Current Intelligence

Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 'pay-for-delay' decisions

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Lundbeck (Case COMP/AT. 39226), Commission decision of 19 June 2013, not yet published; Fentanyl (Case COMP/AT. 39685), Commission decision of 10 December 2013, not yet published.

The European Commission's first decisions on 'pay-for-delay' arrangements attempt a tricky balancing of competing legal and policy objectives, but give rise to as many questions as they answer.

Legal context

In 2009, the European Commission (Commission) published its pharmaceutical sector inquiry report, concluding that competition was not functioning as it should. In particular, the report observed delays in generic medicines coming to market. It expressed concern around the settlement of patent disputes between originators and generics, especially where there was a 'value transfer' from the originator to the generic in return for which the generic agreed to stay off the market, ie 'pay for delay'. The Commission has since monitored all originator–generic settlements annually and launched several investigations. In 2013, it concluded the first two of these, imposing fines of over €160 million: first on Lundbeck and certain generics (*Lundbeck*); and later on Johnson & Johnson and Novartis (*J&J*).

The Commission is clearly following US developments closely, with its *Lundbeck* decision taken two days after the US Supreme Court's first judgment on 'pay-for-delay' settlements in *Federal Trade Commission v Actavis, Inc., et al.* 570 U.S. 756 (2013) (*Actavis*). In the EU, the Commission is also about to publish revised guidance on technology licensing—several proposals in its consultation draft are relevant to 'pay-for-delay' cases (Draft Communication from the Commission: Guidelines on the application of Article 101 TFEU to technology transfer agreements). The Commission is pursuing two further 'pay-for-delay' investigations: *Servier (perindopril)* (Case COMP/AT. 39612); and *Cephalon and Teva* (Case COMP/AT. 39686). The background facts relied on by the Commission in *Lundbeck* and *J&J* according to its press releases are summarized below.

Facts: *Lundbeck*

Lundbeck's blockbuster drug, citalopram, treats the symptoms of depression. By 2002, patent protection for the molecule had lapsed. As is common for many drugs, Lundbeck had obtained further patents over manufacturing processes which were still in force. One generic had entered the market with a competing treatment, while others were preparing to do likewise. Lundbeck entered into discussions with generics regarding patent infringement and, rather than pursuing litigation, reached settlements with four of them. In exchange for agreeing not to launch, the generics received significant lump sum payments and other financial inducements, stocks of the generic medicines were destroyed and the generics were offered guaranteed profits in distribution agreements for citalopram.

The parties apparently referred in internal documents to the formation of a '*club*' and the sharing of '*a pile of $$$*' between them. Lundbeck was fined €93 million and the generics a total of €52.2 million. Each of the parties has appealed on a broad range of grounds. These reveal that the Commission assessed the settlements as infringements of Article 101 '*by object*', ie restrictions with such a high potential for negative effects that it was not necessary to demonstrate any actual 'effects' on the market.

Facts: *J&J*

In 2005, J&J's patent protection for the patch of its painkiller fentanyl had expired in the Netherlands and Novartis was about to offer a generic version through its subsidiary, Sandoz. Rather than entering the market

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with its own product, Sandoz signed a co-promotion agreement with J&J's Dutch subsidiary, Janssen Cilag. This remained in force until December 2006, when a third party was about to launch a generic fentanyl patch.

The Commission found that the agreement was not designed to facilitate co-promotion, but instead to keep the price of fentanyl artificially high in the Netherlands, allowing the parties to share the monopoly profits. The Commission appears to have reached its decision on the basis that: (i) no other co-promotion partners were considered; (ii) Sandoz did not take part in any meaningful promotional activity; and (iii) the payments received by Sandoz exceeded those which it might have expected to receive had it launched its own generic fentanyl. The parties' internal documents referred to dividing up the '*cake*' and keeping '*the current price high*'.

Unlike *Lundbeck*, this case did not relate to the validity and/or infringement of IP rights—the relevant patent had expired. Although strictly not a settlement agreement, Commissioner Almunia stated, '*the logic is the same: a company was paying its competitor to delay the entry on the market of the generic version of its drug*'. The Commission again appears to have characterized the arrangements as infringements of Article 101 '*by object*'. Neither J&J nor Novartis will be appealing the decision, which imposed combined fines of €16.3 million.

Analysis

The Commission has recognized that, in a sector where innovation is in the public interest, IP rights are a '*key element in the promotion of* [that] *innovation*'. 'Pay-for-delay' cases therefore give rise to competing policy and legal issues.

The Commission accepts that the settlement of disputes is '*a legitimate way to find a mutually acceptable compromise to a bona fide legal disagreement*'. Patent litigation is costly in legal fees, management time and commercial uncertainty, meaning that both parties have legitimate interests in bringing disputes to an end: courts and the Commission (in principle) therefore seek to encourage settlement. However, the Commission also warns that '[o]*n the other hand, it is in the general public interest to remove invalid intellectual property rights as an unmerited barrier to innovation and economic activity*'. Particular difficulties arise because the right to exclude conferred by patents is subject to challenge through the courts and thus is in reality only a right to *try* to exclude.

Patent holders can rarely be confident that a court will find a patent valid and infringed. Patents are legal documents and open to varying interpretations, while patent law is complex. Statistics suggest that proving validity and infringement is more difficult for process (as opposed to molecule) claims. To date, the Commission has focused on arrangements concerning patents other than molecule patents.

In *Lundbeck*, the Commission treated a payment from the originator to the generic as a *prima facie* indication of a weak patent, in effect second-guessing the outcome of patent litigation. Caution in applying such rules of thumb may be advisable; even patent experts have grave difficulty in predicting the outcome of a case. It is possible for different courts in different Member States to come to different conclusions on similar issues of infringement and validity—or to reach the same result but on different grounds. The commercial reasons for any payment to a generic might be unrelated, or only partly related, to a party's view of patent strength (and even a patent thought to be weak may by upheld by a court).

While emphasizing that the settlement allowed the parties to eliminate the inherent uncertainty of patent litigation, the *Lundbeck* appellants have also argued that the settlement would have allowed patients to benefit from the introduction of generics many years before the expiry of the patent in question. If the existence of a *prima facie* exclusionary IP right is taken into account, arguably the settlement leads to the guaranteed introduction of competition which otherwise might not have taken place.

The Commission's activities so far leave a number of questions unanswered: how likely must it be that a patentee would lose for a settlement to be seen as an unmerited barrier to entry? Is there a sliding scale against which the size of a payment should be assessed? What would be the impact of a subsequent court judgment on validity? What is the relevance of a finding of validity even though a particular generic wins on infringement issues—arguably public policy issues around the elimination of invalid patents are not relevant in such cases?

Dealing with 'pay-for-delay' settlements as infringements of Article 101 *'by object'* is surprising given the complex IP issues and the underlying policy considerations. It differs from the approach in the US following *Actavis* where the Supreme Court rejected the argument that 'pay-for-delay' agreements should be presumptively illegal on a '*quick look*' approach, and preferred a '*rule of reason*' approach requiring the degree and likelihood of anticompetitive effects to be considered. Some of the *Lundbeck* appellants also argue that characterizing the agreements as *'by object'* restrictions ignores the existence of granted patent rights.

In a sector dependent upon significant revenues during a limited period to sustain R&D, the Commission's reliance on contemporaneous internal documents

is problematic. Perhaps the Commission has conflated two distinct issues: (i) the role of the parties' subjective intentions/objectives, which in this sector and given a granted patent, will often be exclusionary and/or exploitative—relying on the ability to ask the court to exclude infringers to enable a 'monopoly' rent; and (ii) whether agreements ought to be deemed anticompetitive '*by object*', removing the Commission's burden of looking at the actual effects on the market—no easy task given the complex counterfactuals. It remains to be seen whether the EU courts will endorse the Commission's approach.

The Commission's draft Guidelines highlight issues which may arise in future cases. *Lundbeck* and *J&J* concerned payments, but the Commission indicates that settlements may be problematic if an originator provides any inducement, '*financially or otherwise*', for a generic to accept more restrictive settlement terms than would otherwise have been accepted '*based on the merits of the licensor's technology*'. Although there is some guidance in the Commission's settlement monitoring reports, what may constitute a non-financial inducement remains unclear, as does the approach to determining the merits of underlying patents.

The Commission's scepticism around settlements also comes through in its approach to 'no-challenge' clauses, in which the parties agree not to challenge the IP covered by the settlement. Although acceptable in '*bona fide*' settlements, it notes that such clauses might be considered to be anticompetitive '*if the licensor knows or could reasonably be expected to know that the licensed technology does not meet the legal criteria to receive IP protection*'. Given that an originator is unlikely to ever 'know' for certain whether its patent will be upheld as valid (in the absence of final binding judgments in all relevant Member States; or having wrongfully obtained its patent in some way, akin to the US doctrine of fraud on the patent office), this is likely to introduce additional uncertainty. It is difficult to see how one can reach a 'settlement' without some appropriately limited finality on challenge. The cumulative effect of the Commission's approach might well be to discourage settlements, even those that might allow entry before the expiry of valid IP rights.

Practical significance

The significance of contemporaneous evidence of intent cannot be overstated: decisions taken so far suggest that this will be central to the Commission's assessment of the legality of 'pay-for-delay' arrangements. Care should be taken to avoid language which might suggest an anticompetitive intent. The focus both in strategy and in language should always be on protecting IP and other legitimate rights, rather than on exclusion per se. Internal assessment of the strength of patents, expressing any significant doubt about their prospects in litigation, may also jeopardize future ability to settle without competition law scrutiny.

Maintaining legal privilege over documents assessing the validity of IP rights, litigation prospects and related competition law issues becomes key. The Commission's narrow approach to the scope of legal privilege during competition investigations is likely to be important in any proceedings. The precise ambit of privilege in this context remains unclear and is likely to be contentious. The unfortunate exclusion of advice from in-house lawyers from the scope of privilege in EU investigations must be remembered, as should the prospect that patent agents' advice will not be covered. It is always sensible to clearly identify legal advice and to have considered in advance how it falls within the scope of the protection provided by EU law so as to protect its position during any investigation.

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