New York Law Journal
SERVING THE BENCH AND BAR SINCE 1888
WWW.NYLJ.COM
An ALM Publication
VOLUME 250—NO. 112
TUESDAY, DECEMBER 10, 2013

ANTITRUST TRADE AND PRACTICE

Expert Analysis

FTC Broadens Filing Requirements For Exclusive Patent Licenses

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On Nov. 6, 2013, the Federal Trade Commission (FTC) finalized a new rule amending the filing requirements for patent transfers under the Hart-Scott Rodino Act (HSR). The new rule—largely prompted by the evolving licensing structure within the pharmaceutical industry, as well as the growing antitrust importance of licensing practices generally—ultimately broadens the notification requirements for transfers of pharmaceutical patent rights. The FTC maintains the new rule does little more than codify the current policy positions of the Premerger Notification Office (PNO), but there are a few notable changes with antitrust implications for exclusive patent licensing transactions. Under the new rule, a transfer of pharmaceutical patent rights will be potentially reportable under the HSR if the patent owner exclusively transfers all of the "commercially significant rights" to a patent. The rule will begin to take effect on Dec. 13, 2013.

'Make, Use or Sell' Standard

The HSR requires parties to certain proposed large mergers or asset acquisitions to notify both the Antitrust Division and the FTC of the transaction. The parties must allow the enforcement agencies to review the transaction for at least 30 days before completing the deal. Only transactions of a certain size trigger these reporting requirements. Filing is usually required when a proposed deal meets both the size-of-the-person and the size-of-the-transaction tests.

As of February 2013, parties must file premerger notification forms if the size-of-the-transaction, or the value of the acquisition, exceeds $70.9 million. The size-of-the-person test requires that one party to the deal have $141.8 million or more in annual sales or total assets and the other party must have $14.2 million or more in annual sales or total assets.

The FTC historically has considered the sale of a patent to be a reportable asset if the sale satisfied the thresholds above, but it is less obvious whether an exclusive patent license qualifies as an acquisition of an asset.[1] Beginning in the 1980s, the Premerger Notification Office (PNO) issued informal opinions noting patent licenses were HSR reportable asset acquisitions, as these agreements could be viewed as the functional equivalent of a sale of that patent.[2] In order to be reportable, the license must be exclusive. In turn, an exclusive license allowed the licensee to "make, use and sell" the product under the patent. Unless the patent gave the licensee the exclusive right to "develop a product, manufacture the product, and sell that product *without restriction*," the license was not exclusive and therefore not reportable.[3]

The FTC never codified the "make, use and sell" test, but this approach became the standard measure for determining when a license agreement triggered HSR reporting requirements. Recently, however, pharmaceutical companies began to alter the structure of their exclusive licenses, electing to transfer "most, but not all" of the rights to "make, use or sell" under a specific patent to the licensee.[4] The FTC noted two particularly problematic licensing trends: retained manufacturing rights and "co-rights."[5]

Patent licensors began to grant the licensee exclusive rights to use and sell the patent, but retained the right to manufacture the product, albeit solely for the licensee. Under the "make, use and sell" paradigm, retaining the right to manufacture the product "render[ed] the transaction non-reportable even though the licensor would not be manufacturing for its own commercial use, but exclusively for the licensee."[6] The FTC concluded that withholding the manufacturing right defeated true exclusivity, and therefore viewed the transaction as a non-reportable distribution agreement.

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As this practice became more common, the PNO expressed concern about the potential anticompetitive incentives and effects that may arise from these deals. For example, a company could license their patent rights to a competitor—specifically to a competitor with a very similar product—but retain the right to manufacture the product. This allows two competing companies to transfer potentially lucrative patent rights and complete a deal that possibly raises antitrust concerns without ever triggering HSR filings; only if the FTC received complaints would there likely be the potential for an investigation.

A recent pharmaceutical licensing agreement often is identified as illustrating this concern. Questcor is a California-based pharmaceutical company that markets Acthar, a drug prescribed for immune-related deficiencies. Sales of Acthar reached $512 million in 2012, with the price for one vial costing upwards of $28,000.[7] On June 14, 2013, Questcor licensed the rights to a similar drug for $135 million from a company that exclusively sold in Europe.[8] A third company previously bid to acquire this drug and offer it in the United States for significantly less than the price of Acthar. Instead, Questcor offered a higher price to license the drug and per the license agreement, allowed the licensee to retain manufacturing rights. Despite the value of the acquisition far exceeding $70.9 million, the transaction did not require HSR filing. The FTC maintained this type of transaction has the exact same effect as a transfer of all patent rights, yet was a way to circumvent HSR requirements, prompting the need for a rule change.

Additionally, with "increasing frequency" licensing companies carved out what the FTC labeled as "co-rights" in the patent's development process. These often include the right to "co-develop, co-promote, co-market and co-commercialize the product along with the licensee."[9] Retaining co-rights allowed the licensor to assist in marketing and selling the product, with the goal of maximizing any future royalty stream to which the licensor was entitled. Although PNO informal opinions in recent years noted that these "co-rights" did not impact the exclusivity of a license, there were still lingering questions regarding the effects of these type of retained rights—or at least enough concern to permit the FTC to have notice of them.

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New Rule

Motivated by these perceived filing loopholes, on Aug. 13, 2013, the FTC posted a Notice of Proposed Rulemaking and Request for Public Comment. On Nov. 6, 2013, in a unanimous 4-0 vote, the commission adopted the proposed rule change. Now, a license transferring "all commercially significant rights" of a pharmaceutical patent is potentially reportable under the HSR. The rule defines commercially significant rights as "the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)"; all of the three rights to "make, use and sell" need not be transferred.[10] Instead, the concept looks only to whether the recipient will receive those rights that generate profits. Accordingly, "all commercially significant rights are transferred even if the patent holder retains limited manufacturing rights."[11]

Significantly, however, if the licensor retains broader manufacturing rights, such as the right to manufacture for other companies outside of the licensee, the transaction will not be reportable. A transfer of "all commercially significant rights" also occurs even when the grantor retains "co-rights." This portion of the rule change is merely seen as codifying the PNO's current policy.[12] The rule clarifies that retaining "co-rights" does not leave the licensor with any commercially significantly rights to use the patent or part of the patent. If a company wishes to assist in marketing a product, it can still have those provisions in the patent license agreement, but retaining these "co-rights" will not eliminate the reporting requirements.

Certainly this new rule succeeds in clarifying the historical gray areas of "co-rights" and retained manufacturing rights. In the process, however, it replaces a straightforward rule that explicitly listed three rights that made a license exclusive with an arguably ambiguous standard that requires companies to analyze what rights are "commercially significant." It is no surprise, then, that the rule has drawn the ire of some in the pharmaceutical industry for imposing additional burdens on pharmaceutical companies.

The FTC anticipates that the rule will lead to an additional 30 filings per year at an estimated cost of only $1-1.2 million to the industry.[13] Critics, however, disagree with these estimations, stating the FTC "grossly understate[d] the actual costs to individuals and businesses that would result annually from these increased HSR filings."[14] In a public comment opposing the rule change, the Pharmaceutical Research and Manufacturers of America, a trade group representing research and biopharmaceutical companies, contended 30 additional filings is a "material increase" of nearly 50 percent in the patent licensing field.[15] The comment also stated the FTC did not adequately approximate the costs incurred in preparing HSR filings and failed to consider the inevitable transaction costs associated with adapting to any new rule requirement.[16] The FTC meets these concerns with the single observation that "the administrative costs of filing

are very small compared to the profits at stake in the multi-million dollar transactions reportable under the act and are unlikely to deter or materially distort these acquisitions."[17]

Practical Implications

While this new rule will certainly impact drug companies that frequently license patents, the rule's limitation to the pharmaceutical industry suggests it may not initially impact many transactions.[18] Although the FTC does not traditionally enact rules limited to a singular industry, the commission took the position that pharmaceuticals are the only industry currently in need of such a rule modification. For example, for the past five years, the PNO received 66 filings involving exclusive patent licenses, and all were for pharmaceutical companies. The FTC acknowledged that "the PNO has not found other industries that rely on these types of arrangements."[19]

Yet, exclusive license agreements outside the pharmaceutical industry are still quite common, particularly in highly technical industries. These industries are still subject to HSR notification requirements, but the reporting requirements will continue to be based on the "make, use and sell" approach rather than the "commercially significant" test. But given the perceived heightened risk that exclusive licensing may bring across industries, all manufacturers should be on guard, especially those with what could be characterized as potential "market power" or incentives for "opportunistic behavior." Indeed, the FTC has made it quite clear that implementing similar rules in different industries is not off the table. The "agencies will continue to assess the appropriateness of a similar rule for other industries, but they need not take an all-or-nothing approach. In promulgating regulations, agencies may proceed incrementally."[20] Certainly if the "commercially significant" standard leads to more investigations and enforcement actions in the pharmaceutical industry, one cannot rule out the early expansion into other industries.

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One governor of such actions will be the acquisition limitation within HSR. The new rule does not affect the initial threshold requirements for a transaction to be reportable under HSR. As the FTC recognized in explaining why licensing agreements are prevalent in the pharmaceutical industry, it is somewhat common for a new creator of a patent to lack the financial resources needed to secure FDA approval and successfully market the drug.[21] The practical effect of this is that early-stage pharmaceutical collaboration arrangements often are not reportable under the HSR because one party fails to meet the $14.2 million size-of-the-person test or because the fair market value of the license at issue does not exceed the $70.9 million size-of-the-transaction test.[22] Accurately assessing the potential value of the patent license will thus remain key when determining if the broadened filing requirements apply.

While the commercially significant test does eliminate what the FTC perceived as loopholes in the requirements for HSR filings, it does leave pharmaceutical companies with a more ambiguous standard for determining whether to file under HSR and the potential for many more investigations of licensing practices and effects. It is therefore advisable—in all industries characterized by significant patent licensing practices—to monitor closely how the FTC evaluates what is considered "commercially significant" under this new rule and what it does by way of enforcement in the evolving area of antitrust.

1. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,706 (Nov. 15, 2013) (to be codified at 16 C.F.R. pt. 801).
2. Id.
3. Id. (emphasis added).
4. Id.
5. Id.
6. Id. at 68,708.
7. Andrew Pollack, "Questcor Pays $135 Million to Acquire Rights to a Competitor's Drug," N.Y. TIMES, June 14, 2013, at B3.
8. Id.
9. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. at 68,707.
10. Id. at 68,712.
11. Id.
12. The FTC did distinguish between "co-rights" and "co-exclusive licenses." A "co-exclusive" license agreement allows the licensor and licensee to share equally the intellectual property rights in the patent. These agreements remain non-reportable under the HSR Act. Id.
13. Id.
14. Premerger Notification; Reporting and Waiting Period Requirements, Cmt. 2, Pharmaceutical Research and Manufacturers of America (Oct. 12, 2013) at 13.
15 . Id. at 20 (citing the 2011 HSR Annual report, which indicated there were 75 patent license filings last year).
16. Id. at 13. Further, if the agencies issue second requests for patent licenses at the same rate as last year (8 percent) there will be an additional three second requests annually, which the association argues results in a $10-15 million cost to business.
17. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. at 68,710.
18. The rule covers products whose manufacture and sale would "generate revenue within NAICS Industry Group 3254 (pharmaceutical and medicine manufacturing)." Id. at 68,713.
19. Id. at 68,708.
20. Id. at 68,712.
21. Id. at 68,708.
22. Even if a transaction does not require reporting, it still may be investigated and challenged under Section 7 of the Clayton Act, which prohibits acquisitions that could substantially lessen competition.