KIRKLAND **ALERT**

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FTC Finalizes Amendments to HSR Act to Expand Reporting Requirements for Pharmaceutical Patent Licenses

The Federal Trade Commission ("FTC") has finalized proposed amendments to the premerger notification rules that will require firms operating in the pharmaceutical industry to comply with the Hart-Scott-Rodino Antitrust Improvements Act ("Act") when transferring or licensing "all commercially significant rights" to a patent. (Of course, the HSR Act's jurisdictional tests[1] must also be met.)

Under the new rules, transfers of "all commercially significant rights" to a pharmaceutical patent are potentially reportable under HSR.

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)." Under the new rules, for example, 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 prior Premerger Notification Office ("PNO") approach, when the grantor of an exclusive license to patent rights retained the right to manufacture the underlying product, the grant of "use and sell" rights was 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 new test 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. Under the new test, "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 test applies only to patents that cover products whose manufacture and sale would generate revenues in NAICS Industry Group 3254 (Pharmaceutical and Medicine Manufacturing). Although the new test is limited to the pharmaceutical industry, exclusive patent licensing transactions in other industries also potentially may trigger HSR reporting.

The new 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 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 new test also incorporates 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 new rules will result in a small number of additional HSR filings. Nonetheless, pharmaceutical companies will need to review carefully their proposed licensing arrangements to assure compliance with HSR requirements prior to entering into such arrangements. Consequently, the new rules will result in companies investing additional time and energy to determine whether their licensing arrangements require HSR reporting. The new rules will become effective thirty days after publication in the Federal Register, which publication is likely during the week of November 11, 2013.

Information regarding the new FTC rules can be found at http://ftc.gov/opa/2013/11/pmn.shtm.

Pharmaceutical companies will need to review carefully their proposed licensing arrangements to assure compliance with HSR.

1 Under the current thresholds, and subject to certain exemptions, HSR forms must be filed when, as a result of an acquisition, the buyer will hold assets, voting securities, and/or non-corporate interests valued in excess of $70.9 million and the transaction involves parties with annual net sales or total assets valued at $14.2 million or more and $141.8 million or more, respectively. If the value of the assets, voting securities, and/or non-corporate interests to be held after the acquisition will exceed $283.6 million, then — again, subject to certain exemptions — HSR forms must be submitted regardless of the size of the parties.

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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