The Commission's Lundbeck Decision: A Critical Review of the Commission's Test For Patent Settlement Agreements

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Introduction

In the latest development involving patent settlement agreements, the European Commission, on 19 January 2015, published its decision in the Lundbeck case[2]. While the overall outcome was already known, the detailed reasoning could be perceived as symptomatic of a more general trend whereby the Commission views patent settlement agreements with suspicion.

By way of reminder, in June 2013 the Commission fined Danish pharmaceutical company Lundbeck € 93.8 million as well as several generic producers a total of € 52.2 million for alleged anticompetitive practices in the market for antidepressant medicines. According to the Commission, the object of the contested agreements was to delay the entry on the market of cheaper generic versions of Lundbeck's blockbuster drug citalopram, which could theoretically have been launched upon expiry of Lundbeck's patent for the active ingredient. As a result, the Commission considered that these agreements constituted restrictions of competition by object, in breach of Article 101 of the Treaty on the Functioning of the European Union ("TFEU").

This short article will not endeavor to cover all the details of the Commission's findings, which cover no less than 464 single-spaced pages. Here, our purpose is only to offer a review of the analytical framework adopted by the Commission to analyze patent settlement cases, and explain why the test set forth by the Commission does not constitute a good basis to infer the existence of a restriction by object.

Background to the Lundbeck case

The origins of the Lundbeck case go back to January 2002, when Lundbeck's molecule patent on citalopram expired, paving the way for competition from cheaper generic versions of the drug. After the expiry of the molecule patent, Lundbeck still had a number of process patents that covered some, but not all, possible ways to produce citalopram. This meant that generic producers had several options to enter the market. In anticipation of the patent's expiry, several generic producers had already started gearing up for market entry.

Around the same period, a number of patent disputes arose between Lundbeck and generic producers. Among others, these concerned potential infringements of Lundbeck's process patents by the generics, which typically claimed non-infringement or invalidity of the patents in return. While some patent infringement proceedings with some generics went all the way to a final judgment, Lundbeck concluded six agreements with four groups of generic producers (Merck KGaA, Arrow Group ApS, Alpharma, Ranbaxy), according to which the latter agreed to postpone their market entry for short periods (which Lundbeck argued were in line with the time needed to obtain a judgment in the other cases) against financial compensation.

The Commission reportedly became aware of the above patent settlement agreements in October 2003 through information received from the Danish Competition

Authority. It was agreed that the Danish Competition Authority would not pursue the matter further, but interestingly it said in a press statement in 2004 that the "Commission considers that this is a grey area and it is unclear how close we are in this case to the black area" (§652). The case then proceeded at what might be called a leisurely pace: while there was an inspection in October 2005, the Commission only opened proceedings in January 2010; that is, 8 years after the agreements and 7 years after the Commission knew about them. The decision came 3 years later in June 2013.

The skeptical observer might note that the tardy opening of proceedings came just after the conclusion of the sector inquiry in the pharmaceutical sector. The hesitations in moving forward with this case directly contrast with the stigma that the Commission has sought to attach to the agreements both in its decision and its official press statement on the case.[3]

Findings of the Commission

Three-prong test

Presumably in an attempt to clarify the law in the area of patent settlements, the Commission decision contains two lengthy sections on the nature of the infringements and the notion of restriction of competition (sections 9 and 10). They include general considerations about competition in the pharmaceutical sector and set forth, in conclusion, a **three-prong test**, supposedly informative of whether an agreement has "the potential to restrict competition by its very nature," i.e. could be qualified as a restriction by object (§661):

- The originator and the generic producer were at least potential competitors;
- The generic producer committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EEA markets; and
- The agreement was related to a transfer of value from the originator to the generic producer, which substantially reduced the incentives of the generic producer to independently pursue its efforts to enter the market with a generic product.

The Commission found that six agreements met this test

The decision finds that the six agreements concluded by Lundbeck with four generic companies met the test.

First, the Commission found that, at the time of the agreements, the generic companies were **potential competitors**, in particular as Lundbeck's patents were not an obstacle that was impossible to overcome. The Commission relied on internal company assessments, albeit the documents were sometimes nuanced or showed doubt as to the outcome. Even where some internal documents showed that certain generics believed they infringed Lundbeck patents, the Commission found that this did not exclude competition since there remained a possibility that a judge would find otherwise, that the generic would succeed in invalidating the patent, or that it would innovate around it (see e.g. §1031; 1033). The Commission also rejected arguments

that one generic did not have a marketing authorization and thus was not a potential competitor (§1037).

Second, the Commission found that the agreements included a **limitation of the generics**' ability to enter the market against a **value transfer**. The findings contained in the decision, as published, and which are contested in certain respects, are as follows:

- *Merck Agreements*: 1) a UK settlement and supply agreement, whereby Merck agreed for a period of 22 months not to launch any generic version of citalopram in exchange for various *"value transfers"* totaling € 19.4 million and the right to sell Lundbeck's citalopram; 2) an EEA settlement agreement (excluding the UK), whereby Merck agreed for a period of 12 months not to launch any generic version of citalopram in exchange for a total payment of € 12 million in the form of monthly instalments.
- *Arrow*: 1) a UK agreement, whereby Arrow agreed for a period of 22 months not to sell any generic version of citalopram in exchange for several payments totaling € 10.4 million; 2) an agreement for Denmark, whereby Arrow agreed for a period of 10 months not to sell any generic version of citalopram in exchange for a total payment of € 684,000 in the form of monthly instalments.
- *Alpharma*: an EEA agreement, whereby Alpharma agreed for a period of 17 months not to sell any generic version of citalopram in exchange for a total payment of € 11.7 million.
- *Ranbaxy*: an EEA agreement, whereby Ranbaxy agreed for a period of 12 months not to sell any generic version of citalopram in exchange for a total payment of € 12.7 million.

Other important factors

Despite these successes, there are at least three important areas where policy needs to develop.

Prohibitions on anticompetitive regulation

The decision also refers to other *"important factors"* which the Commission took into account in reaching the conclusion that the agreements had an anticompetitive object.

First, the Commission found that each agreement prevented the generic company from selling any citalopram, i.e. the agreement supposedly afforded Lundbeck protection outside the scope of the disputed patent(s). It should be said, however, that that finding was disputed by the parties, which argued that the undertaking not to sell citalopram was limited to potentially infringing citalopram. This sort of fact pattern clearly can give rise to difficult issues: if a generic only had one product and only agreed not to sell it for a short period, even if it was contractually permitted to switch to another supplier, would it have had a realistic ability to find an alternative source or develop and sell a different (and non-infringing) product in a short period of time?

Second, the Commission found that the amounts paid by Lundbeck roughly corresponded to the profit the generics would have made had they entered the market. It can be observed that this is exactly the basis upon which a court would have

compensated the generics if they had been injuncted by Lundbeck and ultimately won the litigation. This is for example what happened in the Neolab settlement (following a voluntary injunction), which the Commission found *"unproblematic"* (see below).

Finally, the Commission found that Lundbeck did not undertake not to sue the generics after the expiry of the agreements. The Commission thus seems to have viewed the agreements as not really settlement of litigation. Looking beyond the Lundbeck case, such an approach may be wrong as a general principle if a settlement is akin to a stay and both parties agree the form of compensation while awaiting the outcome of other currently pending litigation on similar or identical issues.

Comments on the Commission's approach

A cocktail of factors

As described above, the conclusion that the six agreements had the object of restricting competition thus seems to have resulted from the three-prong test and a number of additional factors.[4] It is unclear from the decision what ponderation was given to each of them and whether the absence of some of them would have led to a different conclusion.

In other words, we now know that the cocktail of facts present in the Lundbeck case violates Article 101 TFEU in the Commission's eyes, but we do not know whether a settlement differing by one or more factors would be legal or not. While this is in line with DG Competition's indication in the patent monitoring reports that the legality of patent settlements will be *"assessed on the basis of the circumstances of each individual case,"*[5] this does not much enhance legal certainty in the area and it is difficult to reconcile with the by-object qualification.

The three-prong test

Even if other factors were taken into account in the *Lundbeck* case, the three-prong test remains at the heart of the Commission's theory to review patent settlement agreements, as could already be understood from previous public speeches by DG Competition's officials.[6] As we wrote elsewhere,[7] it is questionable whether this test constitutes a sound basis to qualify a patent settlement agreement as a restriction by object.

First, the definition of *"potential competition"* is very loose. It appears that any chance to invalidate a patent or escape a finding of infringement would be sufficient to qualify a generic as a potential competitor. The test thus does not differentiate between patent disputes where the possible outcome is 50/50 and one where it is 10/90 or 90/10 or even 1/99 or 99/1.

Even assuming that the generics were blocked by the patent, the Commission still finds that they would be potential competitors if it was not impossible to innovate around the patent(s) (see section 9.4.5). In fact, the decision states that potential competition starts when a generic company *"begin[s] to develop a commercially viable production process leading to a product that meets regulatory requirements"* (§616). This is hard to reconcile with the *Visa* case, which held that for a company to be viewed as potential competitor there must be a real, concrete possibility for it to

enter the market within a short period of time.[8] The test proposed by the Commission seems instead to require the parties to show the impossibility of making it to the market within the foreseeable future.

The problem with such a broad definition of a potential competitor is that it will not allow for any distinction between a generic company ready to enter the market and one that has serious hurdles to overcome. The generic may have its own strong incentive to settle or cease the litigation in the latter case. The impact on competition may differ greatly from one situation to another.

Second, the existence of a limitation of the generic's freedom to independently market its product is an inevitable consequence of most settlements, which will often include a non-challenge and a non-infringement clause. In case of a genuine patent dispute, it is normal that the generic would agree not to enter for a certain period of time. In addition, the Commission's test does not seem to leave any room to account for important elements of context: where several litigations dealing with the same issues are running in parallel, the settlement of one of them is unlikely to have any effect on the timing of generic entry if the other litigations continue. But the settlement will avoid further legal costs and proceedings (e.g. injunction request, damages claims etc.), which is desirable from a welfare standpoint.

Third, the presence of a value transfer to the benefit of the generic company cannot be enough to infer the existence of a restriction by object. The decision evokes the scenario of the originator paying a considerable amount of money to the generic for it to exit or not enter the market (§640). This may be a scenario raising competition concerns, but this can hardly be considered as a representative description of all settlement agreements, even ones including a value transfer. Any settlement requires mutual concessions, so it must be expected for a settlement to include some form of transfer from the originator to the generic company. And there is a fundamental difference between one competitor paying another not to compete and the typical scenario of patent litigation: the difference is the patent, which grants one competitor a monopoly. The patent is the elephant in the room, which despite its size and importance seems often to be downplayed or forgotten.

Interestingly, the decision states that not all payments in a settlement agreement will be suspicious, as a payment may be instrumental to the finding of a solution in the patent dispute (§639). For example, the decision notes that when a generic has entered the market (at risk), only to find later that the likelihood of infringement or patent validity is high, a payment from the generic to the patent holder may be expected. Conversely, where the generic had stayed away from the market (wilfully or by means of an injunction), but it turns out in the litigation that the generic will likely win, the Commission considers normal that a settlement allowing immediate entry of the generic would also foresee a compensation of the generic company. But such statements, which in truth concern (anticipations of) defeats rather than real settlements, do not give any useful information about how to settle genuine disputes where both sides think they have a reasonable chance of winning.

The examples given in the decision cleverly avoid responding to the most interesting question – in view of the three-prong test – of whether a settlement that includes a value transfer and a limitation of the generic in the same agreement could be found legal. It is likely a sign that, while the Commission does not want to condemn all such

settlements, it does not know yet where to draw the line between the good ones and the bad ones. Further evidence of this is the fact that, through the annual patent settlement monitoring exercises, the Commission has been notified about 48 settlements agreements with a limitation of the generics' access to market and a value transfer and has not publicly raised objections against any of them.[9]

The decision offers another example of this apparent lack of consistency. The Commission raises no objection against the settlement between Neolab and Lundbeck (§164). In that agreement, Neolab accepted a voluntary injunction (i.e. not to enter the market) until judgment was rendered in the Lagap litigation, in exchange for Lundbeck's undertaking to compensate Neolab if it lost the Lagap litigation. When Lundbeck settled the Lagap litigation, it agreed to compensate Neolab for the lost profits due to the voluntary injunction. In short, the settlement included a postponement of Neolab's entry in the market as well as a value transfer. The Commission found that the settlement was *"unproblematic"* (§639), without however explaining why this would differ from the other agreements.

In sum, the three-prong test of the Commission appears too abstract and simplistic to answer the question of whether a settlement would be by its nature harmful to competition. Indeed the Lundbeck decision even offers an example confirming this point (Neolab). It thus does not form a sound basis to infer an anticompetitive object. It is obvious that determining whether the generic company is a potential competitor and whether its access to market has been restricted is necessary for the analysis, since absent any of such findings Article 101 TFEU would not apply. Likewise, the existence of a value transfer is relevant for the analysis. But these criteria, alone or in combination, are not enough to conclude to a restriction of competition, let alone a restriction of competition by object. Settlements of litigation are usually positive for society – so there ought to be something very obviously wrong about patent settlements to make them fall in the object box.

Settling purely on the merits of the patent case

Interestingly, the Commission indicates in the decision that settlements *"based purely on each party's assessment of the strength of the patent and which impose limitations on the behaviour of the generic undertaking that fall within the exclusivity rights of the patent holder granted by patent law do not, in principle, constitute an infringement of Article 101 of the Treaty"* (§659; §638). The decision also states that when the limitations are not achieved through the strength of the patent, but through inducements that align previously competing interests, then a restriction of competition by object may exist (§659).

While this may sound like a safe harbor, it is difficult to see how it would apply in practice. The suggestion that a settlement should solely be based on the merits of the patent dispute seems difficult to square with the reality of patent litigation. A settlement is rarely if ever concluded on the sole basis of the merits of litigation (e.g. on patent strength). For a start, the two parties rarely share the same views as to patent strength because their knowledge of the issues is typically different. Rather, litigation might depend not only on the perception of strength of patent validity (or risks of infringement), but also on considerations linked to commercial opportunities. Other potential factors influencing parties' decision to settle could also include associated commercial risks, prospective profits, litigation costs, difficulties in

obtaining interim relief, remaining barriers to market entry (e.g. regulatory approvals; getting their generic product ready to produce efficiently in bulk), as well as the existence of other litigation proceedings.

In addition, it is not clear from the decision whether an inducement (which according to the decision takes an agreement outside the safe harbor) would be limited to a payment. In its patent monitoring reports, the Commission has previously stated that an inducement (value transfer) can include a license (even royalty free), a distribution agreement or a side-deal.[10] It thus appears that only a settlement involving nothing else than an agreement on an entry date between the time of litigation and patent expiry, reflecting the parties' assessment of the patent dispute (and it's unclear how the parties would agree on that), would fall in the safe harbor, although this is not entirely sure given that DG Competition was only willing to say that such a settlement *"is not likely to attract the highest degree of antitrust scrutiny."*[11]

Compatible with Cartes Bancaires?

The broad and abstract approach of the Commission may also be questioned in light of the recent *Cartes Bancaires* judgment of the Court of Justice. In that case, the Court of Justice recalled that the notion of restriction by object should be limited to conduct by its nature harmful to competition and must be interpreted restrictively.[12] According to the Court, and the Advocate General in that case, experience and economic theory tell us when a conduct should be viewed as such.[13] Such principles are difficult to reconcile with an approach, which would infer the existence of a restriction by object from an abstract formula.[14] The Commission definitely lacks the experience to say that the presence of the three criteria implies the existence of a serious restriction of competition and economic theory is divided on the issue – something the Lundbeck case shows clearly: how can a *"grey"* case become an obvious by object case a decade later?

In the United States, the Supreme Court rejected the Federal Trade Commission's view (similar to the Commission's views) in the *Actavis* case.[15] It found that there was no reason to apply a *per se* or a *quick look* rule finding patent settlements with a payment to the generic company presumptively illegal. It instead concluded that the rule of reason should be applied to determine whether an agreement had anticompetitive effects. The Supreme Court thus held that the parties can justify the payment and demonstrate pro-competitive effects as well as present arguments that the agreement did not bring about anticompetitive effects. In our view, the Commission should follow the same logic and apply an effects-based test to patent settlements in Europe.

All parties in the *Lundbeck* case have appealed. The last word will therefore be left to the Court, which will have to decide if the Commission was correct to find the agreements were illegal by object. We will only know the outcome in a couple of years' time.

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The views expressed in this article are strictly personal and do not necessarily reflect the views of the firm or of any of its clients.

[2] S Commission decision of 19 June 2013, COMP/ AT. 39226 – Lundbeck.

[3] See Statement by Vice-President Almunia of 19 June 2013: "The practices we are sanctioning are simply unacceptable. By today's decision we are confirming that these so-called 'pay-for-delay' deals constitute severe infringements of EU competition law. They may cause severe harm to patients and taxpayers and must be sanctioned accordingly."

[4] The factors leading to such conclusions are spelled out, for each agreement, at §824; §874; §962; §1013; §1087; §1174 of the decision.

[5] 5th Report on the Monitoring of Patent Settlements, 5 December 2014, §17 (see also §§4; 7; 13).

[6] Alexander Italianer, Competitor agreements under EU competition law, Fordham, 26 September 2013, available here: http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf

[7] J. Killick and P. Berghe, Applying a by object test to patent settlements is very different from the rule of reason, Concurrences N° 2-2014 – pp. 21-24.

[8] Case T-461/07, Visa Europe Ltd and Visa International Service v Commission, judgment of the General Court of 14 April 2011, EU:T:2011:181, § 68 and 166.

[9] S All five patent settlements monitoring reports can be found here: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[10] 5th Report on the Monitoring of Patent Settlements, 5 December 2014, §12.

[11] 5th Report on the Monitoring of Patent Settlements, 5 December 2014, fn. 15.

[12] *Case C-67/13 P, Groupement des cartes bancaires v Commission, EU:C:2014:2204, §50; 58.*

[13] Ibid, §51; Opinion of Advocate General Wahl in Case C-67/13 P, Groupement des cartes bancaires v Commiss*ion, EU:C:2014:1958, §56.*

[14] See also the Opinion of Advocate General Mazak in Case C-439/09, Pierre Fabre, EU:C:2011:113, §26.

[15] FTC v Actavis, No. 12-416, US Supreme Court, 17 June 2013.