KIRKLAND **ALERT**

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FTC's Proposed Modifications to HSR Act Rules Will Affect Pharmaceutical Industry Licensing Transactions

On Monday, August 13, 2012, the Federal Trade Commission ("FTC") proposed amending the premerger notification rules to require firms operating in the pharmaceutical industry to comply with the Hart-Scott-Rodino Antitrust Improvements Act ("Act") when transferring "all commercially significant rights" to a patent. (Of course, the HSR Act's jurisdictional tests must also be met.) The proposed 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 specific indication within a therapeutic area)." Under the proposed amendments, a transaction in which a pharmaceutical patent owner grants exclusive marketing and sales rights to a third party, but retains the right to manufacture product under the patent exclusively for such third party, will be treated as the transfer of an asset potentially reportable under HSR.

Under the current Premerger Notification Office ("PNO") approach, when the grantor of an exclusive license to patent rights retains the right to manufacture the underlying product, the grant of "use and sell" rights is considered a distribution agreement; the entry into a distribution agreement is not an acquisition of an asset and is not subject to the reporting requirements of the Act.

The proposed rule modifies the long-standing PNO position in two respects. First, it limits, but does not eliminate, the relevance of manufacturing rights in determining whether the grant of an exclusive license is an HSR reportable transaction. The proposed modifications make clear that "all commercially significant rights" are transferred even if the patent holder retains some manufacturing rights — specifically, the right to manufacture so as to provide only the recipient of the patent rights with product(s) covered by the patent. Second, the new rule would apply only to the transfer of patents that cover products whose manufacture and sale would generate revenues in NAICS Industry Group 3254 (Pharmaceutical and Medicine Manufacturing).

This rule change reflects the FTC's view that in the pharmaceutical industry, the right to commercialize often is more important than the right to manufacture. If the licensor is restricted to manufacturing product exclusively for the licensee, the FTC considers this arrangement to be substantively the same as the licensor giving the licensee the exclusive rights to manufacture, use and sell the product(s) covered by the patent.

The proposed rule also will incorporate into the HSR rules the existing informal position of the PNO that the retention of co-rights — the patent holder's retention of the right to assist the recipient of exclusive patent rights in developing and commercializing the product covered by the patent — is not a limitation on exclusivity, and thus the retention of such co-rights does not defeat application of the HSR Act.

The FTC expects that the proposed rule, if adopted, will result in a small number of additional HSR filings. Nonetheless, if the proposed changes are adopted, biotech and pharmaceutical companies will need to review carefully their proposed licensing and marketing arrangements to assure compliance with HSR requirements prior to entering into such arrangements. The FTC has asked for comments on the proposed rule; comments are due on or before October 25, 2012.

Information regarding the proposed FTC rule can be found at http://ftc.gov/opa/2012/08/hsr.shtm.

If you have any questions about the matters addressed in this *Kirkland Alert*, please contact the following Kirkland authors or your regular Kirkland contact.

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