Rechtspraak

Octrooirecht/mededingingsrecht

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ECLI:EU:T:2018:918 (T-684/14)

(Perindopril)

Mrs. Gervasoni, Madise en Da Silva Passos

Krka Tovarna Zdravil, te Novo Mesto (Slovenië)
tegen
de Europese Commissie

Samenvatting

Art. 101 EUWV
Although the Commission presented a number of factors suggesting that the licence agreement was beneficial for Krka's commercial interests, it did not demonstrate that the royalty rate of 3% was abnormally low, that is to say to such a degree that it could not be explained by considerations limited to the economic value of the patent to which the licence relates. The Commission has therefore not established that the licence agreement does not constitute a transaction concluded at arm's length. Consequently, the Commission has not established the existence of a reverse payment resulting from the granting of a licence at an abnormally low price and which, since it is not intended to compensate for the costs inherent in the settlement of a dispute, constitutes an inducement. It follows that the Commission was not entitled to find in the present case that there was a restriction of competition revealing a sufficient degree of harm to be classified as a restriction by object.

Arrest

I. Background to the dispute
[…]

D. Patent dispute settlements
16 Servier entered into a series of settlement agreements with a number of generic companies with which it was involved in patent disputes.

17 On 27 October 2006, Servier entered into a settlement agreement and a licence agreement with Krka, supplemented by an amendment made on 2 November 2006.

18 The settlement agreement with Krka provides that the 947 patent also covers equivalent national patents (Annex B).

19 In accordance with the settlement agreement with Krka, in force until the expiry or the revocation of the 947 or 340 patents, Krka undertook to withdraw any existing claim against the 947 patent worldwide and against the 340 patent in the United Kingdom, and not to challenge either of those patents ('the patents at issue') worldwide in the future (Clause I(ii) and (iv)). Moreover, Krka and its subsidiaries were not authorised to launch or to market any generic form of perindopril which would infringe the 947 patent for the duration of the validity of that patent and in the country in which it was still valid, unless otherwise expressly authorised by Servier (Clause V). Similarly, Krka could not supply to any third party a generic version of perindopril that would infringe the 947 patent unless otherwise expressly authorised by Servier (Clause V(2)). In return, Servier was required to withdraw the proceedings pending worldwide against Krka based on the infringement of the 947 and the 340 patents, including its applications for interim injunction (Clause I(i)).

20 Pursuant to the licence agreement concluded with Krka for a period corresponding to the validity of the 947 patent (Article 5), Servier granted Krka an exclusive, irrevocable licence on the 947 patent to use, manufacture, sell, offer for sale, promote and import its own products which contain the alpha crystalline form of erbumine (Article 2) in seven Member States ('the seven Member States' or 'the seven Markets') namely the Czech Republic, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia (Article 1). In return, Krka was required to pay Servier 3% royalties on its net sales prices throughout those territories (Article 3). Servier was entitled, in those States, to use the 947 patent directly or indirectly (that is to say for one of its subsidiaries or for one third party per country) (Article 2).

21 On 5 January 2007, Servier also entered into an assignment agreement with Krka.

22 Pursuant to the assignment agreement, Krka assigned two patent applications to Servier, one concerning a process for the preparation of perindopril (WO 2005 113500) and the other the preparation of formulations of perindopril (WO 2005 094793) (Article 1). The technology protected in those patent applications was used for the production of Krka's perindopril.

23 Krka undertook not to challenge the validity of any patents granted on the basis of the applications at issue (Article 3).

24 In return for that assignment, Servier paid Krka EUR 15 million for each of the applications at issue (Article 2).

25 Servier also granted Krka a non-exclusive, irrevocable, non-assignable, royalty-free licence, with no right to sub-license (other than to its subsidiaries) on the applications or resulting patents, that licence being unrestricted in time, territory or scope of use (Article 4).

[…]

II. Procedure and forms of order sought

[…]

III. Law

[…]

A. Third plea in law, alleging that there was no restriction of competition by object as regards the settlement and licence agreements

[…]

2. Findings of the Court

[…]

(c) Patent dispute settlement

129 It is a priori legitimate for the parties to a dispute relating to a patent to conclude a settlement agreement rather than pursuing litigation before a court. As the Commission rightly stated in recital 1102 of the contested decision, companies are generally entitled to settle litigation, including patent litigation, and those settlements often benefit both parties to the dispute and allow for a more efficient allocation of resources than if litigation were to be pursued to judgment. An applicant is not required to pursue litigation which it voluntarily initiated. It should be added that the settlement of disputes before the courts, in addition to the fact that it generates a cost for society, cannot be regarded as the preferred and ideal route for conflict resolution. An increase in litigation before the courts may reflect failures or shortcomings which could be remedied in other ways or be dealt with by appropriate prevention actions. If the national systems for granting patents or that of the EPO were experiencing such difficulties, for example by being too liberal in granting protection to processes which are devoid of inventive character, those problems could not justify an obligation or even an incentive for undertakings to pursue patent disputes until a judicial outcome is reached.

130 In addition, paragraphs 204 and 209 of the 2004 Guidelines on technology transfer agreements, which are applicable at the very least to agreements concerning the licensing of technology, acknowledge the possibility of concluding settlement and non-assertion agreements which include the granting of licences and indicate that, in the context of such a settlement and non-assertion agreement, non-challenge clauses are generally considered to fall outside the scope of Article 101(1) TFEU. Point 235 of the 2014 Guidelines on technology transfer agreements, which replaced the 2004 Guidelines, also states that 'settlement agreements in the context of technology disputes are, as in many other areas of commercial disputes, in principle a legitimate way to find a mutually acceptable compromise to a bona fide legal disagreement'. That paragraph also states that '[t]he parties may prefer to discontinue the dispute or litigation because it proves to be too costly, time-consuming and/or uncertain as regards its outcome', and that '[s]ettlements can also save courts and/or competent administrative bodies effort in deciding on the matter and can therefore give rise to welfare enhancing benefits'.

131 It follows from all of the foregoing that, for the purposes of reconciling patent law and competition law in the particular context of settlements between parties to a patent dispute, a balance must be struck between, on the one hand, the need to allow undertakings to make settlements, the increased use of which is beneficial for society and, on the other hand, the need to prevent the risk of misuse of settlement agreements, contrary to competition law, leading to entirely invalid patents being maintained and, especially in the medicinal products sector, an unjustified financial burden for public budgets (see, to that effect, judgment delivered today, *Servier and Others* v *Commission*, T691/14, paragraphs 219 to 252).

(d) The reconciliation of patent settlement agreements and competition law

132 It should be noted that the use of a settlement to resolve a patent dispute does not exempt the parties from the application of competition law (see, to that effect, judgments of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 15, and of 8 September 2016, *Lundbeck* v *Commission*, T472/13, under appeal, EU:T:2016:449, paragraph 118; see, by analogy, judgment of 30 January 1985, *BAT Cigaretten-Fabriken* v *Commission*, 35/83, EU:C:1985:32, paragraph 33; see, also, paragraph 204 of the 2004 Guidelines on technology transfer agreements and point 237 of the 2014 Guidelines on technology transfer agreements).

133 The Court of Justice has thus held, in particular, that a non-challenge clause in respect of a patent, including when it was inserted into an agreement intended to settle a dispute pending before a court, might, in the light of the legal and economic context, restrict competition within the meaning of Article 101(1) TFEU (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraphs 14 to 16).

134 It is therefore necessary to identify the relevant factors which justify a conclusion that a non-challenge clause in respect of a patent and, more broadly, a patent settlement agreement restricts competition by object, bearing in mind that determining whether there is a restriction by object entails an examination of the content of the terms of the agreement in question, its objectives, and its economic and legal context (judgment of 11 September 2014, *CB* v *Commission*, C67/13 P, EU:C:2014:2204, paragraph 53).

135 As a preliminary point, it should be noted that a patent dispute settlement agreement may have no negative impact on competition. That is the case, for example, if the parties agree that the patent at issue is not valid and therefore provide for the immediate market entry of the generic company.

136 The agreements at issue in the present case do not fall into that category because they contain non-challenge clauses in respect of patents and non-marketing clauses in respect of products, which are, by themselves, restrictive of competition. The non-challenge clause undermines the public interest in eliminating any obstacle to economic activity which may arise where a patent was granted in error (see, to that effect, judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraph 92) and the non-marketing clause entails the exclusion from the market of one of the patent holder's competitors.

137 Nevertheless, the insertion of such clauses may be legitimate, but only in so far as it is based on the parties' recognition of the validity of the patent in question (and, consequently, of the infringing nature of the generic products concerned).

138 First, non-marketing and non-challenge clauses are necessary for the settlement of some disputes related to patents. If the parties to a dispute were unable to make use of such clauses, the settlement of the dispute would be of no interest in cases in which both parties agree on

the validity of the patent. It must, moreover, be noted in this connection that the Commission stated, in paragraph 209 of the 2004 Guidelines on technology transfer agreements, that '[i]t is inherent in [settlement agreements] that the parties agree not to challenge *ex post* the intellectual property rights covered by the agreement [since] the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes'. It is equally necessary, in order to achieve that purpose, that the parties agree that no infringing product may be marketed.

139 Secondly, the insertion of non-marketing clauses merely, in part, reinforces the pre-existing legal effects of a patent which the parties explicitly or implicitly recognise as valid. A patent normally enables its holder to prevent its competitors from marketing the product covered by the patent or a product obtained through the process covered by the patent (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T321/05, EU:T:2010:266, paragraph 362). By agreeing to a non-marketing clause, the generic company undertakes not to sell products likely to infringe the patent in question. If that clause is limited to the scope of the patent at issue, it may be regarded as essentially duplicating the effects of that patent, in so far as it is based on the recognition of the validity of that patent. As regards non-challenge clauses, the patent cannot be interpreted as affording protection against actions brought in order to challenge the validity of a patent (judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraph 92). The effects of those clauses therefore do not overlap with the effects of the patent. However, when a non-challenge clause is adopted as part of the settlement of a genuine dispute in which the competitor has already had the opportunity to challenge the validity of the patent concerned and ultimately acknowledges that validity, such a clause cannot be regarded, in that context, as undermining the public interest in eliminating any obstacle to economic activity which may arise where a patent was granted in error (see paragraph 136 above).

140 The Commission itself stated, in the contested decision, that non-challenge clauses and non-marketing clauses were generally inherent in any settlement. It thus considered that 'when in a patent dispute or patent litigation, a settlement is reached on the basis of each party's assessment of the patent case before them, such a patent settlement is unlikely to infringe competition law even though it may contain an obligation on the generic company not to use the invention covered by the patent during the period of patent protection (e.g. a non-compete clause) and/or an obligation not to challenge the patent concerned in court (e.g. a non-challenge clause)' (recital 1136 of the contested decision).

141 Thus, the mere presence, in settlement agreements, of non-marketing clauses and non-challenge clauses whose scope is limited to that of the patent in question does not – despite the fact that those clauses are, by themselves, restrictive (see paragraph 136 above) – justify a finding of a restriction of competition sufficiently harmful to be described as a restriction by object, where those agreements are based on the recognition, by the parties, of the validity of the patent (and, consequently, the infringing nature of the generic products concerned).

142 The presence of non-marketing and non-challenge clauses whose scope is limited to that of the patent in question is, however, problematic when it is apparent that the generic company's agreement to those clauses is not based on its recognition of the validity of the patent. As the Commission rightly points out, 'even if the limitations in the [settlement] agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they constitute a breach of Article 101 [TFEU] when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself' (recital 1137 of the contested decision).

143 In that respect, it should be noted that the existence of a 'reverse payment', that is to say a payment from the originator company to the generic company, is doubly suspect in the context of a settlement agreement. In the first place, it must be borne in mind that a patent is intended to reward the creative effort of the inventor by allowing him to make a fair profit from his investment (judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraph 9) and that a valid patent must, in principle, allow a transfer of value to its holder – for example, through a licence agreement – and not vice versa. In the second place, the existence of a reverse payment gives rises to doubts as to whether the settlement is actually based on the recognition, by the parties to the agreement, of the validity of the patent in question.

144 However, the mere presence of a reverse payment does not mean that there is a restriction by object. It is possible that some reverse payments, where they are inherent in the settlement of the dispute in question, may be justified. However, where an unjustified reverse payment occurs in the conclusion of the settlement, the generic company must then be regarded as having been induced by that payment to agree to the non-marketing and non-challenge clauses and it must be concluded that there is a restriction by object. In that case, the restrictions of competition introduced by the non-marketing and non-challenge clauses no longer relate to the patent and to the settlement, but rather can be explained by the conferral of a benefit inducing the generic company to abandon its competitive efforts.

145 It must be pointed out that, although neither the Commission nor the Courts of the European Union are competent to rule on the validity of the patent, it is nevertheless the case that those institutions may, in the context of their respective powers and without ruling on the intrinsic validity of the patent, find that it has been used abnormally, in a manner which has no relation to its specific subject matter (see, to that effect, judgments of 29 February 1968, *Parke, Davis and Co.*, 24/67, EU:C:1968:11, pp. 71 and 72, and of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 7 and 8; see also, by analogy, judgments of 6 April 1995, *RTE and ITP* v *Commission*, C241/91 P and C242/91 P, EU:C:1995:98, paragraph 50, and of 4 October 2011, *Football Association Premier League and Others*, C403/08 and C429/08, EU:C:2011:631, paragraphs 104 to 106).

146 Inducing a competitor to accept non-marketing and non-challenge clauses, in the sense described in paragraph 144 above, or its corollary, accepting such clauses because of an inducement, constitutes an abnormal use of the patent.

147 As the Commission rightly stated in recital 1137 of the contested decision, 'patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to refrain from challenging a patent prior to entering the market'. Likewise, according to the Commission, 'patent holders are not entitled to pay generic companies to keep them off the market and reduce the risks of competition, whether in the context of a patent settlement agreement or otherwise' (recital 1141 of the contested decision). Lastly, the Commission correctly added that 'paying or otherwise inducing potential competitors to stay out of the market [was] not part of any patent right, nor [was] it one of the means provided for under patent law to enforce the patent' (recital 1194 of the contested decision).

148 Where an inducement has been found, the parties may no longer rely on their recognition, in the context of the settlement, of the validity of the patent. The fact that the validity of the patent is confirmed by a judicial or administrative body is, in that regard, irrelevant.

149 It is then the inducement, and not the recognition of the validity of the patent by the parties to the settlement, which must be regarded as the real cause of the restrictions of competition introduced by the non-marketing and non-challenge clauses (see paragraph 136 above), which – since they are in that case entirely illegitimate – therefore reveal a sufficient degree of harm to the proper functioning of normal competition that a restriction by object may be found.

150 Where they involve an inducement, the agreements in question must therefore be regarded as market exclusion agreements, in which the 'stayers' are to compensate the 'goers'. Such agreements actually constitute a buying-off of competition and must therefore be classified as restrictions of competition by object, as follows from the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C209/07, EU:C:2008:643, paragraphs 8 and 31 to 34), and the Opinion of Advocate General Trstenjak in *Beef Industry Development Society and Barry Brothers*, (C209/07, EU:C:2008:467, point 75), referred to in inter alia recitals 1139 and 1140 of the contested decision. Moreover, the exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production (judgment of 8 September 2016, *Lundbeck* v *Commission*, T472/13, under appeal, EU:T:2016:449, paragraph 435), which, in a context such as that of the agreements in question, reveals a degree of harm which is all the greater since the companies excluded are generic companies, the market entry of which is, as a rule, favourable to competition and which also contributes to the public interest in lowering the cost of healthcare. Lastly, that market exclusion is augmented, in the agreements at issue, by the fact that it is not possible for the generic company to challenge the patent at issue.

151 It follows from all of the foregoing that, in the context of patent dispute settlement agreements, a finding of a restriction of competition by object presupposes that the settlement agreement contains both an inducement in the form of a benefit for the generic company and a corresponding limitation of the generic company's efforts to compete with the originator company. Where those two conditions are met, a finding of restriction of competition by object must be made in view of the harmfulness of that agreement to the proper functioning of normal competition.

152 Thus, where a patent settlement agreement contains non-marketing and non-challenge clauses, whose inherently restrictive nature (see paragraph 136 above) has not been validly called into question, the existence of an inducement for the generic company to agree to those clauses permits the conclusion that there is a restriction by object, and does so even if there is a genuine dispute, the settlement agreement includes non-marketing and non-challenge clauses whose scope does not exceed that of the patent at issue and that patent could – having regard, in particular, to the decisions adopted by the competent administrative authorities or courts – legitimately be regarded as valid by the parties to the agreement at issue at the time it was adopted.

153 In the contested decision, the Commission rightly examined whether the settlement agreement at issue in the present case involved a value transfer from the originator company to the generic company representing a 'significant' inducement, that is to say liable to lead the latter to accept non-marketing and non-challenge clauses, and concluded, having found such an inducement, that there was a restriction of competition by object.

154 The Commission thus adopted the inducement criterion, referred to below as the 'inducement' or 'inducive benefit' criterion, for the purpose of distinguishing settlement agreements which constitute restrictions by object from those which do not constitute such restrictions.

155 In some cases, the settlement agreement may provide for a reverse payment, that is to say a transfer of value without any quid pro quo, intended, inter alia, to offer compensation to the generic company. That payment then constitutes an inducement since it does not cover costs inherent in the settlement of the dispute. In other cases, as in the present case, the settlement agreement may be accompanied by a commercial agreement described as a 'side deal' since it is linked to the settlement of the dispute. It must be clarified how, in the latter case, the existence of an inducement may be established by the Commission.

(e) Side deals

156 It follows from Article 2 of Regulation No 1/2003 and from settled case-law that, in the field of competition law, where there is a dispute as to the existence of an infringement, it is incumbent on the Commission to prove the infringements found by it and to adduce evidence capable of demonstrating to the requisite legal standard the existence of the circumstances constituting an infringement (judgments of 17 December 1998, *Baustahlgewebe* v *Commission*, C185/95 P, EU:C:1998:608, paragraph 58, and of 8 July 1999, *Commission* v *Anic Partecipazioni*, C49/92 P, EU:C:1999:356, paragraph 86; see, also, judgment of 12 April 2013, *CISAC* v *Commission*, T442/08, EU:T:2013:188, paragraph 91 and the case-law cited).

157 In that context, any doubt on the part of the Court must operate to the advantage of the undertaking to which the decision finding an infringement was addressed. The Court cannot therefore conclude that the Commission has established the infringement in question to the requisite legal standard if it still entertains any doubts on that point, in particular in proceedings for annulment of a decision imposing a fine (see judgment of 12 April 2013, *CISAC* v *Commission*, T442/08, EU:T:2013:188, paragraph 92 and the case-law cited).

158 It is necessary to take into account the principle of the presumption of innocence resulting in particular from Article 48 of the Charter of Fundamental Rights. Given the nature of the infringements in question and the nature and degree of severity of the penalties which may ensue, the presumption of innocence applies, inter alia, to the procedures relating to infringements of the competition rules applicable to undertakings that may result in the imposition of fines or periodic penalty payments (see judgment of 12 April 2013, *CISAC* v *Commission*, T442/08, EU:T:2013:188, paragraph 93 and the case-law cited).

159 In addition, account must be taken of the non-negligible stigma attached to a finding of involvement in an infringement of the competition rules for a natural or legal person (see judgment of 12 April 2013, *CISAC* v *Commission*, T442/08, EU:T:2013:188, paragraph 95 and the case-law cited).

160 Thus, the Commission must show precise and consistent evidence in order to establish the existence of the infringement and to support the firm conviction that the alleged infringement constitutes a restric-

tion of competition within the meaning of Article 101(1) TFEU (see judgment of 12 April 2013, *CISAC* v *Commission*, T442/08, EU:T:2013:188, paragraph 96 and the case-law cited).

161 It is not necessary for every item of evidence produced by the Commission to satisfy those criteria in relation to every aspect of the infringement. It is sufficient if the set of indicia relied on by the Commission, viewed as a whole, meets that requirement (see judgment of 12 April 2013, *CISAC* v *Commission*, T442/08, EU:T:2013:188, paragraph 97 and the case-law cited).

162 The existence of an anticompetitive practice or agreement must sometimes even be inferred from a number of coincidences and indicia which, taken together, may, in the absence of another plausible explanation, constitute evidence of an infringement of the competition rules (judgment of 7 January 2004, *Aalborg Portland and Others* v *Commission*, C204/00 P, C205/00 P, C211/00 P, C213/00 P, C217/00 P and C219/00 P, EU:C:2004:6, paragraph 57).

163 For example, although parallel behaviour may not by itself be identified with a concerted practice, it may, however, amount to a strong indication of such a practice if it leads to conditions of competition which do not correspond to the normal conditions of the market (judgment of 14 July 1972, *Farbenfabriken Bayer* v *Commission*, 51/69, EU:C:1972:72, paragraph 25).

164 Likewise, the presence of a 'side deal' – the expression used by the Commission in recital 1190 of the contested decision – may constitute, as regards the settlement of a patent dispute, a strong indication of the existence of an inducement and, consequently, of a restriction of competition by object (see paragraphs 144 to 152 above).

165 It should be explained in that respect that a side deal is a normal commercial agreement linked to a settlement agreement which contains clauses which are by themselves restrictive (see paragraph 136 above). Such a link exists, in particular, where the two agreements are concluded on the same day, where they are legally linked, the binding nature of one of the agreements being conditional upon the conclusion of the other agreement, or where, in the light of the context in which they are concluded, the Commission is able to establish that they are indissociable.It may be added that, the shorter the time between the conclusion of each agreement, the easier it will be for the Commission to establish that indissociable nature.

166 It should also be noted that the fact that the settlement agreement and the side deal are concluded on the same day or that there is a contractual link between them is an indication that those agreements form part of a single contractual framework. If those agreements were not concluded on the same day (and if there were no contractual link between them), one of the parties to the negotiation would grant the other party everything it wants without any certainty of ultimately obtaining the expected quid pro quo. That temporal or legal link between the two agreements is also an indication that they were negotiated together.

167 The side deal is a normal commercial agreement that could exist independently without the settlement of a dispute being at issue. Likewise, the conclusion of a settlement agreement does not require the concurrent conclusion of a commercial agreement. Thus, the two agreements do not need to be linked. Moreover, that linkage cannot be justified by the settlement of a dispute because the purpose of a side deal is not to reach such a settlement but rather to carry out a commercial transaction.

168 In addition, a side deal involves value transfers, of a financial or non-financial nature, between the parties. It may involve, in particular, the transfer of value from the patent holder to the generic company.

169 There is therefore a risk that the linking of a commercial agreement with a settlement agreement containing non-marketing and non-challenge clauses, which are, by themselves, restrictive of competition (see paragraph 136 above), is actually intended – under the guise of a commercial transaction, taking the form, as the case may be, of a complex contractual arrangement – to induce the generic company to accept those clauses, through a value transfer provided for in the side deal.

170 Consequently, the fact that a commercial agreement, which does not normally have the settlement of a dispute as its subject matter (see paragraph 167 above), and which serves as a vehicle for a transfer of value from the originator company to the generic company, is, in the circumstances set out in paragraph 165 above, linked with a settlement agreement containing competition-restricting clauses is a strong indication of the existence of a reverse payment (see paragraph 143 above).

171 However, the strong indication referred to in paragraph 170 above is not sufficient and the Commission must therefore support it with other consistent evidence justifying the conclusion that there is a reverse payment. Such a payment, in the specific context of side deals, corresponds to the part of the payment made by the originator company which exceeds the 'normal' value of the asset traded (or, as the case may be, to the part of the 'normal' value of the asset traded which exceeds the payment made by the generic company).

172 It must be emphasised, in that regard, that the Commission stated on several occasions in the contested decision that certain side deals concluded by Servier with generic companies had not been negotiated 'at arm's length' (recitals 1351, 1950 and 1952).

173 It should be noted that the concept of 'normal competitive conditions', which is similar to that of 'arm's length', even though it is not used in relation to agreements, decisions and concerted practices, is not alien to competition law, since it is used in the particular field of State aid in order to determine whether a State has acted like a private investor (judgment of 2 September 2010, *Commission* v *Scott*, C290/07 P, EU:C:2010:480, paragraph 68), that is to say, whether the advantage granted to the undertakings in question constitutes the normal remuneration for a quid pro quo obtained by the State.That concept may therefore constitute, by analogy, a relevant reference parameter when determining whether two companies that concluded a commercial transaction did so on the basis of economic considerations limited to the economic value of the asset traded, that is to say, for example, to its prospects of profitability, and, thus, at arm's length.

174 Where there are indicia or evidence put forward by the Commission in order to support a finding that the side deal was not concluded at arm's length, the parties to the agreements may present their version of the facts, supporting their claims with the evidence that they are able to put forward and which permit the conclusion that the commercial agreement, although linked to the settlement agreement, is justified by reasons other than the exclusion of a competitor by means of a reverse payment. The parties to the agreements may thus argue that the side deal was concluded at arm's length by adducing relevant evidence concerning, for example, the industrial and commercial practices in the sector or the particular circumstances of the case.

175 In the light of all the evidence available to it and, as the case may be, the lack of an explanation or the lack of a plausible explanation from the parties to the agreements in question, the Commission may be justified in finding, following an overall assessment, that the side deal was not concluded at arm's length, that is to say that the payment made by the originator company exceeds the value of the asset traded (or that the value of the asset transferred to the generic company exceeds the payment made by the latter). The Commission may thus conclude that there is a reverse payment (see paragraph 171 above).

176 A reverse payment, if it is not intended to compensate for costs inherent in the settlement, therefore constitutes an inducive benefit (see paragraph 144 above). That is the case where the purpose of a side deal is not to settle a dispute but rather to carry out a commercial transaction (see paragraph 167 above).

177 However, the parties to the agreement may still argue that the benefit in question is insignificant, if the amount of that benefit is insufficient to be regarded as a significant inducement to accept the competition-restricting clauses set out in the settlement agreement (see paragraph 153 above).

178 It should also be noted that, among side deals, the licence agreement has particular features which require a specific analysis of the conditions under which such an agreement may constitute an inducement leading to a finding of a restriction of competition by object within the meaning of Article 101 TFEU.

(f) Licence agreements

179 By way of exception to the considerations relating to side deals set out in paragraphs 164 to 170 above, the linking of a normal commercial agreement to a settlement agreement containing non-challenge and non-marketing clauses no longer constitutes a strong indication of a reverse payment where the commercial agreement in question is a licence agreement concerning the patent in dispute.

180 That exception can be explained by the fact that, while it is true that a licence agreement in relation to a patent does not have as its subject matter the settlement of a dispute, but rather the grant of permission to use that patent, it may nevertheless be justifiable – in contrast to the situation as regards other commercial agreements (see paragraph 167 above) – to link that licence agreement to a settlement agreement concerning a patent which is the subject matter of the licence.

181 In principle, a patent dispute arises when the generic company's wish to enter the market comes into conflict with the patent owner's wish to safeguard the rights that he derives from that patent. Authorising such entry by concluding a licence agreement thus appears to be a particularly appropriate means of resolving the dispute, since it satisfies the wishes of both parties to the dispute.

182 It is also acknowledged that the use of a licence agreement is an appropriate means of resolving a dispute. That is apparent from paragraph 204 of the 2004 Guidelines on technology transfer, according to which 'licensing may serve as a means of settling disputes'. That paragraph is incorporated in paragraph 205 of the 2014 Guidelines on technology transfer agreements.

183 Linking a licence agreement to a settlement agreement is all the more justified since the presence, in a settlement agreement, of non-marketing and non-challenge clauses is legitimate only where that agreement is based on the parties' recognition of the validity of the patent (see paragraphs 137 to 140 above). The conclusion of a licence agreement, which, for any licensee, makes sense only if the licence is actually used, is also based on the parties' recognition of the validity of the patent. To that extent, the licence agreement thus supports the legitimacy of the settlement agreement, which fully justifies the linking of the two.

184 Since it appears justified to link a patent dispute settlement agreement to a licence agreement concerning the same patent, that linking, unlike the situation as regards the other side deals, does not constitute a strong indication of the existence of a reverse payment (within the meaning of that expression in relation to side deals, see paragraph 171 above).

185 It is therefore for the Commission to rely on indicia other than the mere linking of the licence agreement and the settlement agreement for the purpose of establishing that the licence agreement was not concluded at arm's length and that it actually masks a reverse payment inducing the generic company to accept the non-marketing and non-challenge clauses (see paragraphs 170 to 175 above).

186 It should be noted that a finding of the existence of a reverse payment is less evident in the case of a licence agreement because such an agreement does not entail a financial transfer from the originator company to the generic company, but rather from the generic company to the originator company. Thus, in a licence agreement, the licensee pays a royalty to the patent holder.

187 There is, however, a transfer of value from the originator company to the generic company, since the royalty paid to the patent holder constitutes a quid pro quo for the benefit that the generic company receives from the licence agreement, namely the authorisation to use the patent in order to enter the market without risk.

188 It is therefore for the Commission to demonstrate that that quid pro quo is abnormally low, that is to say to such an extent that it cannot be explained by considerations limited to the economic value of the asset to which the contract relates (see paragraph 173 above), and that the licence agreement thus involves a reverse payment to the generic company.

189 It must be particularly clear that the transaction in question was not concluded at arm's length in order to establish a sufficient degree of harmfulness for the purpose of classifying the settlement agreement as a restriction of competition by object, since the restriction of competition by the non-challenge and non-marketing clauses in the settlement agreement is mitigated by the licence agreement.

190 The non-marketing clause is thus rendered ineffective, at least in part. The licence agreement goes even further than a mere partial neutralisation of the effects of that clause, since it encourages the entry of generic products on the market by eliminating the litigation risk associated with the patent.

191 As regards the non-challenge clause, although its restrictive effects persist, they are limited by the fact that the licence allows market entry without a litigation risk. Although it is essential for the generic company to be able to challenge the validity of the patent when it enters the market at risk, that is less the case when it is authorised by the originator company to enter this market through a licence agreement.

192 At this stage of the analysis, it should be noted that, in the context of patent dispute settlement agreements, a finding of a restriction of competition by object presupposes that the settlement agreement contains both an inducement to the generic company and a corresponding limitation of the generic company's efforts to compete with the originator company (see paragraph 151 above). It follows from the foregoing that, where there is a licence agreement, those two elements are mitigated, or even absent, with the result that a sufficient degree of harm to the proper functioning of normal competition (see, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C67/13 P, EU:C:2014:2204, paragraphs 49 and 50 and the case-law cited) cannot easily be identified.

193 It should be added that the exception mentioned in paragraph 179 above is not contradicted by the fact that the linking of a licence agreement and a non-challenge clause are among the restrictions excluded from the exemption laid down in Article 2 of Regulation No 772/2004, or by the case-law of the Court of Justice, first set out in the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraphs 89 and 92), and clarified in the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448).

194 First, according to Article 5 of Regulation No 772/2004, the linking of a licence agreement and a non-challenge clause is one of the restrictions excluded from the exemption provided for in Article 2 of that regulation. However, that exemption, as well as that exclusion, apply, pursuant to Articles 2 and 5 of that regulation, only in so far as the agreements in question contain restrictions of competition falling within the scope of Article 101(1) TFEU. Consequently, the fact that the linking of a licence agreement and a non-challenge clause is one of the restrictions excluded from the exemption provided for in Article 2 of Regulation No 772/2004 does not support the conclusion that such linking is, in all circumstances, a restriction of competition within the meaning of Article 101(1) TFEU and, in particular, a restriction by object.

195 In that respect, the Court of Justice held that, whilst it is true that to grant the benefit of Article 101(3) to a given agreement presupposes that this agreement falls within the prohibition imposed by Article 101(1), the authorisation in Article 101(3) to grant that same benefit to categories of agreements does not imply that because a particular agreement comes within those categories it necessarily fits the descriptions set out in Article 101(1). Therefore, to grant exemptions by categories cannot amount, even by implication, to passing any pre-conceived judgment on any agreement considered individually (judgment of 13 July 1966, *Italy* v *Council and Commission*, 32/65, EU:C:1966:42, pp. 405 and 406).

196 Secondly, the Court of Justice indeed held that a clause in a licence agreement obliging the licensee not to challenge the validity of the patent was incompatible with Article 101(1) TFEU. It added that such a clause clearly does not fall within the specific subject matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error (judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraphs 89 and 92).

197 However, in a judgment delivered two years later, in a case concerning a settlement agreement, the Court qualified the position it had adopted in the judgment of 25 February 1986, *Windsurfing International* v *Commission*(193/83, EU:C:1986:75), this time holding only that a non-challenge clause included in a patent licensing agreement may, in the light of the legal and economic context, restrict competition within the meaning of Article 101(1) TFEU (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 16). Although it also rejected, in that same judgment, the Commission's proposal that the inclusion of a non-challenge clause fell outside the prohibition laid down in Article 101(1) TFEU where the agreement in question was intended to settle litigation pending before a court, it did not, however, conclude that all patent settlement agreements containing such a clause fell within the prohibition laid down in Article 101(1) TFEU.

198 It is true that the licensees under a licence agreement, are, as is clear from paragraph 112 of the 2004 Guidelines on technology transfer agreements, 'normally in the best position to determine whether or not an intellectual property right is invalid' and therefore to challenge it. That is why the linking of a licence agreement and a non-challenge clause is, in principle, prohibited (Opinion of Advocate General Darmon in *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1987:336, paragraph 8). However, where a licence agreement is concluded in the context of the settlement of a genuine dispute involving litigation between the parties concerned, the licensee has already had the opportunity to challenge the validity of the patent in question and if, ultimately, he agrees, without being induced, to a non-challenge clause (and a non-marketing clause), it is because he believes that the patent is valid. In that particular context of a settlement in which the parties ultimately agree that the patent is valid, the basis for prohibiting the linking of a licence agreement and a non-challenge clause no longer appears relevant, provided that the settlement agreement is based on the recognition by the parties to the agreement of the validity of the patent in question, and not on an inducement to the licensee to accept the non-challenge clause (and the non-marketing clause).

199 It follows from the foregoing that, where there is a genuine dispute involving litigation between the parties concerned and a licence agreement that is directly connected with the settlement of that dispute, the linking of that agreement to the settlement agreement does not constitute a strong indication of the existence of a reverse payment. In such circumstances, it is therefore for the Commission to demonstrate, on the basis of other evidence, that the licence agreement does not constitute a transaction concluded at arm's length and thus masks a reverse payment (within the meaning of that expression in relation to side deals, see paragraph 171 above).

200 It must be determined, in the light of the foregoing considerations, whether the Commission was entitled to conclude, in the present case, that the settlement and licence agreements concluded between Servier and Krka could be classified as a restriction by object.

(g) The facts of the case

201 It is necessary, in the first place, to examine whether there were genuine disputes and whether the licence agreement appeared to have a sufficiently direct connection with the settlement of those disputes to justify its linking to the settlement agreement.

202 In that regard, first, it should be noted that there were genuine ongoing disputes between Servier and Krka at the time the agreement was signed and that those disputes came to an end following the settlement agreement, which provided, in Article I(i) and (ii), that both parties were to withdraw from the ongoing proceedings between them.

203 In 2004, ten generic companies, including Krka, had filed opposition proceedings against the 947 patent before the EPO, seeking the revocation of that patent in its entirety on grounds of lack of novelty, lack of inventive step and insufficient disclosure of the invention. On 27 July 2006, the EPO's Opposition Division confirmed the validity of that patent following minor amendments to Servier's original claims. Seven companies then brought an appeal against the EPO decision of 27 July 2006. Krka withdrew from the opposition proceedings on 11 January 2007, pursuant to the settlement agreement concluded with Servier.

204 Likewise, Servier had brought an action for infringement of the 340 patent against Krka before the High Court of Justice (England and Wales), Chancery Division (Patents Court). On 2 August 2006, it had also brought an action for infringement of the 947 patent against Krka and applied for an interim injunction. On 1 September 2006, Krka had brought a counterclaim for annulment of the 947 patent and, on 8 September 2006, a separate counterclaim for annulment of the 340 patent. On 3 October 2006, the High Court of Justice (England and Wales), Chancery Division (Patents Court), granted Servier's application for an interim injunction and denied the motion brought by Krka on 1 September 2006. On 1 December 2006, the ongoing proceedings were discontinued as a result of the settlement reached between the parties and the interim injunction was lifted.

205 Secondly, both the settlement agreement and the licence agreement related to the disputes in question. The settlement agreement and, in particular, the non-marketing and non-challenge clauses which it contained, were limited to the scope of the patents which were the subject matter of the disputes between Servier and Krka. The licence agreement concerned the 947 patent and thus also had a direct link with those disputes.

206 Thirdly, there was, at the time the settlement and licence agreements were concluded, consistent indications capable of leading the parties to believe that the 947 patent was valid (see paragraphs 203 and 204 above).

207 Fourthly, although there were already meetings between Servier and Krka before the EPO decision of 27 July 2006 (see, inter alia, recital 837 of the contested decision), they had not resulted in an agreement (recitals 856 to 859 to the contested decision) and it was only after that decision that new negotiations began (recital 898 of the contested decision). The EPO decision of 27 July 2006 confirmed the validity of the 947 patent and was therefore, at the very least, one of the driving factors leading to the settlement and licence agreements.

208 Thus, having regard to the scope of the terms of the settlement agreement and the licence agreement and the context in which those agreements were signed, it must be held that the linking of those two agreements was justified and therefore does not constitute a strong indication of the existence of a reverse payment from Servier to Krka giving rise to the licence agreement (see paragraph 184 above).

209 In those circumstances, it is necessary to examine, in the second place, whether, in the present case, the Commission established, on the basis of indicia or evidence other than the mere linking of the licence agreement and the settlement agreement, that the licence agreement had not been concluded at arm's length (see paragraph 185 above).

210 In this respect, it should be noted that it is common ground that, unlike the other agreements that were the subject of the contested decision, neither the settlement agreement nor the licence agreement gave rise to a financial transfer from Servier to Krka.

211 The licence agreement even provided that Krka was to pay Servier a royalty of 3% of its net sales.

212 It is true that the royalty constitutes the quid pro quo for the benefit received by the generic company under the licence agreement, namely the authorisation to use the patent in order to enter the market without risk. However, it was for the Commission to demonstrate that that quid pro quo was abnormally low and that the licence agreement thus gave rise to a reverse payment to Krka.

213 Although the Commission presented, in the contested decision, a number of factors suggesting that the licence agreement was beneficial for Krka's commercial interests (see recitals 1738 to 1744 and, in particular, recital 1739), it did not demonstrate that the royalty rate of 3% was abnormally low, that is to say to such a degree that it could not be explained by considerations limited to the economic value of the patent to which the licence relates (see paragraph 188 above).

214 As regards the Commission's assertion that the royalty rate was much lower than Servier's operating profit for 2007 in the Czech Republic, Hungary and Poland, it is not necessarily abnormal that the rate of an operating surplus, which represents the gross profit derived from an activity, greatly exceeds the royalty rate of a licence agreement, which represents only the cost of the right of use of a patent.

215 The same reasoning can also be used to reject the Commission's argument that the royalty represented a small proportion of Krka's profit margins. A fortiori, the generic company would have no interest in concluding a licence agreement if the amount of the royalty did not enable it to generate a sufficient profit margin.

216 Finally, it is not abnormal that the royalty rate of a patent used by Krka was calculated on the basis of the sales price of Krka's product and not on the basis of the sales price of Servier's product.

217 All those elements, even taken together, can, at most, demonstrate that the price of the licence granted to Krka was favourable to its commercial interests, but do not suffice to establish that the transaction in question was not concluded at arm's length, especially since the licence agreement provided that Servier could continue to market its product in the seven Member States to which the licence applied, either directly or through one of its affiliated companies or even via a single third party per Member State. The licence granted was therefore not exclusive, which limited its advantageousness to Krka since there was a risk that Krka's product would be in competition with another generic product, whether marketed or produced by Servier or by a third party.

218 Moreover, it should be added that, in the judgment delivered today, *Servier and Others* v *Commission* (T691/14, paragraph 1072), it is noted that, during the hearing in that case, the Commission itself indicated that it did not dispute that the royalty was consistent with market practices.By stating in the contested decision – admittedly as a subsidiary point – that 'it is not the low level of royalties but the fact that the sole licence was granted against a commitment not to enter or challenge Servier's patents in a number of other, restricted markets, that is central to this analysis' (footnote 2354), the Commission already showed that it incorrectly attached only secondary importance to the fact that the transaction might have been concluded at arm's length.

219 It follows from the considerations set out in paragraphs 213 to 217 above that the Commission has not established that the royalty rate of 3% laid down in the licence agreement was abnormally low, that is to say to such a degree that it could not be explained by considerations limited to the economic value of the patent to which the licence relates. The Commission has therefore not established that the licence agreement does not constitute a transaction concluded at arm's length.

220 Consequently, the Commission has not established the existence of a reverse payment resulting from the granting of a licence at an abnormally low price (see paragraph 173 above) and which, since it is not intended to compensate for the costs inherent in the settlement of a dispute (see paragraph 176 above), constitutes an inducement.

221 It follows that the Commission was not entitled to find in the present case that there was a restriction of competition revealing a sufficient degree of harm to be classified as a restriction by object.

222 That conclusion is not called into question by the other factors relied on by the Commission in the contested decision.

223 First, even if the licence agreement were inducive because it allowed, in the seven Member States – that is to say in a part of the market in respect of which the Commission did not find an infringement – the implementation of an advantageous duopoly between Servier and Krka, as the Commission indicated in the contested decision (see, inter alia, recital 1728, 1734 and 1742), that duopoly did not result from that agreement itself, but from the choices made by Servier and Krka after that agreement, namely, Servier's choice not to grant a licence to another generic company or to sell its own generic version of perindopril at a low price (recital 1727 of the contested decision) and Krka's choice not to adopt an aggressive pricing policy (recital 1744 of the contested decision).

224 The restriction by object found by the Commission, in particular the inducement which is one of the conditions of that restriction (see paragraph 151 above), concerns the settlement and licence agreements concluded between Servier and Krka, and not practices subsequent to those agreements and not determined by them.

225 Even if the duopoly in question could be regarded as an implementation of the settlement and licence agreements, it should be borne in mind that the Commission and the Courts of the European Union cannot, when examining whether an agreement restricts competition by object and, in particular, in assessing the economic and legal context of that agreement, completely ignore its potential effects (Opinion of Advocate General Wahl in *ING Pensii*, C172/14, EU:C:2015:272, paragraph 84). However, it is also apparent from the case-law that establishing the existence of a restriction of competition by object cannot, under the guise, inter alia, of the examination of the economic and legal context of the agreement at issue, lead to the assessment of the effects of that agreement (see, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C67/13 P, EU:C:2014:2204, paragraphs 72 to 82), since otherwise the distinction between a restriction of competition by object and by effect laid down in Article 101(1) TFEU would lose its effectiveness. For the purposes of verifying the specific capability of an agreement to produce competition-restricting effects characteristic of agreements with an anticompetitive object, the analysis of the potential effects of an agreement must therefore be limited to those resulting from information objectively foreseeable at the time of the conclusion of that agreement (see, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C67/13 P, EU:C:2014:2204, paragraphs 80 to 82, and the Opinion of Advocate General Wahl in *ING Pensii*, C172/14, EU:C:2015:272, paragraph 84).

226 In the present case, the alleged potential effects in question, that is to say the duopoly alleged by the Commission, are based on hypothetical circumstances which were therefore not objectively foreseeable at the time of the conclusion of the settlement and licence agreements.

227 In any event, the Commission, referring to the practice of pharmacy stock saturation and to a complaint to the Polish authorities alleging the existence of unfair competition, indicated in recital 1725 of the contested decision that 'Servier's attitude towards Krka in the seven licensed markets could hardly be described as one of cooperation'. Moreover, as is apparent from recital 1728 of the contested decision, the duopoly described by the Commission between Servier and Krka did not exclude a certain degree of competition between those companies.

228 Secondly, according to the Commission, the licence agreement was inducive, in this case, because it enabled Krka to enter certain markets without risk in return for its exclusion from other markets. From that perspective, where the scope of the non-marketing or non-challenge clauses is wider than that of the licence agreement and there is therefore a gap or an 'asymmetry' between those two agreements, according to the Commission's wording in recitals 1706 and 1736 of the contested decision, it is then possible to conclude that there is an inducement, since the licence agreement, by allowing the generic company to enter certain parts of the market without risk, is actually intended to induce that company to agree to withdraw from other parts of the market, to the originator company's advantage.

229 Those arguments cannot be accepted.

230 First of all, the approach put forward by the Commission, whereby the mere conclusion, even on normal market conditions, of a licence agreement linked to a settlement agreement containing restrictive clauses could constitute an inducement, would lead to a paradoxical outcome because, in that case, the wider the scope of a licence agreement, the greater the inducement and thus the easier it would be to find a restriction by object, unless the scope of the licence agreement were exactly identical to that of the settlement agreement.

231 The wider the scope of a licence agreement, especially in relation to the scope of the settlement agreement to which it is linked, the more that agreement is procompetitive, in view of the procompetitive effects of the licence, which encourages the market entry of a generic company and limits the competition-restricting nature of the non-marketing and non-challenge clauses in the settlement agreement (see paragraphs 190 and 191 above).

232 In that respect, it may be noted that in his Opinion in *CB* v *Commission* (C67/13 P, EU:C:2014:1958, point 55), Advocate General Wahl stated that the formalist approach to identifying a restriction by object was conceivable only in the case of conduct in respect of which it could be concluded that the unfavourable effects on competition outweighed the procompetitive effects.

233 In addition, the Commission's argument, which leads to the patent holder being obliged to conclude a licence agreement covering the entire territory to which the restrictive clauses in the settlement agreement apply, does not respect the intellectual property rights of the pat-

ent holder and, in particular, his margin of discretion as regards the grant of licences (see, for a case where the patent holder is in a dominant position, judgment of 17 September 2007, *Microsoft* v *Commission*, T201/04, EU:T:2007:289, paragraph 331). That argument also disregards the margin of discretion that the parties to a dispute must have in order to reach a settlement in good faith.

234 Moreover, the conclusion of an 'asymmetric' licence agreement does not necessarily constitute – for a generic company that does not recognise the validity of the patent in question – a sufficient benefit that it would agree to the non-marketing and non-challenge clauses. For the benefit arising from such an agreement to be regarded as an inducement, it would have to offer that company compensation for the certain loss of expected profits resulting from the acceptance of a settlement with clauses prohibiting entry on certain geographic parts of the market. For a company that does not seriously believe that the patent is valid and which is able to enter the entire market covered by the non-marketing and non-challenge clauses, a licence with a geographic scope more limited than the scope of those clauses does not constitute an economically satisfactory outcome that could lead them to accept those clauses. It is true that the licence partially opens the way for that company to the market covered by the patent by offering it the possibility of obtaining the envisaged profits on that part of the market, but, if it is not established that the royalty rate of that licence is abnormally low in respect of that part of the market, that licence does not give that company any compensation for the other parts of the market, on which it could make a profit if the patent were annulled, and which it is now prevented from accessing.

235 In the present case, Krka's expected earnings in the 18 to 20 markets to which the licence agreement did not apply were far from negligible. The Commission indicates in the contested decision that the expected earnings from Western European markets roughly matched those from the three largest of the seven markets (footnote 2348). Although it must be taken into account that the licence eliminates any risk of further infringement proceedings and that the profits that Krka could obtain through the licence agreement were therefore more certain, the importance that it could attach to such a risk depended to a large extent on its degree of conviction as to the validity of the patent. The fact that Krka recognised the validity of the 947 patent was therefore a decisive factor in its decision to choose a limited – but licence-protected – entry to the seven markets rather than a wider entry to all of the Member States' markets subject to a significant risk of infringement because of the validity of that patent from Krka's perspective.

236 Thirdly, with regard to the other elements that are supposed to establish the inducive nature of the licence agreement for Krka, it should be noted first of all that the fact that the latter estimated the opportunity cost of not entering into the agreement at more than EUR 10 million of 'lost profits' in three years (recital 1738 of the contested decision) is rather an additional indication of the fact that it considered that the 947 patent was valid. The profits in question corresponded to those expected if it entered or stayed on the seven markets. Thus, Krka seems to have considered that in the absence of an agreement with Servier, it was unlikely, if not impossible, that it would enter those markets at risk or stay on those markets, which confirms the fact that it acknowledged the validity of the 947 patent.

237 Next, although it is apparent from recital 1740 of the contested decision, which refers to recital 913 thereof, that the 18 to 20 markets were 'traditionally less important for Krka', the expected profits on those markets were far from negligible (see paragraph 235 above).

238 Thus, the elements set out in paragraphs 236 and 237 above do not establish that the licence agreement was an inducement for Krka.

239 Fourthly, the Commission's finding that the settlement and licence agreements constituted market sharing between Servier and Krka (see the title of section 5.5.3 of the contested decision and, inter alia, recital 1745 thereof) is unfounded.

240 As regards the seven markets covered by the licence agreement, although the Commission did not find an infringement in respect of that part of the internal market, it nevertheless took account of the conduct of Servier and Krka on those seven markets, including the conclusion of the licence agreement, which the Commission classified as an inducement, in order to establish the existence of market sharing based on a distinction between the 18 to 20 Member States, on the one hand, and the seven Member States, on the other.

241 However, Servier was not excluded from the markets of the seven Member States where Krka and it were in competition (see paragraph 227 above).

242 Thus, there was no part of the market which, under the settlement and licence agreements, was reserved for Krka. It therefore cannot be concluded that there was market sharing – in the sense of a hermetic division between the parties to the agreement – of that part of the internal market.

243 Furthermore, it should be noted that, in those seven Member States, the licence agreement contributed to the entry or continued presence on the market of a generic competitor of the originator company. It therefore had a positive effect on competition by comparison with the previous situation in which the generic companies could only enter or remain on the market at risk, since the validity of the main patent in question – the 947 patent – had just been confirmed by the competent authorities (see paragraph 206 above) and there was a risk, which Krka perceived as a serious risk, that its product was infringing.

244 It should be added that the fact that, at the time the settlement and licence agreements were concluded, the national equivalents of the 947 patent had not yet been granted to Server in some of the seven markets, whereas Krka was already selling its product (recital 1755 of the contested decision), does not support the conclusion that the licence agreement had no positive effect on competition. Although it is true that Krka could already have entered the markets before the licence agreement without facing an immediate risk of infringement proceedings and although, consequently, the licence did not play a decisive role in relation to Krka's entry of the markets in question, it nevertheless allowed Krka to remain on those markets without the risk of facing such a challenge.

245 The licence agreement's positive effect on competition noted in paragraphs 243 and 244 above supports the conclusion that there was no market sharing as regards the seven Member States.

246 The licence agreement's positive effect on competition is further confirmed by an extract from Krka's reply to a request for information which appears in recital 913 of the contested decision. That extract states, inter alia, as follows:

> 'Getting a license and withdrawing oppositions was considered as the best option for Krka at that time – to be able to sell perindopril on Kr-

ka's key markets in [Central and Eastern Europe] immediately, it means in 2006.

According to all other scenarios, a launch was not possible earlier than in at least 2 years after July 2006, and even after such period a launch was not warranted (risk that 947 is maintained, development risks for non-alpha).'

247 The extract cited in paragraph 246 above supports the conclusion that Krka considered that, without a licence agreement, it would be impossible to enter or remain on the market in the seven Member States because of the 947 patent (see paragraphs 235 and 236 above).

248 As regards the 18 to 20 markets, that is to say the only part of the market in respect of which the Commission found an infringement, it should be noted that, since it has not been shown that there was an inducement (see paragraph 220 above), the non-marketing and non-challenge clauses must be regarded as arising from a legitimate patent dispute settlement agreement which is linked to a licence agreement (see paragraph 199 above). Such a contractual framework, based on the recognition of the validity of the patent, cannot, therefore, be classified as a market exclusion agreement.

249 Accordingly, no part of the market was unlawfully reserved for Servier.

250 The market sharing on which the Commission also based its finding of a restriction by object is therefore not established.

251 Fifthly, the Commission failed to demonstrate that Servier or Krka had intended to conclude a market sharing or market exclusion agreement, that Servier had intended to induce Krka not to compete or that Krka had intended to agree, in exchange for an inducive benefit, not to exert competitive pressure on Servier.

252 As a preliminary point, it should be borne in mind that it is normal for the activities which anticompetitive practices and agreements entail to take place in a clandestine fashion, for meetings to be held in secret, and for the associated documentation to be reduced to a minimum. It follows that, even if the Commission discovers evidence explicitly showing unlawful contact between traders, it will normally be only fragmentary and sparse, so that it is often necessary to reconstitute certain details by deduction (judgment of 25 January 2007, *Sumitomo Metal Industries and Nippon Steel* v *Commission*, C403/04 P and C405/04 P, EU:C:2007:52, paragraph 51). It must be noted, however, that the agreements at issue in the present case are genuine contracts which, moreover, were well publicised (recital 915 of the contested decision). Since the Commission could easily obtain the full content of the agreements at issue, the applicability of the case-law which has just been cited is less evident. Thus, inferences drawn from partial extracts of e-mails or other documents purporting to establish the intentions of the parties cannot easily call into question a finding based on the actual content of the agreements, that is to say on the legally binding relationship which the parties have decided to establish between themselves.

253 It should also be noted that, in the present case, documents which postdate the EPO decision of 27 July 2006, or the interim injunction of 3 October 2006 delivered in the United Kingdom against Krka, are best able to shed light on the intentions of the parties when they concluded the settlement and licence agreements. Those two events substantially altered the context in which the agreements were concluded, in particular as regards the perception that Krka, as well as Server, could have of the validity of the 947 patent.

254 As regards Krka, the documents on which the Commission relies in order to determine that company's intentions (see, inter alia, recitals 849 to 854 and 1758 to 1760 of the contested decision, as well as the recitals to which they refer) concern periods before those events.

255 The extracts cited are, in any event, too fragmentary or ambiguous to establish – contrary to what the Court has repeatedly noted (see, inter alia, paragraphs 235, 236 and 247 above) – that Krka did not recognise the validity of the 947 patent and, a fortiori, that, at the time the settlement and licence agreements were signed, it intended to conclude market sharing or market exclusion agreements.

256 As regards Servier, the only extract from a document – which postdates the two events mentioned above – purportedly showing its anticompetitive intentions and which is referred to in the section of the contested decision devoted to those intentions (recitals 1761 and 1762), is the following: '4 years gained = great success'.

257 That extract appears in the record of a meeting of the top management of Servier, which refers to the judgment of 6 July 2007 of the High Court of Justice (England and Wales), Chancery Division (Patents Court), according to which the 947 patent was invalid for lack of novelty and inventive step of that patent in relation to the 341 patent.

258 Even assuming that it could be inferred from that extract that Servier's management had considered, following that judgment, that the interest of the 947 patent lay in allowing it to gain an additional four years of protection, it cannot be concluded from this that, on 27 October 2006, when the settlement and licence agreements were concluded, Servier intended to conclude market sharing or exclusion agreements nor, a fortiori, can it be concluded that the settlement and licence agreements were restrictive of competition by object.

259 Furthermore, the observation made by another generic company, according to which 'it would seem the rationale for this settlement from Servier's view is that it protects the key markets where high level substitution and/or [international nonproprietary name] prescribing is prevalent' (recital 1730 of the contested decision), cannot, even taken into account with all the other evidence relied on by the Commission, establish the existence of an intention on Servier's part to adopt market sharing or market exclusion agreements with Krka.

260 Lastly, the Commission's repeated references in the contested decision to a document entitled 'Coversyl: defense against generics' are not convincing. That document predates the EPO decision of 27 July 2006 and the interim injunction of 3 October 2006 delivered in the United Kingdom against Krka, which considerably limits its relevance (see paragraph 253 above). Moreover, it is apparent from the contested decision itself that that document does not elaborate a strategy concerning Krka, but, at most, that it follows from 'the nature and structure of the document' and from 'the context in which reference is made to Krka' that a defence was 'considered' against it (footnote 2386). Lastly, it is not apparent from the extracts from that document cited in the contested decision that Servier expressed doubts as to the validity of the 947 patent.

261 In any event, for the purposes of casting doubt on the conclusion reached by the Court in paragraph 221 above and establishing that the aim of the agreements at issue was – contrary to the conclusion implied

by an analysis of their content and of the context in which they were concluded – the buying off of a competitor in order to exclude it from the market, it would fall to the Commission, in light of the considerations set out in paragraph 252 above, to produce a body of relevant and consistent evidence. The Commission has not been able to produce such evidence.

262 Sixthly, the fact that Krka continued to challenge Servier's patents and to market its product even though the validity of the 947 patent had been upheld by the EPO decision of 27 July 2006 is not a decisive factor for the purpose of establishing the existence of a restriction of competition by object, since the fact that Krka continued to exert competitive pressure on Servier can be explained by Krka's desire, despite the expected litigation risks, to strengthen its position in the negotiations that it was likely to have with Servier with a view to reaching a settlement.

263 In addition, continuing to challenge Servier's patent did not cause Krka to run any further risks in terms of infringement. It merely increased its litigation costs. As for the fact that it continued to market its product, it limited itself to five Central and Eastern European markets, and the Commission indicated, in the contested decision, that Krka had 'eventually ceased to consider entering at risk in the UK, France and other Western European markets in the aftermath of the Opposition [Division's] Decision' (recital 1693). In addition, in five of the seven markets covered by the licence, the equivalents of the 947 patent had not yet been granted (recital 1755 of the contested decision). Thus, the risks incurred by Krka, in at least some of the markets in which it remained, were limited.

264 Having regard to the considerations set out in the two preceding paragraphs, the fact that Krka continued to challenge Servier's patents and to market its product even though the validity of the 947 patent had been upheld by the EPO Opposition Division does not – contrary to the Commission's submissions – support the conclusion that the EPO decision of 27 July 2006 did not have a decisive impact on Krka's perception of the 947 patent and, consequently, on its subsequent choice to agree to settle with Servier.

265 Seventhly, although the Commission has adduced some evidence showing that the settlement and licence agreements were the subject of commercial negotiations between Servier and Krka, with Krka seeing to maximise the advantages that it could gain from those agreements and even making the licence agreement a condition of its acceptance of the non-marketing and non-challenge clauses (see, inter alia, recitals 913 and 1746 to 1748 of the contested decision), that evidence, even taken together with all of the other evidence relied on by the Commission, does not establish that the licence agreement was not a transaction concluded at arm's length, that is to say that the royalty rate of 3% stipulated in the licence agreement was not chosen on the basis of commercial considerations, but rather in order to induce Krka to accept the non-marketing and non-challenge clauses in the settlement agreement.

266 In addition, it should be borne in mind that the conclusion of a licence agreement, which, for any licensee, makes sense only if the licence is actually used, is based on the parties' recognition of the validity of the patent (see paragraph 183 above). Thus, the fact that the generic seeks to obtain the licence agreement which is most favourable to his commercial interests is not sufficient to show that that company did not conclude the agreement in question on the basis of its recognition of the validity of the patent.

267 It should be added that an agreement benefiting Krka enabled it to enter the parts of the market where its position was strongest and where it could rapidly market or continue to market its product, which is beneficial to competition. Thus, the interests of a generic company such as Krka, which seeks to obtain from the originator company the licence that is most beneficial to its commercial interests, converge with those of the consumer since, due to the licence agreement, a generic company will rapidly enter the market or remain there.

268 It follows from all the foregoing that the conclusion set out in paragraph 221 above must be affirmed, since the settlement and licence agreements at issue do not reveal a sufficient degree of harm to competition that the Commission could validly conclude that they constituted a restriction by object. The plea is therefore well founded.

B. Fourth plea in law, alleging that there is no restriction of competition by object as regards the assignment agreement

[…]

2. Findings of the Court

[…]

280 The Commission first of all found that, under the assignment agreement, Krka had assigned two patent applications to Servier, one concerning a process for the synthesis of perindopril (WO 2005 113500) and the other concerning the preparation of perindopril formulations (WO 2005 094793), and that the technology covered by those patent applications was used for the production of Krka's perindopril (recital 1770 of the contested decision).

281 On the basis of that finding, the Commission sought to demonstrate that the assignment agreement reinforced the competitive position of Servier and Krka which arose from the market sharing that had been established, according to the Commission, by the settlement and licence agreements (recitals 1766 and 1804 of the contested decision).

[…]

292 However, as indicated above (see paragraph 250 above), that finding is incorrect.

293 Consequently, the Commission's finding of a restriction by object with regard to the assignment agreement must also be held to be invalid.

294 It should be added that the assignment agreement is not a 'side deal' to the settlement agreement, within the meaning of the considerations set out in paragraphs 164 et seq. above.

295 That assignment agreement was not concluded on the same day as the settlement agreement, there is no contractual link between the two agreements and the Commission has not established that they were indissociable (see paragraph 165 above).

296 The Commission even stated that there was no link between, on the one hand, the EUR 30 million payment by Servier to Krka under the assignment agreement and, on the other hand, the settlement agreement, in the sense that that payment did not constitute an inducement for Krka to accept the non-marketing and non-challenge clauses in the settlement agreement. That is apparent, inter alia, from the following extracts from the contested decision:

'(1678) Two months later, Servier purchased from Krka patent applications for competing technologies to produce perindopril for EUR 30 million. Krka considered that Servier feared that this technology could otherwise be assigned or licensed to other competitors. While some elements point in the direction of the existence of a link between the Settlement Agreement and the payment of [EUR] 30 million by Servier, this decision does not draw any conclusion on this point, and the analysis of those agreements is not based on the existence of such a link.

…

(footnote 2419) Servier contests that there was a link between the payment for patent applications and the settlement agreement. (Servier's reply to the Statement of Objections, paragraph 1084, ID 10114, p. 363). As it evidently flows from section 5.5.3.3.3, the assessment of the Krka Settlement Agreement does not consider the payment of EUR 30 million as an inducement for Krka to accept the restrictive settlement terms, and leaves open as undecided the question whether there was a link between the settlement agreement and the [assignment and licence agreement].'

297 Thus, the assignment agreement cannot compensate for the fact that the inducement which, according to the Commission, arises from the licence agreement and allowed it to conclude that the settlement agreement was actually intended to exclude one of Servier's competitors is not established (see paragraph 220 above).

298 It follows from all of the foregoing that the Commission erred in finding, as regards the assignment agreement, a restriction of competition by object. The present plea is therefore also well founded.

[…]

IV. Overall conclusion

[…]

V. Costs

[…]

On those grounds,

THE GENERAL COURT (Ninth Chamber)

hereby:

1. Annuls Article 4 of Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Article 101 and Article 102 TFEU (Case AT.39612 – Perindopril (Servier)) in so far as it finds that Krka Tovarna Zdravil d.d. participated in the agreements referred to in that article;

2. Annuls Article 7(4)(a) of Decision C(2014) 4955 final;

3. Annuls Articles 8 and 9 of Decision C(2014) 4955 final, in so far as they concern Krka Tovarna Zdravil;

4. Orders the Commission to pay the costs.

Noot

Servier – Verboden octrooischikkingen

Inleiding

Na afloop of na vernietiging van hun octrooien op een geneesmiddel zien farmaceuten de prijzen van het betreffende geneesmiddel doorgaans snel dalen als gevolg van nieuwe concurrentie van generieken. Dit dreigende verlies aan omzet heeft in het verleden ertoe geleid dat sommige originators met generieken (schikkings)overeenkomsten zijn aangegaan waarbij werd afgesproken dat in ruil voor een waardeoverdracht van de originator aan de generiek, de generiek vertraagd op de markt zou komen en geen vernietiging van het betreffende octrooi zou vorderen, – zogenaamde *pay-for-delay* afspraken, of *reverse payment settlements*.[1] Doorgaans worden deze overeenkomsten gesloten kort voor afloop van het octrooi of wanneer geldigheidsprocedures tegen het octrooi aanhangig zijn. Op deze manier blijft de originator, net als daarvoor, de enige op de markt met het betreffende geneesmiddel en kan hij de prijzen hoog houden. Zo ook Servier die in de jaren 2000 met haar blockbuster perindopril jaarlijks een wereldwijde omzet behaalde van meer dan 1 miljard USD, goed voor ongeveer 30% van haar totale omzet.

Dat hardcore pay-for-delay afspraken niet zijn toegestaan, lag al vóór de eerste boetebesluiten van de Europese Commissie voor de hand.[2] Het kartelverbod uit artikel 101 van het EU-Werkingsverdrag verbiedt immers afspraken die het doel of het gevolg hebben dat de markt wordt verdeeld of de productie wordt beperkt. Toch is er een grijs gebied tussen wat wel of niet is toegestaan, zoals de gedeeltelijke vernietiging door het Gerecht van het Commissiebesluit over perindopril[3] wel weer bewijst.

Commissiebesluit en arrest

Perindopril is een geneesmiddel voor de behandeling van hypertensie en hartfalen, ontwikkeld door farmaceut Servier. Op 9 juli 2014 heeft de Europese Commissie Servier en vijf producenten van generieke geneesmiddelen, Niche/Unichem, Matrix, Teva, Lupin en Krka, beboet voor het aangaan van schikkingsovereenkomsten met betrekking tot octrooien van Servier over perindopril. De vier eerste generieken hebben in ruil voor financiële compensatie van Servier hun geldigheidsprocedures tegen de octrooien ingetrokken en toegezegd de markt voorlopig niet

1 Besluiten van de Europese Commissie van 19 juni 2013, zaak AT.39226 (*Citalopram*) en 10 december 2013, zaak AT.39685 (*Fentanyl*).
2 Idem.
3 Besluit van de Commissie van 9 juli 2014, zaak AT.39612 (*Perindopril*) (hierna: "Commissiebesluit").

te betreden met een generieke versie van perindopril. Met de vijfde generiek, Krka, is Servier een licentieovereenkomst aangegaan. Krka mocht in zeven landen op de markt komen, in ruil waarvoor Krka het octrooi niet zou aanvallen en zij een (volgens de Commissie abnormaal lage) royalty zou betalen van 3% van de omzet behaald met het geneesmiddel. De Commissie oordeelde dat dit pay-for-delay afspraken waren die het doel hadden de markttoetreding van de generieken te vertragen en dus in strijd waren met het kartelverbod. De Commissie heeft een totale boete opgelegd van € 427,7 miljoen aan Servier en de generieken.

Servier en de generieken zijn in beroep gegaan bij het Gerecht. Bij arrest van 12 december 2018 bekrachtigde het Gerecht het Commissiebesluit tegen Niche, Matrix, Teva en Lupin.[4] Het Gerecht vernietigde echter het besluit wat betreft de afspraak tussen Servier en Krka.[5] Reden hiervoor is dat deze afspraak niet het *doel* kon hebben de mededinging te beperken. Bovendien had de Commissie niet bewezen dat een royalty van 3% abnormaal laag was en dat de afspraak dus het *gevolg* had dat de mededinging was beperkt.[6]

Bij de beoordeling van de onderhavige afspraken volgt het Gerecht de driecriteriatoets van de Commissie: (i) waren Servier en de generieken potentiële concurrenten, (ii) waren in de schikking niet-aanvechtingsbedingen en handelsverboden voor de generieken opgenomen, en (iii) waren deze afgesproken in ruil voor een waardeoverdracht van Servier aan de generieken die voor de generieken een prikkel vormde om deze afspraken aan te gaan.[7] Aan de twee eerste vereisten was voor alle generieken voldaan. Dit zal doorgaans ook relatief eenvoudig vast te stellen zijn. Deze noot zal focussen op het laatste criterium en de inzichten die het Gerecht hierover geeft: wat is een waardeoverdracht en wanneer is een omgekeerde betaling (d.w.z. een betaling van originator naar generiek) toegestaan.[8]

Waardeoverdrachten

Uit het laatste Commissierapport over de *Monitoring of Patent Settlements* volgt dat een waardeoverdracht van originator naar generiek verschillende vormen kan aannemen. De meest voor de hand liggende is een rechtstreekse betaling. Deze betaling kan dienen om de voorraad van de generiek over te nemen, maar kan ook tot doel hebben om direct of indirect de productlancering uit te stellen of de octrooien (kunstmatig) in stand te houden. Een waardeoverdracht is ook aanwezig wanneer de originator de generiek een ander commercieel voordeel toekent, denk aan distributieovereenkomsten, co-promotieafspraken, licenties of andere zogenaamde *side-deals*, zoals de generiek toestaan om de markt te betreden voordat het octrooi in een ander geografisch gebied afloopt of met een ander product dan door de originator op de markt wordt gebracht.[9] Met andere woorden: alle afspraken die een commerciële waarde hebben voor een generiek worden beschouwd als waardeoverdracht.

Een octrooi wordt behoudens bewijs van het tegendeel vermoed geldig te zijn en zou dus geld voor de octrooihouder moeten opleveren. Daarom wringt het op het moment dat een schikking gepaard gaat met een waardeoverdracht van de octrooihouder aan de inbreukmaker. Als het octrooi geldig zou zijn, zou de generiek juist voor het gebruik van dat octrooi moeten betalen, en geen geld moeten ontvangen van de octrooihouder.[10] Dit betekent echter niet dat alle omgekeerde betalingen in het kader van schikkingen zijn verboden. Waar het hier om gaat is dat de waardeoverdracht een *prikkel* vormt voor de generiek om niet op de markt te komen. Net als in *Lundbeck,*[11] de eerste en enige andere zaak van het Gerecht over pay-for-delay, lijkt in *Servier* de vraag of een omgekeerde betaling is toegestaan wederom dus voor een groot deel te draaien rond de aard en omvang van deze betaling.

Betalingen die onlosmakelijk zijn van de schikking

Het Gerecht overweegt in de onderhavige zaak dat sommige betalingen van octrooihouder naar inbreukmaker gerechtvaardigd zijn omdat deze waardeoverdrachten de kosten dekken die inherent zijn aan octrooischikkingen, zoals proceskosten. Kosten die buiten (de beslechting van) het geschil vallen, zoals de productie- en ontwikkelingskosten van de generiek, kunnen niet als inherent worden beschouwd. Het Gerecht benadrukt dat de bewijslast voor het aantonen dat de omgekeerde betalingen de kosten dekken die inherent zijn aan de schikking of het geschil op de schikkende partijen rust.[12]

Waardeoverdrachten in het kader van side-deals

Een *side-deal* is een commerciële overeenkomst die verbonden is met een schikkingsovereenkomst die zelf beperkend van aard is (bijvoorbeeld omdat daarin wordt afgesproken dat de generiek niet op de markt zal komen). Een side-deal bij een schikking is aanwezig wanneer de twee overeenkomsten op dezelfde dag zijn gesloten of dat uit de inhoud ervan expliciet dan wel impliciet volgt dat ze onlosmakelijk van elkaar zijn verbonden. Dit is bijvoorbeeld het geval wanneer het bindende karakter van de éne overeenkomst afhankelijk is van de sluiting van de andere overeenkomst.[13] Het Gerecht overweegt in *Servier* dat side-deals een "ernstige" aanwijzing vormen van een mededingingsbeperking.[14] Reden hiervoor is dat het risico bestaat dat side-deals dienen als middel om omgekeerde betalingen door middel van complexe contractuele regelingen te verhullen.[15]

Een voorbeeld van een side-deal die in het onderhavige geval was gesloten, was de verkoop van octrooiaanvragen door Lupin aan Servier voor (volgens de Commissie) "disproportioneel hoge bedragen" zonder garantie van verlening van de betreffende

4 Gerecht 12 december 2018, zaken T-677/14, T-679/14, T-680/14, T-682/14, T-701/14 en T-705/14.
5 Het Commissiebesluit is ook vernietigd met betrekking tot het oordeel dat Servier, met deze afspraken, een uitsluitingsstrategie heeft gevolgd die misbruik van haar machtspositie vormde ingevolge artikel 102 EU-Werkingsverdrag. Deze noot zal hier echter niet op ingaan.
6 *Servier*, par. 1032 en *Krka* par. 213.
7 *Servier*, par. 406 (en in mindere duidelijk *Krka* par. 151).
8 In een annotatie voor het tijdschrift *Markt & Mededinging* (nog niet gepubliceerd) ga ik met mijn collega mr. P.P.J. van Ginneken in op andere vragen die in *Servier* speelden, i.e. de marktafbakening in de geneesmiddelensector in het kader van misbruik van machtspositie en de relevantie van de geldigheid van octrooien bij de beoordeling van mededingingsafspraken.
9 Europese Commissie, "8th Report on the Monitoring of Patent Settlements (period: January-December 2016)", gepubliceerd op 9 maart 2018 (hierna: "EC Report on the Monitoring of Patent Settlements"), par. 12-13.
10 *Krka*, par. 143 en *Servier*, par. 253-276.
11 Gerecht, zaak T-472/13, 8 september 2016 (*Lundbeck/Commissie*) ("*Lundbeck*").
12 *Krka*, par. 174-1877 en *Servier*, par. 277-280, 680-683.
13 *Krka*, par. 165-166 en *Servier*, par. 798.
14 *Krka*, par. 170 en *Servier*, par. 796-797 ; *Krka*, par. 164.
15 *Krka*, par. 169 en *Servier*, par. 800-801.

16 Andere voorbeelden van gebruikelijke side-deals zijn co-promotieafspraken en distributieovereenkomsten.
17 *Krka*, par. 179-200 en *Servier*, par. 945-998.
18 EC Report on the Monitoring of Patent Settlements, par. 9. Er bestaat dus ook geen verplichting voor de generiek om een procedure uit te procederen zoals weleens werd gedacht naar aanleiding van de eerste *sector enquiry* van de Commissie over octrooischikkingen.
19 Richtsnoeren voor de toepassing van artikel 101 van het Verdrag betreffende de werking van de Europese Unie op overeenkomsten inzake technologieoverdracht (2014/C 89/03) ("Richtsnoeren voor technologieoverdracht"), par. 239.
20 *Krka*, par. 219-220 en *Servier*, par. 949.
21 *Krka*, par. 188 en *Servier*, par. 976.
22 *Krka*, par. 234 en *Servier*, par. 998.
23 *Krka*, par. 227 en *Servier*, par. 1005-1007.
24 Vgl. EC Report on the Monitoring of Patent Settlements, par. 11.
25 EC Report on the Monitoring of Patent Settlements, par. 13 en voetnoot 12: "*is not likely to attract the highest degree of antitrust scrutiny*".

octrooien.[16] Dit kon worden beschouwd als een poging om de omgekeerde betaling in de schikking te verbergen. Deze side-deal werd door de Commissie en het Gerecht bestempeld als mededingingsbeperkend.

Ook het verstrekken van een licentie door Servier aan Krka was een side-deal. Echter, over licentieovereenkomsten is het Gerecht genuanceerder. Licenties zijn bij uitstek geschikt om een einde te maken aan een geschil en de generiek krijgt precies wat hij wilde: hij mag de markt op. Daarnaast gaan licenties (impliciet) gepaard met een erkenning van de geldigheid van het octrooi en brengen zij een toename van de concurrentie mee: de generiek krijgt de mogelijkheid om de markt te betreden zonder het risico te lopen in rechte te worden betrokken in een inbreukprocedure.[17] Uit het Commissierapport over de *Monitoring of Patent Settlements* volgt dat licenties om niet sowieso zijn toegestaan wanneer een generiek ook gelijk op de markt kan komen zonder beperkingen met betrekking tot hoeveelheden, samenstelling van het product, prijs of andere marketingsvoorwaarden.[18] Logisch, dergelijk licenties kennen immers geen markttoetredingsbeperkingen. Anderzijds volgt uit de Richtsnoeren voor technologieoverdracht dat licenties wel mededingingsbeperkend kunnen zijn wanneer ze leiden tot een vertraagde of anderszins beperktere mogelijkheid voor de licentienemer om zijn product op één van de betrokken markten te lanceren.[19] Denk aan een licentie die beperkt is tot een bepaald geografisch gebied of een zogenaamde *early entry*, dat wil zeggen een afspraak om vóór verval van het octrooi maar wel pas in de toekomst op de markt te komen. Dit roept de vraag op hoever licentieovereenkomsten mogen gaan zonder in strijd te komen met het mededingingsrecht. Hier waren het Gerecht en de Commissie het niet over eens.

De Commissie was van oordeel dat de licentie van Servier aan Krka, die is beperkt tot een bepaald geografisch gebied en met een "abnormaal lage royalty" van slechts 3% van de behaalde omzet, het doel had om de mededinging te beperken. Het Gerecht vernietigt dit oordeel. Het Gerecht overweegt dat bij een licentieovereenkomst sprake is van een dubbele waardeoverdracht: van originator aan generiek (de licentie) en van de generiek aan originator (de royalty). Volgens het Gerecht had de Commissie in een dergelijk geval moeten bewijzen dat de licentieovereenkomst niet onder normale marktvoorwaarden was gesloten en werd gebruikt als middel om een omgekeerde betaling te verhullen.[20] Met andere woorden, de Commissie had dus moeten bewijzen dat de royalty abnormaal laag was.[21] Het Gerecht overweegt bovendien dat als Krka niet in de geldigheid van het octrooi in kwestie had geloofd, de licentieovereenkomst niet een voldoende prikkel voor Krka zou hebben gevormd om akkoord te gaan met de niet-aanvechtingsbedingen en het handelsverbod voor de overige landen. Het voordeel dat uit de licentie volgt, kan alleen als een prikkel worden beschouwd als de originator een compensatie biedt voor het verlies aan verwachte winst in de delen van de markt die de generiek als gevolg van de schikking niet mag betreden. Voor een generiek die niet serieus gelooft in de geldigheid van een octrooi en dus denkt in staat te zijn de volledige markt te betreden, vormt een licentie waarvan de geografische reikwijdte beperkter is dan de reikwijdte van het octrooi dus geen economisch bevredigende oplossing die tot een schikking zou kunnen leiden. Weliswaar stelde de licentie in casu een deel van de markt open voor Krka; echter, omdat niet vaststaat dat de royalty van 3% voor dat deel van de markt abnormaal laag was, lijkt de licentie Krka geen enkele compensatie te geven ten opzichte van de andere (verboden) delen van de markt, waarop zij in geval van nietigverklaring van het octrooi winst had kunnen maken.[22] Daarnaast was de licentie voor Krka niet exclusief en concurreerde zij ook met Servier op de betreffende markten.[23]

Hoe zit het dan met early entry afspraken die partijen in het kader van schikkingen regelmatig willen maken? Een afspraak kan in wezen worden beschouwd als een (gratis en dus in beginsel abnormaal goedkope) licentie. Een dergelijke afspraak is commercieel veel waard omdat een generiek daarmee vóór alle andere generieken de markt op mag en zo zijn marktpositie veilig kan stellen. Aan deze early entry zijn handelsbeperkingen verbonden wanneer met de generiek wordt afgesproken dat hij niet onmiddellijk maar pas in de toekomst de markt op zal mogen.[24] Samengevat, originator en generiek spreken in het kader van een schikking af dat de generiek in ruil voor een waardeoverdracht van de originator (de early entry) later ("delayed") op de markt zal komen en het octrooi niet zal aanvechten.

De Commissie heeft reeds overwogen dat een "*pure early entry*" waarbij early entry wordt afgesproken zonder enige andere beperking voor de generiek dan de datum van toetreding tot de markt waarschijnlijk niet (heel) mededingingsbeperkend zal zijn.[25] Een early entry afspraak heeft namelijk tot gevolg dat een nieuwe concurrent de markt mag betreden en de prijzen voor het geneesmiddel daardoor worden gedrukt. Anderzijds kan worden betoogd dat de originator die in de kracht van zijn octrooi gelooft, met name wanneer sprake is van een blockbuster, niet (snel) akkoord zal gaan met een nieuwe concurrent vóór verval van zijn octrooi. Er zou dus een vermoeden kunnen bestaat dat de originator die akkoord gaat met een dergelijke afspraak zijn positie op de markt kunstmatig probeert te waarborgen door met een generiek af te spreken dat hij eerder de markt op mag als hij akkoord gaat met het niet aanvechten van het octrooi.

In het licht van de beoordeling van de Krka-afspraak lijkt de waarde van deze early entry tevens te moeten

worden geschat en te worden afgewogen tegen de winst die de generiek had gemaakt als hij de zaak had uitgeprocedeerd en rechtstreeks op de markt zou zijn gekomen. Bij een "pure" early entry afspraak krijgt de generiek naast de licentie geen aanvullende compensatie voor het niet betreden van de markt. Voor een generiek die niet in de geldigheid van het octrooi gelooft, zou dit wellicht onvoldoende prikkel zijn om akkoord te gaan met de schikking. Ook relevant is of verdere afspraken tussen originator en generiek zijn gekoppeld aan de early entry die de zaak verder zouden kunnen kleuren.[26] Of een early entry afspraak is toegestaan, is dus (zoals wel gebruikelijk in het mededingingsrecht) afhankelijk van de omstandigheden van het geval.

Cross undertakings

Wel toegestaan, zijn (zo lijkt het) afspraken omtrent schadevergoeding van de originator aan de generiek als de generiek toezegt niet op de markt te komen in afwachting van een geldigheids- en inbreukoordeel van de rechtbank. Ergens verscholen in de 124 pagina's van *Lundbeck* overwoog het Gerecht dat een omgekeerde betaling is toegestaan wanneer het "*noodzakelijk is om een in de ogen van de partijen aanvaardbare en rechtsgeldige oplossing te vinden en wanneer dit niet gepaard gaat met beperkingen die bedoeld zijn om de markttoetreding van de generieken te vertragen*". Zo noemde het Gerecht het voorbeeld van generiek Neolab, waarmee originator Lundbeck had afgesproken dat zij niet op de markt zou komen in afwachting van geldigheid- en inbreukoordelen van de bevoegde rechtelijke instanties, in ruil voor vergoeding van de schade die Neolab hierdoor had geleden mocht het octrooi toch worden vernietigd – ook wel bekend als een *cross undertaking*. De betreffende zaak is vervolgens geschikt en Lundbeck heeft de schadevergoeding aan Neolab betaald. Deze omgekeerde betaling werd niet problematisch geacht omdat deze daadwerkelijk tot doel had om een geschil tussen de partijen te beslechten, zonder de markttoetreding van de generiek te vertragen.[27]

Het Gerecht en de Commissie leggen niet uitgebreid uit wat de grondslag is van deze keuze – en dit roept de nodige vragen op. Een generiek heeft in Nederland recht op schadevergoeding als een vonnis door de originator onrechtmatig ten uitvoer wordt gelegd, dat wil zeggen wanneer hij in kort geding of in eerste aanleg ten onrechte een inbreukverbod heeft gekregen. Dit geldt echter niet wanneer een generiek die de mogelijkheid heeft om de markt op te komen, dit om hem moverende redenen vrijwillig toch niet doet. Een cross undertaking voorziet dus in schadevergoeding in een situatie waarin de generiek hier anders geen recht op had gehad. Partijen spreken dus af dat de generiek niet of vertraagd met zijn goedkope producten op de markt zal komen in ruil voor een waardeoverdracht. Als de schade die de generiek lijdt (gederfde winst) lager is dan de winst die de originator maakt – en dit zal vrijwel altijd het geval zijn, omdat de originator geneesmiddelen vóór verval van het octrooi altijd duurder zijn dan de generieke versies –, hebben zowel originator als generiek financieel baat bij het maken van de afspraak. Immers, de generiek krijgt zijn kosten alsof hij op de markt was geweest, zonder dat hij het risico loopt dat hij later schadevergoeding moet betalen, en de originator behoudt de tijd van het beroep tegen zijn in eerste aanleg vernietigd octrooi zijn hoge prijzen, en daarmee ook de marge tussen de schadevergoeding aan de generiek en de gemaakte winst.

Anderzijds biedt een cross undertaking een oplossing voor de generieken die na winst in eerste aanleg niet de markt op durven, vrezend voor hoge schadeclaims van de originator, mocht het vonnis in eerste aanleg worden vernietigd en de geldigheid van en inbreuk op het octrooi toch worden bevestigd. Een terechte vrees: die schadevergoeding ligt hoger dan een eenvoudige winstafdracht door de generiek: de schade van de originator omvat ook de marge tussen de prijs van de generiek en de prijs van de originator. Hierdoor kiezen sommige generieken er in de praktijk voor om zonder cross undertaking niet de markt op te gaan. Betoogd kan worden dat een cross undertaking de mededinging veelal niet beïnvloedt omdat de generiek in het alternatieve scenario zonder cross undertaking (de zogeheten "counterfactual") toch niet op de markt was gekomen In het Verenigd Koninkrijk zijn cross undertakings overigens wel gebruikelijk. Als partijen deze niet vrijwillig aangaan, kan de rechter ze ook op basis van een belangenafweging voor de duur van de procedure opleggen. Verdedigbaar is dus dat cross undertakings marktconform zijn en "onlosmakelijk zijn van de schikking". Dan zal er rond deze afspraken meer moeten spelen om deze mededingingsbeperkend te achten.

Conclusie

De beoordeling van reverse payment settlements is erg casuïstisch en moet per geval worden beoordeeld. In veel gevallen is nog geen eenduidig antwoord te geven over wat al dan niet is toegestaan omdat daar nog geen oordeel over is gegeven door de Commissie of het Hof van Justitie. Inmiddels hebben de Commissie, Servier en de generieken (m.u.v. Krka) hoger beroep ingesteld tegen de arresten van het Gerecht.[28]

Andere zaken die bij het Hof van Justitie in de pijplijn zitten, zijn de hoger beroepen tegen de *Lundbeck*-arresten die op het moment van het schrijven van deze noot voor conclusie van de advocaat-generaal staan.[29] Tevens heeft de Engelse Competition Appeal Tribunal in 2018 prejudiciële vragen gesteld aan het Hof van Justitie in een zaak met GlaxoSmithKline.[30]

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26 EC Report on the Monitoring of Patent Settlements, par. 13.
27 *Lundbeck*, par. 350-351.
28 HvJ zaken C-144/19 P, C-151/19 P, C-164/19 P, C-166/19 P, C-176/19 P C-197/19 P, C-198/19 P, C-201/19 P.
29 Zie voor *Lundbeck/Commissie*: HvJ zaak C-591/16 P.
30 HvJ zaak C-307/18 (*Generics c.s./ Competition and Markets Authority*). Volgens het Withdrawal Agreement zullen hangende prejudiciële vragen nog na de Brexit worden beantwoord.