Competition Law Association
British Group of the
Ligue Internationale du Droit de la Concurrence
(International League for Competition Law)

Webinar: Navigating Competition Law Issues in IP Settlements

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i. The Conundrum

- Competition law issues in IP settlements in the pharmaceutical sector typically arise where an originator company (Company A) has developed a novel active pharmaceutical ingredient (API) and acquired a compound patent to protect its invention. As the compound patent approaches expiry, a manufacturer of unbranded generic products (Company B) will typically spend significant amounts of time and money in developing a cheaper (generic) version of the API.

- Numerous generic manufacturers will join Company B in the race to be the first to enter the market. Company A will then typically consider how best to defend itself against generic entry. Following the *Paroxetine and Lundbeck* decisions, it is not (or not necessarily) a breach of competition law for Company A to defend its legitimate commercial interests. The *Lundbeck* decision considers 4 possible courses of action for Company A:

    1. bringing patent infringement claims against generic manufacturers;

    2. applying for further patent protection, such as divisionals;

    3. intervening in the marketing authorisation applications of generics; or

    4. entering into settlement agreements with generic manufacturers that prevent the latter from entering the market.

- While the first three are often considered legitimate, entering into settlement agreements can give rise to competition concerns of the kind considered in the *Paroxetine* and *Lundbeck* cases.

- Where Company A brings patent infringement proceedings against the generic manufacturer (Company B), Company B also has 4 options. It can either:

    1. continue to litigate which may or may not be successful. This is considered as the counterfactual to settlement agreements;

    2. completely withdraw from the market;

    3. enter into a settlement with Company A without any value transfer. This might include being authorised to sell the product under certain conditions; or

    4. enter into a settlement with Company A with a value transfer.

- Assuming that Company A & B settle the dispute on the following terms:

- Company B must not enter the market for a certain time period (note that Ivax Pharmaceutics did not have this sort of clause in *Lundbeck*);

- Company B must not challenge the patent's validity (note that this was also not the case in *Lundbeck*)

- Company A will make a substantial value transfer to Company B; and

- Company A will supply Company B with fixed volume of A's product (as was the case in both *Servier* and *Generics*),

the conundrum is whether the settlement described above has as its object and/or effect, the restriction of competition. In *Lundbeck* the Commission only alleged by object restriction whereas in *Servier* and *Generics*, both by object and effect restrictions were alleged.

ii. The law

- There have been 4 recent judgements that have considered this conundrum; *Servier (Case T-691/14), Generics (C-307/18), Lundbeck (C-591/16P) and Paroxetine [2021] CAT 9.*

- From these cases it is clear that it is irrelevant whether litigation has been commenced as long as there is a 'genuine dispute'. It is equally clear that the competition law analysis is unaffected by the fact that the outcome of the patent litigation may be uncertain (in the sense that neither the competition authority nor the appellate court can say who would have won had the litigation proceeded to trial).

- The key factors that the competition authority or court should consider are neatly summarised in the judgment of the Court of Justice in *Lundbeck.* The court must consider (i) if Company A & B were potential competitors (ii) whether Company B accepted restrictions on its own efforts to enter the market and (iii) whether Company A transferred a sufficient value to incentivise Company B not to compete.

Potential Competition

- In considering whether there is potential competition, a competition authority court should two issues: whether Company B had a firm intention and an inherent ability to enter the market and whether there are any genuine insurmountable barriers to entry. A patent should not be regarded as an insurmountable barrier to entry since it is often possible for a generic to invent around the patent. A court should also not assume that the generic product will necessarily infringe a valid patent since the issues of validity and infringement are typically contested in the litigation (*Generics* at [46]).

Restriction of Company B's efforts to enter

- The most obvious restriction of Company B's efforts to enter the market is a contractual commitment not to manufacture or market its own generic product during the term of the agreement. There may also be contractual commitments not to challenge the patent's validity. These are the 'delay' aspect of the 'pay for delay' settlement. The value transfer is the 'pay' aspect. This may take the form of a cash transfer, a licence or volumes of Company A's stock to Company B.

Sufficient value transferred

- When it is plain from the analysis of a settlement agreement that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the patent holder and the party allegedly infringing the patent not to engage in competition on the merits, it must be characterised as a 'restriction by object'.

- In order to make that assessment, it is necessary to: (a) take account of all the transfers of value made between the parties, whether those were pecuniary or non-pecuniary, including indirect transfers resulting from profits to be obtained by a generic from a distribution contract with the originator; (b) assess whether the net gain arising from the transfers of value by the originator to the generic company may be justified by the existence of any quid pro quo or waivers by the manufacturer of generic medicines that are proven and legitimate; and (c) determine whether that net gain is sufficiently large actually to act as an incentive to the generic to refrain from entering the market concerned.26 There is no requirement for the payment to exceed the generic's expected profits on entry; rather "all that matters is that those transfers of value are shown to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits …": see *Generics* at [90]–[94].

- As for restrictions by effect, the CJEU has now confirmed that it is not necessary to show that, in the absence of the agreement in question, the generic company would probably have been successful in the patent litigation, or the parties to the agreement would probably have concluded a less restrictive settlement agreement: *Generics* at [119]

- Once it is recognised that each of the generic companies in *Paroxetine* was a potential competitor to GSK at the time when it entered into the relevant agreements, the CAT held that clear effect of that Agreement was completely to remove that potential competition for the duration of the Agreement: see *Paroxetine* at [75].

iii. Possible practical implications

When might Company A & B not be competitors for the purpose of assessing a reverse payment settlement agreement?

- Company B should not be considered a potential competitor where it took steps to enter the market but had to give up due to lack of viable production method. Strong evidence would be required to prove this. Likewise, strong evidence would be required to show that there was an insurmountable barrier to entry, such as an MA being rejected or an injunction being issued as part of the patent infringement proceedings.

Can Company A & B settle a patent dispute on the basis of a reverse payment from A to B?

- It is not right that all cash payments in the wrong direction are automatically an infringement as was made clear in the *Lundbeck* litigation. A settlement agreement entered into between Lundbeck and Neolab included a voluntary injunction with commitments linked to the outcome of other litigation. When Lundbeck settled this litigation, Neolab was released and was free to enter the market. The value transfer in this case was compensation for lost sales while the injunction was wrongly in place rather and not a tool for delaying market entry (see [350] of the *Lundbeck* General Court decision).

- The argument that a value transfer is made as an alternative to incurring litigation costs was run in *Generics* (see [86]). It was noted that while litigation costs can be significant, the value transfers are likely to be considerably higher. For Alpharma, they were in the tens of millions. A value transfer would therefore need to be much lower for this argument to succeed.

- Providing remuneration via a supply agreement, as was the case in the *Generics* case will also be considered an illegitimate value transfer.

Settling patent dispute on different terms in different countries

- It is rare that one settlement agreement is suitable across all jurisdictions. Whether any disparity between settlement agreements could be considered a market sharing agreement has been considered in two cases; *KRKA v Commission (Case T-684/14)* and *In re: Humira [Adalimumab] antitrust litigation* in the US. Both these judgements reach a consistent

conclusion; both are, however, currently on appeal to respectively the Court of Justice and the 7th Circuit Court of Appeals.

- In *KRKA*, a dispute arose between the originator (Servier) and a Slovenian generic manufacturer (KRKA). There was litigation between the companies in England and Wales and also a challenge to Servier's patents before the EPO. An important feature of the case was that the EPO Opposition Division confirmed Servier's patent before the parties settled. The High Court also granted an interim injunction against KRKA and dismissed KRKA's application for summary judgment shortly before the parties settled. What sets the Servier/KRKA settlement apart is that the parties settled without any cash payments. Instead, they settled on the basis of KRKA accepting non-compete and non-challenge clauses and, at the same time, Servier granted KRKA a sole licence to launch (or remain) in 7 markets across Central Eastern Europe (CEE). The Commission concluded that this licence was equivalent to a value transfer from Servier to KRKA. It considered that the combination of the settlement and licence agreements was to allocate Western Europe to Servier exclusively and to divide up CEE between Servier and KRKA, to their mutual benefit.

- On whether settlement and licence agreements could be regarded as a by object restriction, the General Court (GC) was unequivocal in stating that such a licence is generally a legitimate and pro-competitive arrangement that allows new entrants to enter the market (see [179]). The Commission therefore has the burden of proof in showing that such a licence equates to a reverse transfer and is anti-competitive. In *KRKA*, the GC held that the Commission had not discharged its burden of showing that royalty rate was abnormally low or that the licence had not been concluded at arm's length: at [211] to [220].

- According to the GC, the Commission's approach in *KRKA* was paradoxical since it suggested that the wider the licence granted by an originator to a generic, the greater the inducement to the generic and therefore the more likely there would be an infringement by object is (see [230]). The Commission has appealed the GC decision to the CJEU and the hearing date for the appeal is currently being set.

- In *Re Humira* the Patentee settled with various generics but allowed the generics early entry to the European market before the patent expired and before generics were allowed to launch in the US. The plaintiffs argued that this amounts to a market sharing agreement.

- Following *Actavis,* allowing a generic early entry to a market without any value transfer is not an infringement since it facilitates competition ahead of the patent expiring. Any agreement that facilitates further competition should not be objectionable.

When might a reverse payment not have anti-competitive effect?

- The CAT in *Paroxetine* clearly stated that not all reverse payments from an originator to a generic company constitute restrictions by effect. The CAT emphasised the size of the value transfers and whether there was any real possibility that the generic would have been able to compete (see [76]).

- Notably, the GC judgment in *KRKA* rejected the Commission's argument that a licence had the effect of restricting or distorting potential competition. The GC makes it clear that the Commission had failed to demonstrate that the settlement and licence agreement had actual restrictive effects on competition (which it was required to show). According to the GC, it appeared paradoxical — where the clauses of an agreement have been implemented and their impact on competition can be measured by taking into account the relevant factual developments, including those subsequent to the conclusion of the agreement, which took place before the Commission issued its decision — to allow the Commission to demonstrate merely the anticompetitive effects that such clauses are likely to have: at [360]. Further and in any event, the Commission had now shown to the requisite legal standard that, in the absence of the relevant agreements, KRKA would have entered the Western European markets at risk more quickly than, in fact, it did: at [398].

- In *KRKA* the Commission had argued that it had only to demonstrate the elimination of a potential competitor in order to be able to find — in the context of a market structure characterised by a lack or shortage of sources of competition and by market power on the part of the originator company — a restriction of competition by effect. The GC rejected that approach since (in the Court's view) it implied that a restriction by effect could be made out by considering only two of the three conditions required in order to find a restriction by object, namely the existence of potential competition and the presence of clauses restrictive of competition, are met. This was an error of law on the Commission's part: at [467].

iv. *Questions*

How does a court consider the likely outcome of litigation if advice is covered by privilege?

- The issue was considered by the CAT in *Paroxetine* when a patent attorney gave evidence on the prospects of success having provided Glaxo with advice on their prospects of success during the patent infringement proceedings. Glaxo was given the choice to waive privilege and discuss the advice in detail or provide alternate non-privileged evidence. The CAT made it clear that hinting/alluding to privileged documents was not to be allowed.

- It remains unclear what weight the court should attach to evidence of the parties' beliefs should have compared to facts.

What is the impact of the Servier decision on the market definition tests?

- Both the CMA and the Commission had taken a very narrow approach to defining the market. In the *Servier* decision, the General Court concluded that the market for Perindopril was wider than just between the originator and generics and included therapeutic equivalents.

- The case puts more emphasis on doctor's choice and less focus on price comparisons. This change in approach and widening of the market definition test is in contrast to previous case law and is likely to result in the Commission publishing a revised market definition notice.

- The implications of this decision are likely to be of importance outside of the pharmaceutical industry and will be of particular importance in mergers.