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Is the FTC Picking on the Pharmaceutical Industry Through New HSR Rules?

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Effective December 16, 2013, Hart-Scott-Rodino (HSR) coverage of exclusive licenses of patents will change. As HSR practitioners know well, the Federal Trade Commission's Premerger Notification Office (PNO) has long-interpreted HSR to cover exclusive licenses as a reportable acquisition (assuming all other requirements are met) if the licensor did not retain any rights to "make, use or sell" under the patent. Now, the PNO's formal rules will consider a patent license a reportable acquisition even if the licensor retains the right to manufacture—but solely for the licensee—or if the licensor retains the right to co-market, but, again, solely with the licensee. The PNO's thinking is that, despite the retention of those limited rights, the licensor essentially is transferring "all commercially significant rights" to the patent, and so the license is akin to an acquisition.

Normally, such a technical change to HSR interpretations would garner little attention outside the small community of HSR aficionados. So, why has this change generated some grumbling in the broader antitrust and corporate communities? Because new rule §801.2(g) applies only to transfers of patent rights within NAICS Industry Group 3254, the pharmaceutical industry.

HSR and its regulations apply to all industries. As PhRMA (Pharmaceutical Research and Manufacturers of America) pointed out in its lengthy objection to the PNO's notice of public rulemaking, HSR allows the FTC to exempt certain industries and transactions from coverage but does not allow the FTC to single out a specific industry for increased burdens. In its final rule, the PNO explained that it is not expanding coverage or increasing burdens for anyone, only clarifying which transactions must be notified.

It is not clear why the PNO chose to focus this rule solely on the pharmaceutical industry. Certainly, as the PNO explains well in the *Federal Register* notice, its experience with these types of licenses—and the HSR questions they generate—comes solely from the pharmaceutical industry. Still, in the past when the PNO had the ability to craft an exemption that could have focused on a single industry, it chose to write it to apply to all similar transactions. For instance, §802.3 provides an exemption for certain acquisitions of carbon-based mineral reserves, such as oil, natural gas and coal. It applies to all such transactions, no matter the company or industry involved. It appears the PNO could have written this clarification on reportability of patent licenses to apply generally, and then used its pharmaceutical industry experience as explanations and examples.

The PNO seems to understand that concern. More than once in its *Federal Register* notice, the PNO says, “to the extent that other industries engage in similar exclusive licensing transactions, such transactions remain potentially reportable events under” HSR and existing rules. So, the new rule will require attorneys with such transactions in the pharmaceutical industry to file but, perhaps, attorneys with similar transactions in other industries can convince the PNO that the same logic does not apply to their transactions. Also, the PNO put other industries on notice that it “will continue to assess the appropriateness of a rule for other industries.” While that statement might make the pharmaceutical industry feel better— that it might not end up being the only industry singled out—it raises the specter of special rules for these types of transactions. And, perhaps, for other transactions and other industries. It is that uncertainty that raises concerns outside the pharmaceutical industry.

The PNO has a well-deserved reputation for consistently and evenhandedly interpreting HSR rules, helping many a confused filer submit forms correctly and consulting with HSR frequent filers before making changes. Here, it seems the PNO could have drafted or explained this new rule differently and avoided some consternation within the antitrust community.

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