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FTC Expands Reporting Requirements for Transfers of Pharmaceutical Patent Rights

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The U.S. Federal Trade Commission ("FTC") issued final changes to the premerger notification rules that affect whether pharmaceutical companies must report certain proposed acquisitions of exclusive patent rights to the FTC and the Antitrust Division of the Department of Justice ("**DOJ**") for antitrust review under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**"). The final rules apply solely to the pharmaceutical industry and will become effective 30 days after their publication in the Federal Register. The amendments do not change the current HSR reporting requirements related to exclusive licenses in other industries.

Key Takeaways

- A patent holder's retention of limited manufacturing rights no longer renders a transaction non-reportable.
- The FTC reaffirms that a patent holder's retention of co-rights to assist in developing and commercializing the product does not render a transaction non-reportable.

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"Exclusive" patent licensing in the pharmaceutical industry has become more complex over time, evolving from a straightforward license allowing a company to "make, use and sell" a drug under a patent to licensing arrangements where the patent holder may retain some manufacturing rights or co-rights for the purpose of joint development, marketing, or commercialization of the drug. The rule largely clarifies and codifies the FTC's current treatment of exclusive licenses, but reverses the FTC's current practices with regard to licensing arrangements where the licensor retains limited rights.

The HSR Act requires parties to certain proposed transactions to file a notification with the FTC and DOJ and then observe a statutory waiting period before consummating the transaction. The acquisition of a patent is treated as a potentially reportable acquisition of an asset under the HSR Act. The transfer of patent rights, however, also may be deemed a potentially reportable asset acquisition.

Under the FTC's previous analysis, the transfer of exclusive rights to "make, use and sell" a product under a patent is a potentially reportable asset acquisition under the HSR Act. The FTC's longstanding practice also has been to treat the acquisition of exclusive marketing and distribution rights, but not manufacturing rights, as non-reportable. Thus, up until now, pharmaceutical companies have not been required to report the transfer of exclusive rights to commercialize a product under a patent if the licensor retained the right to manufacture the product.

The final rule defines and applies the concepts of "all commercially significant rights," "limited manufacturing rights," and "co-rights" in determining whether the rights transferred with regard to a patent or part of a patent in the pharmaceutical industry constitute a potentially reportable asset acquisition under the HSR Act.

- Commercially Significant Rights: The final rule codifies the FTC's current treatment of transactions within the pharmaceutical industry involving the transfer of "all commercially significant rights." These rights are defined as 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). However, all commercially significant rights are deemed transferred even if the patent holder retains "limited manufacturing rights" or "co-rights."
- Limited Manufacturing Rights: In certain licensing arrangements, the patent holder retains the right to manufacture while the licensee acquires the exclusive rights to use and sell under a patent (i.e., the licensor retains the right to manufacture exclusively for the licensee). These transactions historically have been treated as non-reportable distribution agreements as opposed to potentially reportable asset acquisitions. The final rule treats these types of exclusive arrangements as the potentially reportable transfer of "all commercially significant rights"—this is a significant departure from the FTC's current practice.
- Co-Rights: In some exclusive licensing arrangements, the licensor retains "co-rights," often in order to facilitate co-development and co-marketing efforts. The final rules codify the FTC's current practice to treat the licensor's retention of these co-rights as not rendering the license non-exclusive. Thus, such licensing arrangements remain potentially reportable under the HSR Act.

Going forward

The final rules reflect the FTC's view that, in the pharmaceutical industry, the right to commercialize often is more important than the right to manufacture. If the patent holder is restricted to manufacture the product exclusively for the licensee, then the FTC will treat the arrangement the same as the patent holder giving the licensee the exclusive rights to make, use and sell the product

covered by the patent. Accordingly, the patent holder's retention of limited manufacturing rights no longer will result in a non-reportable transaction.

The final rules also will codify the FTC's informal position that the retention of co-rights to assist in developing and commercializing the product covered by the patent does not render a license non-exclusive, and thus the retention of such co-rights may still result in a reportable transaction.

The practical effect of these changes is that more transactions in the pharmaceutical industry will be reportable transactions. The FTC has estimated an increase of approximately 30 transactions per year.

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Please feel free to contact the following attorneys if you have any questions about this alert.

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