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FTC Sights Set on Pharma Deals – Calls for Additional Hart-Scott-Rodino Reporting

August 28, 2012

The Federal Trade Commission has proposed expanding Hart-Scott-Rodino reporting and waiting period obligations for certain pharmaceutical, biologics and medicine manufacturing licenses. The new rules are subject to public comment and would not take effect until later this year, but could impact transactions currently underway. According to the agency, an estimated 30 transactions per year presently not subject to reporting will be captured by the proposed rule change.

Under the HSR Act, certain stock or asset acquisitions are subject to notification and waiting period requirements prior to consummation to allow antitrust enforcers to evaluate potential anticompetitive effects. Patent transfers or assignments are treated as asset acquisitions under the HSR Act and are potentially reportable, but it has not always been clear when an exclusive patent license qualifies as an acquisition of an asset for HSR purposes.

The proposed rules would make two important changes from the current state of play and would codify one informal FTC position. First, even if a patent holder retains the exclusive right to manufacture the product covered by the patent for the third-party licensee, the licensing transaction could still be reportable as a transfer of "all commercially significant rights" – a new term in the proposed rule. Second, the new rule would apply only to the transfer of patents that cover products whose manufacture and sale would generate revenues in NAICS Industry Group 3254 (Pharmaceutical and Medicine Manufacturing). Third, even if the patent holder retains the right to assist the recipient of exclusive patent rights in the development and commercializing of the product covered by the patent – co-rights – the license may still be subject to the Act.

Historically, transactions where the licensee is not granted exclusive manufacturing rights have been able to escape HSR review since without the right to manufacture, they were viewed more as distribution agreements than asset acquisitions. The agency has for some time voiced dissatisfaction with this treatment and promised a fix, noting in the proposed rulemaking that, unique to the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize. Thus, under the proposed new rule, licensors that grant exclusive commercialization rights but retain the right to manufacture for the licensee will be deemed to have retained only "limited manufacturing rights," a newly defined term, and to have granted an exclusive license subject to HSR notification and antitrust review.

According to the Statement of Basis and Purpose for the proposed rulemaking, "the proposed all commercially significant rights test should greatly simplify the question of whether an asset acquisition is occurring as the result of the transfer of rights to a patent in the pharmaceutical industry." Experience in practice, though, tells that this will remain an area subject to interpretation, and that will be guided not only by experience with the variety of rights associated with pharmaceutical industry license agreements but by experience with agency practice and approach.

The comment period on the proposed rulemaking expires October 25, 2012, and we expect that a number of significant comments will be lodged. If you believe your business or transaction may be impacted by the potentially expanded reporting requirements, we are available to discuss whether comments, either on an individual basis or as part of a larger group, may be fruitful.

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