaning of Article 101 TFEU:

- whether the originator (Servier) and the generic manufacturers were at least potential competitors;
- whether the settlements at issue contained non-challenge and non-commercialisation clauses;
- whether the originator obtained the commitment of the generic manufacturers to accept the non-challenge and non-commercialisation clauses in the patent settlements in return for a value transfer and not due to the parties’ assessment of the validity of the underlying patent right.[5]

Unlike its decision in *Lundbeck* – whereby the Court had stressed that the size of a reverse payment may constitute an indicator of the weakeness of the patent at issue and of the possibility that it is held invalid –[6] the Court’s decision in *Servier* discussed the size of the reverse payment settlements only indirectly, e.g. when examining which costs are “inherent” to a settlement.

II. Potential competition vis-à-vis the presumption of patent validity

An undertaking constitutes a potential competitor if there are real and concrete possibilities that it enters the market and competes with the already established undertakings, following an economically viable strategy,[7] without facing insurmountable obstacles on its entry to the market.[8] In *Servier*, the Court discussed whether the existence of the patents at issue and of the obligation for the generic manufacturers to obtain marketing authorization for their generic products could be considered as insurmountable barriers to entry.[9] Confirming its approach in the *Lundbeck* decision,[10] the Court stressed that potential competition may exist in a market before the expiration of a patent[11] and that the presumption of patent validity did not impede competitors from launching their generic drug product at risk.[12] A very important point of the Court’s reasoning is that patent validity does not exclude *ipso facto* potential competition from the market, unless it is combined with a finding of infringement of the patent by the respective generic drug versions.[13] As long as generic manufacturers have the possibility to contest patent validity and the infringement of the relevant patents by their generic versions, such patents do not constitute insurmountable barriers to generic entry.[14] The Court also found that it was sufficient for the Commission to establish the existence of a marketing authorization application and of the active participation of the generic company to the application procedure in order to show if such generic company exercised competitive pressure. The burden would then shift to the undertakings to show that there were problems which objectively prevented the grant of a marketing authorisation.[15]

III. Reverse payments & costs inherent to patent settlements

Following the same approach as in the *Lundbeck* decision,[16] the Court stressed that even if the limitations imposed on the generic challenger’s commercial autonomy do not exceed the material scope of the patent, such limitations may constitute a breach of Article 101 TFEU if they cannot be justified and do not result from the parties’ assessment of the patent validity and infringement but from a transfer of value.[17] The Court noted that the existence of a reverse payment may raise suspicions as to whether the settlement is based on the recognition of the validity of the underlying patent by the parties; however, this is not sufficient to establish a restriction of competition by object.[18] The Court found that in order to determine whether a reverse payment constitutes an incentive for the generic manufacturers to accept clauses of non-challenge and non-commercialisation as part of the patent settlements, it was relevant to examine i) the payment’s nature; ii) the payment’s justification; iii) whether such reverse payment covered costs that were inherent to a patent settlement.[19] According to the Court, costs inherent to patent settlements are for instance the litigation costs of the generic company in the context of the dispute at issue. On the contrary, costs that are external to the dispute and to the settlement, such as for instance the manufacturing costs of the allegedly infringing generic products or the costs of Research and Development incurred by the generic manufacturer, cannot be considered as inherent. The Court stressed that the burden of proof is on the settling parties to show that the reverse payments at issue covered costs that were inherent to the settlement or the dispute and to then justify the amount of the reverse payment.[20]

IV. Side deals concealing value transfers vs. the Krka licensing and assignment agreements

Side-deals were a core element Servier’s settlements with the generic manufacturers, which were polyvalent and highly complex, forming a net of licensing, distribution and acquisition agreements. In its decision in *Servier*, the Court drew a clear distinction its analysis between side-deals in general and the licensing and assignment agreements between Servier and Krka. As a general point, the Court confirmed that the existence of a side-deal is likely to constitute a serious indication of an inducement not to compete, and therefore an indication of a restriction of competition by object.[21] Side-deals were defined by the General Court as usual commercial agreements that are connected to the patent settlement agreement and which include clauses which have a restrictive character. Such a connection may be either temporal or legal, e.g. if the two agreements were concluded the same day; if the agreements are legally connected; if the binding character of either agreement is contingent on the conclusion of the other agreement; or if the Commission is in a position to prove that they are inseparable.[22] A temporal or legal link between the two agreements constitutes an indication that they were the object of a common negotiation.[23] The Court noted that there is a risk that such a side-deal serves as a vehicle to conceal transfers of value from the patent holder to the generic manufacturer, taking the form of a complex contractual arrangement in order to incentivize the generic company to accept the non-challenge and non-commercialisation clauses of the patent settlement agreement.[24] Therefore, the Court accepted that the existence of such a side-deal combined with a patent settlement that includes clauses restricting competition constitutes a serious indication of the existence of a reverse payment.[25]

One of the most noteworthy parts of the *Servier* case is the clear exception the Court made for licensing agreements, finding that they do not in principle fall under the category of suspicious side-deals.[26] Apart from the patent settlement between the Servier and Krka, the parties had also concluded a licensing agreement under which Krka was granted a license to Servier’s perindopril patent, limited to the territory of the Czech Republic, Hungary, Lithuania, Latvia, Poland, Slovakia and Slovenia, in return for a 3% royalty on Krka’s net sales.[27] Moreover, in the context of a separate assignment agreement, Servier had purchased two patent applications from Krka, in return for €30 million.[28] In its decision, the Commission had considered that the settlement agreement and the licensing and assignment agreements between Krka and Servier amounted to a single and continuous infringement under Article 101 TFEU and a restriction of competition either by object or by effect.[29]

The Court noted that a grant of a license may serve as an appropriate means of putting an end to a dispute; linking a licensing and a settlement agreement is justified since a licensing agreement is based on the parties’ recognition of the validity of the patent and thus confirms the legitimacy of the patent settlement agreement.[30] According to the Court, the burden is on the Commission to rely on other indications in order to establish that the licensing agreement was not concluded under normal market conditions and that it was used as a means to conceal a reverse payment.[31] The Court accepted that in the context of a licensing agreement, the transfer of values occurs both ways: from the generic challenger to the originator in the form of the license fee, but also from the originator to the generic manufacturer, since the latter can enter the market without risk.[32] The Court found that the burden was on the Commission to prove that the royalty was abnormally low and that the licensing agreement involved a reverse payment,[33] stressing that the deviation from the normal market conditions needed to be more than evident in order to establish a degree of harm sufficient to qualify as a restriction of competition by object.[34] The Court held that the Commission had not sufficiently shown that the 3% royalty on Krka’s net sales was abnormally low, thus a restriction of

competition by object was not sufficiently established.[35] Moreover, the Court reversed the Commission's finding of a restriction of competition by effect, finding that the Commission had failed to show the restrictive effects that the non-challenge and non-commercialisation clauses had in the context of the settlement between Krka and Servier.[36]

V. The importance of the definition of the relevant market in pharmaceutical cases

When determining the therapeutic substitutability between pharmaceutical products, competition authorities normally use the Anatomical Therapeutic Chemical (ATC) classification system order to define the relevant market, which divides medicines into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. ATC3 level comprises all pharmaceutical products with the same therapeutic indications, ATC4 constitutes a further subdivision based on therapeutic and pharmacological criteria such as molecule class, formulation or mode of action, while ATC5 level is more narrow, limited only to individual active substances.[37] In *Servier*, the Commission had defined the relevant market on the basis of the ATC5 level as being limited to perindopril, patent-protected and generic.[38] The Court noted that even though this choice was not criticized *per se*, all other sixteen ACE inhibitors were grouped under ATC3 or ATC4 levels,[39] while according to published medical research perindopril did not differ therapeutically from them in terms of efficacy.[40]

The Court found erroneous the Commission's finding that perindopril was heterogeneous and had particular characteristics with regard to its therapeutic usage, while it also rejected the finding of the "inertia" mechanism of doctors that allegedly restrained the competitive pressure exercised on perindopril from other pharmaceutical products.[41] Additionally, the Court found that the Commission had underestimated the patients' inclination to change treatment from perindopril and did not properly take into consideration the promotional efforts of other companies and their importance when analyzing the competitive relationships. Finally, the Court noted that the Commission had misunderstood the particular characteristics of competition in the pharmaceutical markets by finding that perindopril was not subject to significant competitive pressures from other ACE inhibitors.[42]

In the Court's view, the Commission failed to establish that the relevant market was limited to the perindopril molecule only;[43] since the product market was erroneously defined, the calculation of the market shares by the Commission was also found to be erroneous.[44] The Court found that irrespectively of the definition of the relevant geographic market, Servier's perindopril was never found in a dominant position amongst ACE inhibitors in terms of sales, within the time-period examined in the Commission's decision.[45] Since the Commission had failed to show that the relevant market was limited to perindopril, patent-protected and generic, it also could not properly estimate Servier's market share and its alleged economic rents;[46] therefore, the Court reversed the Commission's finding of an abuse of dominant position and annulled the respective fine imposed.[47] If anything, the Court's approach highlights the manifest importance of a concrete economic analysis when defining the relevant pharmaceutical market, beyond ATC levels which may serve as helpful starting point in the definition of relevant market.

Conclusion

Similarly to its approach in the *Lundbeck* decision, the General Court in *Servier* confirmed that potential competition may exist in a market before the expiration of the relevant patent, while it also upheld the three criteria used by the Commission in order to determine whether the patent settlements at issue constituted restrictions of competition by object. The Court further agreed with the Commission's reasoning in determining whether a transfer of value from an originator to a generic challenger constitutes a reverse payment aiming to prevent competition. One of the most interesting parts of the *Servier* decision that merits further scrutiny is the Court's analysis with regard to side-deals as part of patent settlements and the finding that a licensing agreement may be an appropriate means of resolving a patent dispute. Last but not least, the *Servier* decision stresses the importance (and the difficulty) of defining the relevant market in pharmaceutical cases, making it clear that such market definition must be based on a thorough analysis that takes into consideration the overall regulatory, therapeutical and economic context.

Dr. iur., LL.M., legal counsel. All opinions are my own.

---

[1] Judgment of the General Court of 12 December 2018, *Servier SAS and Others v European Commission*, Case T-691/14, EU:T:2018:922 (hereinafter "Case T-691/14, *Servier v. Commission*, EU:T:2018:922").

[2] Judgment of the General Court of 8 September 2016, Case T-472/13, *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, EU:T:2016:449 (hereinafter "Case T-472/13, *Lundbeck v. Commission*, EU:T:2016:449").

[3] See also EU Commission Decision, *Servier*, 2014, paras 19-40, 44.

[4] EU Commission Decision, *Servier*, 2014, paras 1-2.

[5] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 406 and 418, upholding EU Commission Decision, *Servier*, 2014, para. 1154. See also Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 264-273.

[6] Case T-472/13, *Lundbeck v. Commission*, EU:T:2016:449, paras 353, 366-367, 500.

[7] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 318.

[8] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 319, citing case T-519/09, *Toshiba Corp. v European Commission*, EU:T:2014:263, para. 230, confirmed by Case C-373/14 P, *Toshiba Corp. v European Commission*, EU:C:2016:26, paras 28, 29, 32, 34; and Case T-208/13 *Portugal Telecom SGPS, SA v European Commission*, EU:T:2016:368, para. 181.

[9] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 321-329.

[10] Case T-472/13, *Lundbeck v. Commission*, paras 131-132, finding that the presumption of patent validity and the related IP rights did not prevent the finding that the parties to the settlements were potential competitors.

[11] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 356.

[12] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 360.

[13] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 360-361.

[14] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 368.

[15] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 478-479.

[16] Case T-472/13, *Lundbeck v. Commission*, paras 495, 539.

[17] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 263, citing EU Commission Decision, *Servier, 2014*, para 1137.

[18] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 264-265.

[19] Case T-691/14, *Servier v. Commission* ,EU:T:2018:922, paras 277-280, 680.

[20] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 682-683.

[21] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 797.

[22] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 798.

[23] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 799.

[24] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 801-802.

[25] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, para. 803.

[26] Case T-691/14, *Servier v. Commission,* EU:T:2018:922, paras 943-963.

[27] EU Commission Decision, *Servier*, 2014, paras 907-911.

[28] EU Commission Decision, *Servier*, 2014, paras 923-928.

[29] EU Commission Decision, *Servier*, 2014, paras 1804-1859.

[30] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 946-947, referring also to Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C 89, 28.3.2014, p. 3–50, paras. 204-205.

[31] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 949.

[32] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 950-951.

[33] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 952.

[34] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 953, 963.

[35] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 975-985, 1030-1032.

[36] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 1140-1213, 1232-1234.

[37] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1426.

[38] EU Commission Decision, *Servier*, 2014, para. 2403 repeating this market definition in the analysis of Servier's abuse of dominant position under Article 102 TFEU; and *idem* paras 2535-2546, presenting in detail the Commission's analysis with regard to the relevant product market.

[39] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1428.

[40] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1457.

[41] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1589.

[42] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1589.

[43] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1590-1592.

[44] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1603.

[45] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, para. 1605.

[46] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 1605-1606.

[47] Case T-691/14, *Servier v. Commission*, EU:T:2018:922, paras 1607, 1620-1622.