FTC Issues Final Rule Expanding Hart-Scott-Rodino Act Reporting Obligations for the Transfer of Pharmaceutical Patent Rights

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The Federal Trade Commission ("FTC") has finalized amendments to the premerger notification rules under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Act") expanding and to some extent clarifying the reporting requirements for the transfer of rights involving pharmaceutical patents. The final rule will become effective 30 days after publication in the Federal Register, which will likely happen within the next day or so.

The HSR Act requires filings to be made with the FTC and the U.S. Department of Justice for certain mergers and acquisitions of assets, voting securities, and non-corporate interests that exceed specified monetary thresholds (currently $70.9 million), including certain patents and patent licenses.

The outright sale of a patent has been and continues to be a type of asset transfer that can trigger HSR filing obligations. However, under FTC Premerger Notification Office ("PNO") informal opinions, the transfer of patent rights through a license has only been considered a potentially HSR reportable asset acquisition if the license is exclusive even as to the licensor and the licensee rights include the exclusive rights to "make, use and sell" a patented device or drug. The PNO view has been that without the exclusive right to manufacture, a patent license is akin to a distribution agreement, which has long been held by the PNO to be a non-reportable asset transfer.

According to the FTC, in recent years the "make, use and sell" approach has become an inadequate approach for evaluating HSR reportability in the pharmaceutical industry for two reasons. First, a licensor will sometimes retain limited rights to manufacture under the license agreement exclusively for the licensee. In such a case, application of the "make, use and sell" approach would result in a conclusion that the asset transfer is non-reportable, yet according to the FTC the license has transferred the exclusive rights to use a patent for commercial purposes. Second, it is now more common for licensors to retain certain rights to co-develop, co-promote, co-market and co-commercialize the product along with the licensee (so-called "co-rights"), which has also raised questions about the adequacy of the "make, use and sell" approach. Although the PNO has taken the view that retention of co-rights does not render a patent license non-exclusive and thus non-reportable, there has been confusion and frequent requests for guidance from the PNO as to reportability of licenses involving co-rights.

Under the new rule, the licensing of a pharmaceutical patent right will be considered a potentially reportable HSR asset transfer as long as the licensor transfers "all commercially significant rights" to a patent or part of a patent, even if the licensor retains certain limited

rights. The rule defines "all commercially significant rights" 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 for a specific indication within a therapeutic area)."

The new rule will now require HSR reporting for the exclusive licensing of certain pharmaceutical patents where the licensor retains the right to manufacture only for the licensee. However, if the licensor retains broader manufacturing rights, such as the right to manufacture for others, the transaction will not be reportable.

The new rule also codifies the PNO's informal position that the retention of co-rights does not render a license agreement non-reportable. Thus, rights retained by a licensor to support development, sales and marketing of products and thereby enhance its own royalty stream will not in themselves change the conclusion that the licensee has acquired the exclusive right to commercially use a patent. However, in the case of a co-exclusive license, the final rule makes clear that no exclusivity exists and thus the agreement would not be reportable.

The applicability of the new rule to specific license agreements is certain to raise issues of interpretation relating in particular to the boundaries of "all commercially significant rights" and "co-rights," and the PNO will no doubt be required to further clarify HSR reporting obligations through its traditional informal interpretation process.

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