

EU Court Writes Prescription For Pay-For-Delay Enforcement

By Eric Kroh

Law360, New York (September 13, 2016, 8:11 PM EDT) -- A European Union court recently upheld €146 million (\$163.79 million) in fines on Danish drugmaker Lundbeck and four generics producers for agreeing to delay the introduction of generic depression drug citalopram, a decision that experts said sets the stage for additional pay-for-delay actions by the EU and national regulators.

The Sept. 8 decision by the General Court — which found that H. Lundbeck A/S eliminated competition by inducing Merck KGaA and other generics companies to stay out of the market in return for significant payments — was the first time an EU court had ruled that such pay-for-delay agreements are violations of European competition law in the pharmaceutical sector.

The decision was a vindication for the European Commission, which has taken the position that agreements to delay entry of generic drugs in return for a transfer of value are violations of EU law “by object,” meaning they restrict competition by their very nature. The EC has levied several-hundred millions of euros in fines over the practice.

By confirming the commission’s strict approach to the settlements, the General Court has paved the way for the commission to enforce more pay-for-delay cases against pharmaceutical companies and for EU member state national competition authorities to follow suit, according to Becket McGrath, a partner at Cooley LLP.

“The commission would take the view that by bringing this case, it has helped define the boundary of EU law in this area,” McGrath said. “They’ve got a clear template laid out for them [to bring additional actions.] ... They’ll also be keen for national authorities to bring them as well.”

The EC in June 2013 announced that it had imposed fines of €92.3 million on Lundbeck and €52.2 million on the generics companies for making agreements in 2002 to delay the market entry of generic citalopram, an antidepressant medicine that at the time was Lundbeck’s best-selling product.

When the agreements were made, Lundbeck’s patents for citalopram and two production processes had expired, and the company could no longer completely block companies from making generic versions of the drug, according to a public version of the commission’s prohibition decision against the companies published in 2015.

Several of Lundbeck’s process patents, however, were still in effect, meaning it had the power to sue producers of generic versions of the drug for infringement, according to the decision. In fact, Lundbeck

had claimed patent infringement against the generics companies named in the EC's decision, the commission said.

Before a court could rule on the patent suits, Lundbeck settled with the companies, which agreed to delay market entry of generic citalopram in exchange for a transfer of value from Lundbeck, according to the decision. Internal documents referred to a "pile of \$\$\$" being given to the generics companies, amounting to tens of millions of euros. Lundbeck also purchased the generics companies' stock for the sole purpose of destroying it and offered them guaranteed profits in a distribution agreement, the EC said.

In its decision, the commission emphasized that not all patent infringement settlements are potentially problematic, but the Lundbeck agreements broke the law because they removed potential competitors from the field.

"What is important from the perspective of Union competition law is that each of the agreements covered by this decision prohibited entry by a potential competitor," the commission said. "Each agreement was characterized by the fact that it contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter's agreement not to market generic citalopram in the geographic area concerned for the duration of the agreement."

Lundbeck appealed the commission's decision to the General Court, arguing, among other things, that the EC was wrong to conclude that the settlements were restrictions of competition by object. Lundbeck said the commission did not have to examine whether the agreements had an anti-competitive effect to show they violated antitrust laws. The court, however, upheld the commission's reasoning.

"The Commission did not err in considering, in the contested decision, that the very existence of reverse payments and the disproportionate nature of those payments were relevant factors in establishing whether the agreements at issue constituted restrictions of competition 'by object' ... in that, by those payments, the originator undertaking provided an incentive to the generic undertakings not to continue their independent efforts to enter the market," the General Court said.

In its decision, the General Court comes close to saying that as soon as there is a value transfer in a patent infringement settlement, there is a restriction of competition by object, according to Suzanne Rab, barrister at Serle Court Chambers in London.

Though the U.K. and U.S. antitrust regimes are not directly analogous, the General Court's analysis is similar to saying that pay-for-delay agreements should be held to a strict per se standard, rather than the rule-of-reason approach taken by the U.S. Supreme Court in *FTC v. Actavis*, Rab said.

The General Court's opinion is also difficult to square with the EC's 2013 Lundbeck decision, in which the commission acknowledged that not all so-called reverse-payment settlements are problematic, she said.

"If this decision is not overturned on appeal, it will be very hard to justify any settlement that involves a payment or other transfer of economic value to the putative licensee," Rab said.

McGrath disagreed that the General Court's analysis deviated far from that of the Supreme Court, saying the General Court was careful to contrast the Lundbeck agreements with legitimate settlements.

"I suspect that the differences between Actavis and Lundbeck are not as significant as might first

appear," McGrath said.

Lundbeck said in a statement that it strongly disagrees with the General Court's judgment and maintained that the agreements did not restrict competition. The company said it would study the General Court's judgment and decide whether to appeal it to the European Court of Justice. Lundbeck's deadline for appeal is two months and 10 days from notification of the judgment.

Another appeal of pay-for-delay fines imposed by the EC is pending before the General Court. French pharmaceutical company Servier and generics producers are challenging some €428 million in penalties imposed by the commission in 2014.

The Servier case will give the court another opportunity to define the contours of European law regarding pay-for-delay. Although there are differences between the Servier and Lundbeck cases, by backing the EC's arguments in the Lundbeck judgment, the General Court has firmly indicated that it will not take a lax approach to pay-for-delay settlements.

The Lundbeck decision is "important because it upholds the commission's approach in every way," McGrath said.

The case is H. Lundbeck A/S et al. v. Commission, case number T-472/13, in the General Court of the European Union.

--Editing by Christine Chun and Philip Shea.