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CLIENT MEMORANDUM

# FTC Amends HSR Rules to Clarify Treatment of Exclusive Patent Licenses

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AUTHOR

**Jonathan J. Konoff**

The Federal Trade Commission released new rules that codify, and in some ways expand, the circumstances under which entry into an exclusive patent license (or other arrangement that transfers patent rights[1]) will be treated as an "acquisition" that is potentially reportable under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. The new rules, effective for all transactions that would close on or after December 16, 2013, provide that any pharmaceutical patent license that transfers to the licensee "all commercially significant rights to a patent for any therapeutic area (or specific indication within a therapeutic area)" is a transaction that may be covered by the HSR Act.

Notably, and in a significant departure from prior policy, a transfer of "all commercially significant rights" may arise even where the patent owner retains limited manufacturing rights. Further, consistent with prior policy, the owner's retention of "co-rights" relating to the development and commercialization of the product(s) covered by the patent does not render the license non-exclusive. In the eyes of the FTC, neither limited manufacturing rights nor certain co-rights impair the ability of the licensee solely to "commercially use" the patent to the exclusion of all others.

[1] The new rules do not use the term, "license," and apply equally to all forms of transfers of patent rights. For ease of reference, this memorandum characterizes all such arrangements as licenses, and utilizes associated terminology.

The FTC believes that the new, broader definition of a reportable license arrangement addresses "the evolving structure of exclusive patent licenses in the pharmaceutical industry," where an increasing number of licenses have been structured in a way that avoids a filing obligation under the HSR Act. The FTC further believes that the "all commercially significant rights" test more aptly covers those licensing arrangements that merit pre-closing review than the previously used "make, use, and sell" test, described below. The FTC's public announcement of the new rules can be accessed via http://www.ftc.gov/opa/2013/11/pmn.shtm.

**The Prior "Make, Use, and Sell" Policy**

Until the adoption of these rules, the application of the HSR Act to patent licensing was the result of an unwritten, though well understood, policy buttressed by informal interpretations. Under the prior policy, notification under the HSR Act, and observance of the requisite waiting period, was potentially implicated only where the patent owner transferred all "make, use, and sell" rights on an exclusive basis to the licensee, even as against the grantor. Treatment of that type of license as an "asset acquisition," and therefore subject to jurisdiction of the HSR Act, was deemed warranted, as such a license is substantially identical to a sale, as it relates to the specific therapeutic area, or indication therein. Where the "value" of the license, as determined under HSR-specific valuation rules, based on anticipated license payments, exceeded the minimum notification threshold, a fileable event may have arisen. Indeed, such licenses have been typically reported under the HSR Act since the early 1980s.

Importantly, anything short of the exclusive license of the full panoply of "make, use, and sell" rights rendered the transfer less than an "asset acquisition," and thus, no filing obligation would arise. If a patent owner retained rights to manufacture the product(s) covered by the patent, but ceded all remaining rights on an exclusive basis to the licensee, the arrangement was viewed as a non-reportable distribution agreement, even if the owner could manufacture solely for the benefit of the licensee.

**The New "All Commercially Significant Rights" Test**

The FTC notes that, in recent years, licenses have "evolved," so that an increasing number of them exclude some element of the "make, use, and sell" triad, typically manufacturing rights. Thus, parties have entered into such licenses without having to comply with the obligations of the HSR Act, even where the licensor retained no ability to commercially use the patent. The FTC also believes that the prior "make, use, and sell" test has allowed far too many developmental companies to transfer all rights necessary to develop and commercialize a pipeline product to a rival who may have been developing a competing product on its own, thereby stifling competition in the development of pharmaceuticals, without pre-closing scrutiny. The FTC adopted the new rules to address these concerns.

Under the new rules, the FTC does not view the retention of manufacturing rights over products covered by the patent where all other exclusive rights have been transferred as "commercially significant." Where such limited manufacturing rights are retained, the FTC nevertheless views the licensee as the only party capable of commercially using the patent. Therefore, a reportable event may arise even though the patent owner retains such limited manufacturing rights.

The rule also codifies the previously informal policy that an exclusive license may be potentially reportable, even where the owner retains "co-rights" relating to the marketing or commercialization of the product(s) covered by the patent, such as co-development, co-marketing, co-promotion, and co-commercialization rights. In the FTC's view, these retained co-rights do not include the right to "commercially use" the patent and are generally retained and used by the owner solely in support of the development, sales, and marketing efforts of the licensee - the only party that can "commercially use" the patent. Thus, the FTC will not treat the retention of such co-rights as preventing the transfer of "all commercially significant rights."

While not part of the rules, the Statement of Basis and Purpose accompanying the adoption of the new rules clarifies that "co-exclusive" licenses, under which the owner and licensee share equally in the intellectual property rights, continue to be non-reportable and are distinguishable from co-rights. In such licenses, no "exclusivity" exists.

**Rules Limited to Pharmaceutical Industry**

The FTC has limited the new rules to licenses in the pharmaceutical sector, principally because that industry has historically generated virtually all reportable license transactions. The FTC has observed that the pharmaceutical industry "presents unique incentives for the use of exclusive licenses," as innovators often lack the necessary resources fully to develop and exploit a patented compound. Thus, the pharmaceutical industry is particularly well suited to deep-pocketed licensees who have the financial wherewithal to marshal the developmental process to hoped-for fruition, but typically demand "exclusivity" in light of the risk associated with developing a new compound the success of which is uncertain. To the extent the FTC observes significant exclusive licensing arrangements in other sectors, the FTC said that it will consider whether a similar rule is warranted for those other industries.

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If you have any questions about the new rules, or the HSR Act generally, please contact Jonathan J. Konoff (212-728-8627, jkonoff@willkie.com) or the Willkie attorney with whom you regularly work.

Willkie Farr & Gallagher LLP is an international law firm with offices in New York, Washington, Paris, London, Milan, Rome, Frankfurt and Brussels. The firm is headquartered at 787 Seventh Avenue, New York, NY 10019-6099. Our telephone number is (212) 728-8000 and our facsimile number is (212) 728-8111. Our website is located at www.willkie.com.

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