

CLIENT ALERT

FTC Finalizes New HSR Rules for Transfer of Pharmaceutical Industry Patent Rights

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On November 6, 2013, the FTC issued final HSR rules clarifying when a transfer of rights to a patent, or part of a patent, in the pharmaceutical industry may be reportable under the HSR Act.

The FTC has long considered the acquisition of certain exclusive patent rights to constitute the acquisition of an asset, potentially subject to premerger notification. Historically, the FTC applied a "make, use and sell" test, *i.e.*, if the acquired patent rights provided the exclusive right to make, use and sell the patented drug – to the exclusion of all others – the transaction was potentially reportable. But the FTC recently determined that the "make, use and sell" test no longer fits the evolving structure of exclusive patent license transfers.

The new rules replace the "make, use and sell" test previously used by the FTC with a test that asks whether "all commercially significant rights to a patent . . . are transferred to another entity." If so, the transfer constitutes an asset acquisition, even if the patent holder retains limited manufacturing rights or co-rights. The new rules define "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 specific indication within a therapeutic area)." The new rules also explicitly define the terms "limited manufacturing rights" and "co-rights," further focusing the analysis on whether the licensee has the exclusive right to commercially use the patent or part of the patent, not on the kind, magnitude, or scope of rights retained by the licensor.

While the new rules expressly limit the "all commercially significant rights" test to patents covering products relating to the pharmaceutical industry, the FTC's rulemaking implies that a similar analysis could be used for assessing the reportability of exclusive licenses in other industries, even if such analysis is not formally codified in the Premerger Notification Rules.

The final amendments go into effect on December 16, 2013.

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