Pay for delay

How the European Commission views restriction by object

*by **John Ratliff****

The aim of this article is to focus on the approach by the European Commission (EC) to restriction by object in the two pay-for-delay decisions which the EC published in the last year, Citalopram (Case AT.39226) (also known as Lundbeck) and Fentanyl (Case AT.39685).

The cases are topical in part because the EC explains its approach to restriction by object in "non-obvious" cases. Both decisions were taken in 2013, so before the judgment by the Court of Justice (ECJ) in *Cartes Bancaires* (Case C-67/13 P), in which the Court suggested that the concept of restriction by object should be interpeted restrictively and only applied to particularly harmful agreements. Citalopram is being appealed.

Put shortly, the EC's approach is to say that these pay-for-delay agreements are just market exclusion agreements in a particular context and therefore, by their nature, restrictions by object. However, the EC also states that, since restrictions on competition have to be assessed in their specific context, new findings of restriction by object are quite possible, even in non-obvious cases.

It will be interesting to see what the European Courts say about it all but, in the meantime, the messages for those concerned are clear: (1) pay-for-delay cases, as defined by the EC, will be treated as market exclusion cases; and (2) the EC is not giving up on restrictions by object findings in new settings, if the practices concerned are sufficiently harmful to competition by their nature.

It may be useful to run through the main points on this in the two decisions and then offer further comment.

Citalopram

In June 2013, the EC fined Lundbeck, a Danish pharmaceutical company, and four generics groups as regards six agreements, which the EC found had prevented the market entry of citalopram, a leading antidepressant medicine, in 2002-2003. (See generally "The Lundbeck decision" *CLI* 17 March 2015.) The generics companies involved were Merck, Arrow, Alpharma and Ranbaxy. The geographic market concerned was the entire EEA but in particular the UK and Denmark.

The European Comission noted that Lundbeck's basic patent for the citalopram compound and the two original production processes had expired at the time the agreements were concluded. This could have allowed generics companies to enter the market freely. The agreements were thus concluded in the context of potential patent disputes (notably about whether process patents may have been infringed) but, except for one, they were actually concluded before any litigation started.

The EC considered that the agreements infringed the competition rules because:

- Lundbeck and the generics producers were (at least potentially) competitors.
- The agreements provided for a transfer of value from Lundbeck to the other party to avoid the latter's entry into a specific geographic market for citalopram for a certain duration.
- They did not resolve any patent disputes but postponed them as long as the agreements were applicable.
- Lundbeck did not provide any commitment not to start infringement proceedings if any generics producer entered the market for citalopram once the agreement expired.
- The agreements prevented the generics companies from producing and selling citalopram, even if their production would not have infringed Lundbeck's patents, a result which Lundbeck would never have obtained from a court's ruling.

The EC fined Lundbeck €93.8m and the generics producers a total of some €52.2m.

The essential case found by the EC is that Lundbeck, the originator of citalopram, sought to delay generic entry of citalopram, while it launched and established a new version of the drug, escitalopram. There are sections of the decision where the EC finds that Lundbeck purchased manufacturers of generic citalopram and focused on possible patent disputes, litigation and/or deals with the generic producers concerned in order to delay entry.

The EC also found that Lundbeck and a generic producer would have aligned incentives in making such a deal. The generic producer would achieve profit without the uncertainties and efforts of market entry, while Lundbeck would benefit because, as prices did not fall, it maintained sales volume for its product and launched escitalopram. As the EC sees it, there was, as a result, a "rent-sharing agreement".

In the case of the Lundbeck/Merck UK agreement, the EC found that Lundbeck paid Merck for a stock of product which it had purchased from an Indian supplier; plus a guaranteed profit, even if Merck did not sell products supplied from Lundbeck over a year; and an increased guaranteed profit for an additional period. The value transfer to Merck was some €19.4m.

The EC also emphasises that it is not challenging patent dispute settlements as such. What it is challenging is agreements delaying market entry that do not resolve a patent dispute. The EC states that its issue with transfers of value to resolve disputes concerning a potentially infringing product is that they lead to market exclusion, and may result in no further clarification as to whether there is an infringement or whether the originator's patent is invalid. The settlement agreement may also induce the generic company to accept wider restrictions on its conduct than it would have done otherwise.

In the decision, the EC also sets out which patent settlements it considers to be lawful and which not. The EC states, in particular (see paras 637-646):

> "…if the limitations on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they are likely to breach article

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> 101…when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself, but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market…
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> "…such restrictions are all the more likely to be illegal when the restrictions agreed do go beyond the substantive scope of the patent, in the sense that the same restrictions could not have been obtained by the patentee's right to oppose possible infringement before the court…"

The EC considers the agreements concerned to be restrictions by object, despite the background, because it considers them to be essentially market exclusion agreements.

Then the EC challenges the notion that restrictions by object are just restrictions that are "obviously" or "patently" restrictions of competition. It states (see para 651) that "a restriction by object must be serious, but it is not necessarily obvious, because there is no restriction by object without individual and specific examination of the content and objective of the agreement and the legal and economic context of which it forms a part".

In this context, the EC also quotes AG Trstenjak in the Irish beef case (Case C-209/07, BIDS)

> "…it is clear that the category of restrictions of competition by object cannot be reduced to agreements which obviously restrict competition. If not only the content of an agreement but also its legal and economic context must be taken into account, classification as a restriction of competition by object cannot depend on whether that object is clear at first sight or becomes evident only on closer examination of the circumstances and the intentions of the parties…In my view, the notion of restriction of competition by object cannot be reduced to an exhaustive list either…" (See Citalopram decision at para 651.)

Applying that approach to pay-for-delay, the EC states (see para 659) that if the limitations on entry in question are not achieved "through the strength of the patent, but through inducements from the originator to the generic undertaking aligning previously competing interests, then a restriction of competition by object may exist, including in particular, when the limitations in question exceed the substantive scope of the patent".

The EC then looked at whether each agreement had the potential to restrict competition by nature; whether the transfer of value was linked to the expected profits of the generic; whether the agreement actually settled the patent dispute; and whether the obligations on the generic were wider than could have been achieved in the patent litigation. The EC's conclusions in each case were that the agreement was a restriction by object.

Fentanyl

In December 2013, the EC fined Johnson & Johnson (J&J) some €10.8m and Novartis Sandoz €5.5m for having delayed market entry in the Netherlands of the generic version of Fentanyl, a strong painkiller, in the form of transdermal patches used for chronic pain conditions (such as cancer, low back pain and osteoarthritis).

The EC found that, in 2005, when the data exclusivity protection of J&J's Fentanyl was about to expire, a company called Hexal started to prepare the commercialisation of a generic version of the painkiller. Hexal was then acquired by Sandoz, a subsidiary of Novartis.

Instead of putting the painkiller on the market, Sandoz/Hexal then signed a "co-promotion agreement" with J&J's Dutch subsidiary, Janssen-Cilag. That agreement provided that Hexal would carry out certain promotional activities for J&J, although the EC noted that they were "undefined", nor was it clear that much was done. On the other hand, Hexal received just under €5m. The EC also found that the agreement was conditional on Hexal/Sandoz's non-entry to the market.

The EC found that the agreement was designed to delay Hexal/Sandoz's entry to the market, offering a payment that was more than Hexal expected to earn, but only part of what J&J stood to lose in terms of price decrease and loss of market share. In its decision, the EC went through various internal documents showing the nature of the agreement.

Then the EC reviewed in detail why it thought that the co-promotion agreement amounted to a restriction by object.

As in Citalopram, the EC referred to the Irish beef case, insofar as it involved an agreement that certain companies would receive financial compensation for leaving the market, which the EC considered similar to the facts here.

The EC noted three factors that it would take into account to decide whether the agreement had the potential to restrict competition by its very nature (see para 219):

- Were the generic undertaking (Hexal/Sandoz) and the originator undertaking (J&J) at least potential competitors?
- Had the generic producer limited its independent efforts to enter the market with its generic product due to the co-promotion agreement?
- Did the co-promotion agreement involve a transfer of value from the originator which substantially reduced the incentives of the generic producer independently to pursue its efforts to enter the market with its generic product?

Then, the EC considered in detail the economic and legal context of the co-promotion agreement, the content and objectives of the agreement and the intentions of the parties in relation to it, concluding that it was a restriction by object.

Comment

There are three main points to be emphasised from these cases.

First, in both instances, the EC's approach is to find a market exclusion agreement, similar to the Irish beef case. There, certain undertakings that stayed in the market paid financial compensation to others who agreed to leave the market, a situation which AG Trstenjak called "the 'buying off' of competition" (see opinion, 4 September 2008 at para 77; Citalopram, para 658). The EC considered that the same applied in these pay-for-delay cases.

Second, despite the length of these decisions, going through the agreements and context in great detail (Fentanyl is 147 pages, Citalopram is 464 pages), the EC's approach is that these cases are clear infringements.

Third, perhaps to state the obvious, other patent settlements may well not be restrictions by object, or even infringements. However, after these EC cases, companies will have to be careful to settle, not delay, and to review the merits, scope and form of settlement to ensure that investigating regulators should not perceive matters otherwise.