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FTC Broadens Notification Requirements for Transfers of Pharmaceutical Patent Rights

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The Federal Trade Commission (FTC) has revised the rule for determining when a transfer of exclusive rights to a patent in the pharmaceutical industry (including biologics and medicine manufacturing) results in a potentially reportable asset acquisition under the Hart-Scott-Rodino (HSR) Act. The ***new rule*** will go into effect 30 days after publication in the Federal Register.

The HSR Act established the premerger notification program, which requires parties to mergers and acquisitions that meet certain size thresholds to make a filing with the federal antitrust agencies, the FTC and the Department of Justice, and observe a waiting period before consummating such reportable transactions. The FTC has long taken the position that the grant of an exclusive patent license is a potentially reportable asset acquisition under the HSR Act, since it is functionally equivalent to the sale of a patent.

Under previous FTC interpretations, exclusive patent licenses were only reportable if they gave the licensee all rights to "make, use, and sell" the patented product. Under the new rule, which applies only to the pharmaceutical industry, a license (or other form of transfer) that gives the licensee "all commercially significant rights" to a pharmaceutical patent "for any therapeutic area (or specific indication within a therapeutic area)" is a potentially reportable asset acquisition. The FTC explains that a therapeutic area covers the intended use for a patent or a part thereof (such as neurological use, for example), while an indication encompasses a narrower segment of a therapeutic area (such as Alzheimer's disease). Such exclusive licenses may be reportable even where the patent holder retains a right to manufacture the product for the licensee, or retains various co-rights to assist the licensee in developing and commercializing the patented drug.

According to the FTC, the new rule is designed to address the evolution of pharmaceutical patent licenses, since it has become more common for pharmaceutical companies to retain some rights. Under the old test, for example, deals in which the patent owner keeps the right to manufacture the drug for its exclusive licensee were not subject to review under the HSR Act. Now such deals are potentially notifiable. The new rule thus provides the antitrust agencies with an opportunity to assess under the HSR Act the competitive impact of exclusive pharmaceutical patent licenses that may not have been reportable under the prior approach.

A highly unusual feature of the new HSR rule is that it is limited to a single industry. The FTC justifies this approach by noting that the pharmaceutical sector is the only industry where it has seen these types of exclusive patent licenses in the past five years. However, the agency leaves

open the possibility that it may adopt a similar rule for other industries in the future and states that even in the absence of such a specific rule, exclusive patent licenses in other industries remain potentially reportable under the HSR Act. This could lead to greater uncertainty, although parties to such a transaction outside of the pharmaceutical area (or their counsel) can contact the FTC for advice.

In light of the new rule, pharmaceutical companies will need to reassess whether their exclusive licensing deals are required to be notified under the HSR Act. For transactions that are determined to be reportable, they will also need to factor in the time and cost of preparing an HSR filing, as well as the mandatory 30-day waiting period before the transaction can close.