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New Federal Trade Commission ("FTC" or the "Commission") rules targeting the pharmaceutical industry will soon require Hart-Scott-Rodino Act (HSR) notices for a broader array of licensing transactions, expanding the types of deals that have to be notified to the government to allow the antitrust enforcement agencies to scrutinize whether those deals may violate antitrust law.

The new rule was published in the Federal Register today, November 15, and will take effect on December 16.

HSR filings are generally required for mergers and acquisitions valued over about $70 million, and the FTC has long required notification of exclusive licenses to patents—that transfer the right to "make, use and sell" a product, such as a drug, to another firm. But today, if the licensor retains rights to manufacture or use the product, the license is considered non-exclusive and no HSR filing is required.

The new rule will require notification of licenses that transfer "all commercially significant rights" to "any therapeutic area (or specific indication within a therapeutic area)" even if the licensor retains manufacturing or other rights.

Under the new rule, the FTC formally establishes the position that reserving "co-rights" will not render an otherwise exclusive license non-exclusive for HSR purposes. Co-rights—including the right to co-develop, co-promote, co-market or co-commercialize, to assist the licensee in developing and commercializing the product—are ones that the FTC views as not affecting whether the grantee has received exclusive rights.

Importantly, these rules are *only applicable to the pharmaceutical industry* (including in-vitro diagnostic and biologic as well as medical and botanical manufacturing), underscoring the Commission's intense scrutiny of the industry. In all other industries, if the licensor retains rights to manufacture or use the product, the license will continue to be considered non-exclusive and non-reportable under the HSR Act.

Protecting competition in the pharmaceutical industry is at the top of the FTC antitrust enforcement agenda. The new notification requirements will provide the Commission with the authority to review and potentially challenge additional transactions in the industry—including transactions by innovators that grant rights to larger firms to develop and commercialize a product.

The new rule is a significant development for pharmaceutical companies because it sets up hurdles to the use of common business arrangements that have immense importance to the industry.

Significant burdens will be added to transactions as a result—even for transactions that ultimately pass scrutiny—including increased costs (i) to determine if a transaction's value (based on what would have been paid for an up-front license without royalties and milestones) exceeds the HSR thresholds, (ii) to prepare the HSR filing, and (iii) to defend the substantive merits if the FTC staff decides to investigate the potential competitive effects of a transaction. Companies must take the delay of HSR review into their plans when considering license agreements.

As noted above, the new rule will take effect December 16. Thereafter, any contemplated exclusive pharmaceutical license agreement that meets the HSR thresholds must be notified, and the parties must observe the mandatory HSR waiting period, before the license becomes effective.

Determining whether the transfer of exclusive patent rights is subject to the HSR Act under the "all commercially significant rights"

test will raise novel issues. As violations for failure to file under the HSR Act can result in significant penalties, including fines up to $16,000 per day, parties to pharmaceutical licensing transactions must be mindful of these important developments.

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