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FTC Patent License Rule Sure To Annoy Drugmakers

By **Melissa Lipman**

Law360, New York (November 07, 2013, 8:54 PM ET) -- The Federal Trade Commission's newly finalized rule requiring pharmaceutical companies to report more exclusive patent licenses for antitrust approval under the Hart-Scott-Rodino Act will increase costs and delays for the industry while leaving drugmakers struggling to figure out whether their licenses require notification, attorneys said Thursday.

Under the rule published Wednesday, pharmaceutical companies will now have to notify the agency of any license that gives an exclusive licensee "all commercially significant rights" to use a patent or part of one — even if the licensor holds on to the right to manufacture the drug. The new rule replaces the old test, which required companies to provide notification for licenses that give the licensee the right to "make, use and sell" the patented product.

The FTC maintains that the change better captures the kind of patent licenses it and the U.S. Department of Justice have always intended to review. But experts say that even with the agency's definition and examples, pharmaceutical companies will have to invest significant time and energy to suss out whether they must notify the agency of their licenses.

And for those that do file, the change means added filing costs, legal fees and a 30-day waiting period for the agencies to review the licensing agreement.

"We, over the last several years, had quite a few exclusive licenses where the pharmaceutical company retained significant rights and thus [the agreements] didn't have to be reported, and now they will," said Kaye Scholer LLP partner Claudia Higgins. "The key thing is not just having to report it, but once you report, it you have a 30-day waiting period — and that's the most bothersome thing, in my opinion."

Under Hart-Scott-Rodino, straightforward patent sales have long been a clear-cut example of the type of deal that is reportable as long as it triggers filing thresholds. But patent rights transfers — which usually take the form of an exclusive patent license — have tended to pose stickier questions for the FTC's Premerger Notification Office, the agency said when it proposed the change in August 2012.

Using the old test of whether an agreement transferred the exclusive rights to "make, use and sell" the patented product, officials generally viewed agreements that shifted the entire trio of rights to a new company to be reportable transactions. But they have usually considered arrangements in which the patent holder keeps the right to manufacture the product as nonreportable distribution agreements, rather than asset transfers.

The new test, however, is designed to address the evolution of pharmaceutical patent licenses, as it's more common now for the drugmaker to retain the right to produce the drug exclusively for the licensee to sell, the agency said in its Federal Register Notice.

The watchdog said that in practice, the only difference between the old test and the new one was that deals in which the patent owner keeps the right to manufacture the drug for its exclusive licensee will now be subject to review. Otherwise, "the rule treats the reportability of exclusive licensing arrangements, including those where the licensor retains co-rights, in the same way that the [Premerger Notification Office] has for decades," the FTC said.

But attorneys warned that it would take some time to hash out just what exactly the boundaries of the new test were.

"They give some examples, but what is commercially significant? We don't have case law on that," Higgins said. "People are going to say, 'Well, does this have to be filed?,' and there will be letters back and forth [and] yet more impediments and delay and cost."

As a result, pharmaceutical companies will have to spend time doing internal reviews just to decide whether their exclusive licensing deals need notification, according to Mayer Brown LLP's Christopher Kelly.

"[The FTC] seem[s] to think that the right to sell in the pharmaceutical industry is really what's commercially significant, but I think you're still going to find that it's going to be necessary for pharmaceutical companies to really look closely at each particular license," Kelly said. "It does mean now that a pretty extensive and expensive review of each license is going to have to get done in instances where, up until now, people have been able to tell pretty quickly that they didn't have a filing obligation."

Then there is the actual cost of preparing a filing and finding the documents and data needed for a Hart-Scott-Rodino notification, as well as the filing fee and the 30-day waiting period that follows.

Responding to criticism leveled at the proposal by industry group Pharmaceutical Research and Manufacturers of America, the FTC said that assuming the new rule would lead to the filing of 30 additional licensing agreements per year, the estimated cost to the industry would be only $1 million to $1.2 million a year.

"In the PNO’s experience, the administrative costs of filing are very small compared to the profits at stake in the multimillion-dollar transactions reportable under the act and are unlikely to deter or materially distort these acquisitions," the FTC's notice said.

And given that the new test should clarify the issue of whether licensing agreements count as acquisitions under Hart-Scott-Rodino and offers the agencies the chance to review more such agreements, the FTC said that the "benefits outweigh any potential additional burden on filing parties."

But the costs will add up for pharmaceutical players who use many of these types of licenses, according to Kaye Scholer antitrust practice group Co-Chairman Saul Morgenstern.

"If you have a small enough company, you might find yourself doing fewer of these [licenses]. But if you have a really big one whose lifeblood is developing products and licensing, it might have less of an impact in terms of doing fewer of these, but it certainly increases the cost," Morgenstern said.

Attorneys also questioned why the FTC had chosen to single out the pharmaceutical industry. Experts say it is virtually unheard of for a Hart-Scott-Rodino rule to target a specific industry, and note that similar licensing arrangements crop up in the technology sector.

The agency said in its filing that it wasn't aware of these types of arrangements coming up in other sectors but warned that it would consider whether a rule would also make sense for other industries.

That could yield even more uncertainty beyond the pharmaceutical world, according to Kelly.

"The funny thing is that although the FTC has chosen pretty consciously to adopt a rule that by definition is meant to apply only to the pharmaceutical industry, they also say at a couple points in this notice. ... 'Well, actually it really does apply to everybody else, too, if it turns out your license is kind of like this,' which injects a whole new level of uncertainty for everybody," Kelly said.

--Editing by Kat Laskowski and Philip Shea.