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FTC's New Rule Zeroes In On More Pharma Patent Deals

By **Melissa Lipman**

Law360, New York (August 13, 2012, 8:17 PM ET) -- The Federal Trade Commission revealed plans Monday to broaden the types of exclusive pharmaceutical patent rights licenses that require antitrust approval, part of the agency's continuing drive to scrutinize agreements that could limit competition in the industry, attorneys say.

The FTC, in consultation with the U.S. Department of Justice, proposed amending its premerger notification rules governing what types of exclusive patent rights transfers require antitrust approval. The change, which is limited to the pharmaceutical industry, means that deals in which the patent owner hands over exclusive marketing and sales rights to another company but retains the exclusive right to manufacture the drug for the distributor might be reportable under the Hart-Scott-Rodino Act.

In the past, holding onto exclusive manufacturing rights generally kept an agreement from becoming a transfer of exclusive patent rights in the eyes of antitrust officials, and as a result, the change will increase the burden on pharmaceutical companies entering that kind of licensing deal, experts said. Though the move will only affect a relatively small number of transactions, according to attorneys and the FTC's own estimates, it is part of the antitrust agencies' ongoing efforts to keep a close watch on deals in the pharmaceutical industry.

"This could add hundreds of thousands of dollars to a relatively straightforward exclusive patent license," Baker Botts LLP partner Stephen Weissman said. "What it [also] does though is emphasize yet again that the agencies, particularly the FTC, are keeping a vigilant watch on the pharmaceutical industry and monitoring the various types of deals and transactions that companies enter for their effects on competition."

Under HSR, straightforward patent sales have long been a clear-cut example of the type of deal that is reportable as long as it triggers the filing thresholds. But patent rights transfers — which usually but not always take the form of an exclusive patent license — have tended to pose stickier questions for the FTC's Premerger Notification Office, according to the agency's Federal Register notice.

In order to assess an agreement, the office generally looked at whether the deal transferred the exclusive rights to "make, use and sell" the patented product. While officials have considered agreements that shifted the entire trio of rights to a new company to be reportable transactions, the PNO has generally viewed arrangements in which the patent holder keeps the right to manufacture the product as nonreportable distribution agreements rather than asset transfers.

Now the FTC plans to change that practice based on the unique dynamics of the pharmaceutical industry, in which the right to manufacture a drug is "far less important than the right to commercialize" it, according to the agency, which is taking comments on the proposal through Oct. 25.

As a result, agreements in which a patent holder with manufacturing technology keeps the right to supply the licensee exclusively but gives the licensee the exclusive rights to market the drug are somewhat common, the commission said.

"As the licensor is manufacturing solely for the use of the licensee, this is substantively the same as giving the licensee the exclusive right to manufacture, use and sell the product(s) covered by the license," the FTC said.

The antitrust watchdog conceded that treating that type of exclusive licensing arrangement as potentially reportable was a "significant change in the weight given to manufacturing rights in determining whether or not exclusive rights to a patent are being transferred."

The proposed rule does offer some further clarity for pharmaceutical companies about what kinds of exclusive licenses have to be notified, according to Weissman. But it will still only affect a relatively small number of licensing deals, he said, mainly because most agreements of this sort in the pharmaceutical industry are between small innovating firms that lack the resources to turn a discovery into a marketable drug and so usually include the full package of patent rights that the PNO already considered reportable.

Still, the additional burdens for those agreements that would become reportable under the proposed rule are significant, according to Mayer Brown LLP partner Christopher J. Kelly.

"By their own estimate, it's going to mean that 30 transactions a year that weren't reportable in the past are going to be now," Kelly said. "That's not very much of an effect on [the FTC]. I think they estimate it's going to cost them maybe another $1.2 million or so, but just starting with filing fees the aggregate cost of filings for these 30 transactions a year is going to be double that, and then of course, you have the costs that go with doing a Hart-Scott-Rodino filing."

All in all, that means the proposed rule would create a "substantial cost" for pharmaceutical and biotech companies that enter these kinds of licensing deals, according to Kelly.

"The problem generally is that it's not at all clear that this [means] the FTC is now going to be able to identify anti-competitive deals that otherwise had evaded its review," Kelly said. "There's nothing they say in this notice ... that suggests why these particular agreements would be any more likely to raise competitive problems other than the fact that ... they involve the pharmaceutical industry, which the FTC generally takes a jaundiced view of."

Even for the types of exclusive licensing agreements that were already reportable, the FTC has not been particularly active in the past, according to Kelly.

"It's an area that's not been the subject of a significant amount of enforcement action, and evidently they have some concern that some transactions like these are worth a look, but they haven't explained why," Kelly said. "The way the notice reads it seems like you've got ... the commission just generally overriding the historic view of the Premerger Notification Office on this point."

Regardless of its effects, the plan is of a piece with the agency's overall interest in the pharmaceutical industry, attorneys said. Drugmakers have since 2003 had to notify the agencies about any patent settlements they enter, with the FTC pursuing a number of antitrust cases over so-called pay-for-delay deals despite having little success until the Third Circuit endorsed the agency's approach in July.

The agency has already taken that fight from litigation to merger reviews with the conditions it placed on Perrigo Co.'s $540 million purchase of rival generic drugmaker Paddock Laboratories Inc. last month.

Among other restrictions, the FTC barred Perrigo from signing any pay-for-delay deals with Androgel-maker Abbott Laboratories based on concerns that those deals might hinder competition for generic versions of the testosterone gel.

While a similar limitation would be an "unusual remedy" for an exclusive patent licensing agreement, the FTC is "looking for all sorts of tools in their toolbox to counteract these arrangements that they don't like," Weissman said.

The issue could arise in the context of a licensing deal because the right to sue to enforce the patent, and thus to settle infringement cases with generic manufacturers, shifts from a small innovator to a large pharmaceutical company, according to Weissman.

"[The big company's] ability to sue and resources to settle the case and its incentives in settling the case may be different than the smaller company," Weissman said. "This is yet another way that the FTC can monitor and if appropriate enforce Section 7 of the Clayton Act to better understand the incentives of pharmaceutical companies who have the right to enforce patents."

"That wouldn't be a driver, but that may be a byproduct of the amendments, an added bonus for the agency," Weissman added.

--Editing by Elizabeth Bowen and Lindsay Naylor.