

EU General Court Upholds Commission's Landmark Patent Settlement Agreement Decision

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In a much-anticipated series of judgments, running to some 579 pages, the EU's General Court on 8 September 2016 upheld a 2013 decision of the European Commission that imposed fines of almost €150 million on the innovative pharmaceutical manufacturer, Lundbeck, and a number of generic manufacturers with whom Lundbeck had entered into agreements to settle patent disputes (Patent Settlement Agreements). The General Court's judgments are the first pronouncement by the EU Courts on a series of controversial cases brought by the Commission in relation to Patent Settlement Agreements in the pharmaceutical sector. The judgments uphold the test advanced by the Commission for determining when a Patent Settlement Agreement can be deemed to restrict competition for purposes of Article 101 of the Treaty on the Functioning of the EU (TFEU). In doing so, the judgments reject Lundbeck's – and others' – arguments that a Patent Settlement Agreement cannot be deemed to restrict competition where the restrictions on the conduct of a generic fall within the restrictions arguably already in place by virtue of the scope of the patent(s) at issue (the so-called "Scope of the Patent Test").

The Background

Danish innovator Lundbeck held a patent for the antidepressant citalopram and a number of process patents in relation to the manufacture of citalopram. The patent for citalopram itself expired in 2002, but certain process patents remained in force several years thereafter. Between January 2002 and December 2003, faced with potentially infringing conduct from generics looking to enter (or already having entered) the citalopram market, Lundbeck concluded six separate agreements with such generics. The details of the agreements varied, but all provided for: (1) the generic agreeing not to enter the citalopram market for a period of time; and (2) Lundbeck making payments to, or providing other incentives to, the generic. Among the other factors taken into account by the Commission was that the obligations on the generics went, in the Commission's view (though Lundbeck contested this), beyond the rights that Lundbeck could have enforced as a patent holder.

The Judgments

When the Commission issued its 2013 decision finding that Lundbeck's agreements infringed Article 101 TFEU, and imposing fines totaling almost €150 million, Lundbeck and the generics lodged appeals. Given that the competition law assessment of Patent Settlement Agreements had never before been subject to EU Court scrutiny, the appeals raised dozens of pleas at law, many of which consisted of multiple parts. In the judgments, the General Court dismissed every part of each and every plea at law.

The Key Legal Test

In relation to many of the pleas at law advanced by Lundbeck and the generics, the General Court's judgments turned, ultimately, on its acceptance of a key legal test set out in the Commission's decision. That test provided that a Patent Settlement Agreement would be a restriction of competition for purposes of Article 101 TFEU where: (1) the innovator and generic were at least *potential* competitors; (2) the generic had agreed to limit its independent efforts to enter one or more EEA markets with generic product; and (3) there was a transfer of value from the innovator to the generic which substantially reduced the incentives of the generic manufacturer to independently pursue its efforts to enter.

The Scope of the Patent Test

In accepting the Commission's key legal test, the General Court also rejected the notion that the Scope of the Patent Test could operate as a kind of safe harbor for parties to Patent Settlement Agreements. For the General Court, the Scope of the Patent Test, as advanced, would have required that, in order to establish an infringement of Article 101 TFEU, the Commission would have had to demonstrate that the limitations agreed to by the generic went *beyond* the scope of the protection already afforded by the (presumptively valid) patents at issue. If accepted, this test would have been akin to one which had been espoused by a number of U.S. courts at the time of the Commission's decision.

However, the General Court held that the Scope of the Patent Test should not provide a safe harbor, and that, even if the restrictions on generics in a Patent Settlement Agreement were within the scope of the innovators' patents, such Patent Settlement Agreement would still need to be subject to a case-by-case assessment. As such, for the General Court, notwithstanding the fact that restrictions operate only within the scope of a patent, they could nevertheless constitute restrictions on competition because they transform potential uncertainty around generic entry into a certainty that it would not take place during the term of the agreements at issue.

Restrictions of Competition "By Object"

The General Court's judgments are also interesting in respect of its conclusions on restrictions of competition "by object." A restriction of competition by object is a restriction which, by its very nature, reveals a sufficient degree of harm to competition that there is no need for the Commission to examine whether in a given instance the restriction actually had anti-competitive effects.

In this regard, the General Court's judgments build on a number of prior judgments from the Court of Justice, the most important of which is the 2014 judgment in *Cartes Bancaires*. Lundbeck advanced arguments aimed, *inter alia*, at requiring the Commission to refer to more robust experience (such as economic analysis or prior case law more directly on point) before characterizing a restriction as a restriction of competition by object. However, the General Court held that the mere fact that the Commission has not, in the past, considered that a certain type of agreement was, by its very nature, restrictive of competition does not prevent it from doing so in the future. The General Court's judgments on the parties' by-object arguments appear to rest, in large part, on the affirmation of the Commission's version of the key legal test as set out above, and a resultant conclusion that the Patent Settlement Agreements were akin to market sharing agreements. Nevertheless, the judgments remain of note in this regard as they represent yet another affirmation of the Court of Justice's judgment in *Cartes Bancaires*.

Initial Reactions

In a press release, Lundbeck stated that it strongly disagrees with the Commission's 2013 decision and the General Court's judgments, and that it is considering whether to appeal. The judgments are clearly very significant, and it would be no surprise to see appeals to the EU's top court, the Court of Justice.

For its part, the Commission welcomed the judgments, noting that this was the first time that the General Court had ruled on what the Commission describes as "pay-for-delay" agreements in the pharmaceutical sector. The Commission also highlighted the General Court's conclusions that the Commission had been correct in finding that, irrespective of any patent dispute, the generics had agreed with Lundbeck to stay out of the market in return for value transfers and other inducements, and that this constituted, according to the Commission's decision and the General Court's judgment, "a buying-off of competition."

With further Patent Settlement Agreement cases already before the EU Courts, and the possibility of appeals to the Court of Justice in relation to yesterday's judgments, this is far from being the final chapter on this issue. However, the judgments will clearly be seen by the Commission as a vindication of the controversial approach it has taken in relation to Patent Settlement Agreements, an approach which dates back to its 2008-2009 Sector Inquiry.

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