Client Alert

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Changes to FTC Premerger Rules Expand HSR Notification Requirements for Pharmaceutical Patent License Transactions

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Yesterday, the U.S. Federal Trade Commission ("FTC") issued its final rule (the "New Rule") to the Hart-Scott-Rodino ("HSR") Act Premerger Notification Regulations to clarify and expand the coverage of the HSR Act to patent license and collaboration agreements in the pharmaceuticals industry where the licensee acquires "all commercially significant rights" to the pharmaceutical patents.

Under the existing HSR Act regulations and policy, the outright acquisition of a patent and the exclusive license of a patent are potentially HSR reportable transactions (assuming the other HSR criteria, such as size of person and size of transaction, are satisfied). Thus, existing HSR regulations do not require an HSR notification for non-exclusive patent licenses, even if the licensor retains only very limited rights. The New Rule clarifies and expands the HSR reporting obligation, but only with respect to patent license agreements in the pharmaceuticals industry. The New Rule will become effective 30 days after publication in the Federal Register, which will likely happen within the next few days.[1]

The FTC has indicated that the New Rule is intended to capture transactions that are functionally equivalent to the outright purchase of a patent or the grant of an exclusive license to a patent, and therefore may have the same potential effects on competition. Under the New Rule, transactions that transfer "all commercially significant rights" to a pharmaceutical patent or part of a patent will be considered "asset acquisitions" for purposes of the HSR Act (as is the case today with the grant of an exclusive license), and may trigger a premerger notification obligation if the HSR Act's other requirements are satisfied, even if the licensor retains certain limited rights under the patent. The New Rule defines "all commercially significant rights" to mean 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. The principal features of the New Rule are discussed below.

RETENTION OF "LIMITED MANUFACTURING RIGHTS" WILL NOT ELIMINATE HSR REPORTABILITY

The biggest change in the New Rule is the expansion of HSR coverage to pharmaceutical patent license agreements where the licensor retains "limited manufacturing rights," which in this context is defined to mean the right to manufacture but only for the licensee. Until now, the FTC has applied a "make, use, and sell" approach to HSR coverage of patent license agreements, in which a license would not constitute an asset acquisition unless it conveyed the exclusive rights to develop, manufacture, and sell without restriction.

The breadth of the change is limited, however. If the patent holder would retain any right to manufacture for the benefit of itself or others, the transaction is not reportable. And, once again, the New Rule applies only to agreements involving pharmaceutical patents.

[1] The FTC Press Release and the text of the Federal Register notice are available at http://www.ftc.gov/opa/2013/11/pmn.shtm.

RETENTION OF "CO-RIGHTS" TO ASSIST THE LICENSEE IN DEVELOPMENT OR COMMERCIALIZATION WILL NOT ELIMINATE HSR REPORTABILITY

The New Rule also expands HSR coverage to pharmaceutical patent license agreements where the licensor retains certain limited "co-rights" to assist in development or commercialization. The New Rule defines the relevant "co-rights" as shared rights retained by the patent holder *to assist the licensee* in development and commercialization, and they include rights to co-develop, co-promote, co-market, and co-commercialize. Under this definition of co-rights, the patent holder works to maximize the licensee's sales of the product (with the licensee typically booking all revenue from sales of the product), and thereby increases its own royalty revenue stream.

License agreements that allow the patent holder to make direct commercial use of the licensed patent (or part of the patent) continue to be outside the scope of HSR reporting obligations. The FTC has specifically stated that co-exclusive licenses are not reportable, even under the New Rule.

THE NEW RULES ARE SPECIFIC AND LIMITED TO PHARMACEUTICAL PATENTS, BUT MAY BE A BELLWETHER FOR OTHER INDUSTRIES

The New Rule explicitly applies only to "transfers of patent rights within NAICS Industry Group 3254." This industry group is limited to the manufacturing of pharmaceuticals, in-vitro diagnostic substances, biologicals, and medical and botanical products. In confining the New Rule to pharmaceutical patents, the FTC uses industry terms of art to specify that "part of a patent" refers to a license for "any therapeutic area (or specific indication within a therapeutic area)."

The FTC states that it is limiting the New Rule to the pharmaceutical industry because of the FTC's significant experience reviewing license agreements in the pharmaceutical industry and their potential competitive effects. The FTC believes that similar licenses are uncommon in other industry areas, but nonetheless notes that similar patent license transactions in other sectors may be reportable under existing HSR regulations.

The applicability of the New Rule to specific fact patterns will certainly raise interpretation issues, and we expect that the FTC will further clarify the scope of the New Rule in informal interpretations.

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