CLIENT UPDATE

FTC EXPANDS SCOPE OF REPORTABLE PHARMA PATENT LICENSES UNDER THE HART-SCOTT-RODINO ACT

NEW YORK
Daniel M. Abuhoff
dmabuhoff@debevoise.com

Kyra K. Bromley
kkbromley@debevoise.com

Gary W. Kubek
gwkubek@debevoise.com

Michael Schaper
mschaper@debevoise.com

The Federal Trade Commission has announced revisions to the rules implementing the Hart-Scott-Rodino ("HSR") Act that clarify and expand somewhat the types of patent licenses in the pharmaceutical industry for which a filing must be made before such licenses may become effective. The revised rules require a filing for a license that gives the licensee "all commercially significant rights," defined as the exclusive right "to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)," even if the licensor retains (i) the right to manufacture the product(s) covered by the patent solely for the licensee, and/or (ii) "co-rights" to assist the licensee in developing and commercializing the products covered by the patent. The FTC describes the co-rights provision as merely codifying its existing application of the HSR Rules, but it acknowledges that the inclusion of licenses in which the licensor retains the right to manufacture exclusively for the licensee is an expansion of the existing filing requirements.

The HSR Act requires parties to certain acquisitions of voting securities, non-corporate interests and assets to submit a filing to the FTC and the Department of Justice, and observe a waiting period (generally 30 days, unless terminated early or extended by the agencies), before consummating the reported transaction. An acquisition of a patent is clearly a potentially reportable transaction (if it satisfies certain size criteria), but the FTC has also required a filing for a patent license that gives the licensee the right to use the

patent commercially to the exclusion of all others, including the licensor, either for all uses or in a specific use or geographic area, because it has the same effect on competition as an outright acquisition of the patent.[1] The exclusivity test was often described as the exclusive right to "make, use and sell" a product under the patent.

In recent years, however, the FTC has noted the increased use of licenses that allow the licensor to manufacture a product under the patent solely for the licensee and/or to co-develop, co-promote, co-market and co-commercialize the product with the licensee. Because such licenses give the licensee the sole right to "commercially use the patent" to generate revenue from customers, the FTC views them as raising the same risks of anticompetitive effects as an exclusive license that lacks such provisions. The FTC thus proposed, and has now adopted, rules requiring that such a license be treated as an acquisition of an asset subject to the HSR filing requirements.

The FTC rejected a comment opposing the proposed rule submitted by the Pharmaceutical Research and Manufacturers of America, which objected to adoption of a rule focused on a single industry. The FTC noted, based on filings and requests for advice over the last five years, that "exclusive patent licensing agreements that transfer all of the rights to commercially use a patent or part of a patent almost solely occur in the pharmaceutical industry."[2]

As noted, the FTC stated that the new rule constitutes an expansion of its existing application of the HSR Act and Rules only insofar as it now includes licenses allowing the licensor to manufacture solely for the licensee. However, the "co-rights" provision also clarifies the application of the Act and the Rules and may result in additional filings. The FTC anticipates that the new rule will result in filings for about 30 additional transactions annually, a substantial increase over the recent level of approximately 13 filings annually for exclusive licenses (66 over the last five years).

---

1 Exclusive patent licenses, like all potentially reportable transactions, are subject to filing only if the value of the acquired license exceeds $70.9 million (a threshold that is revised annually to reflect changes in GNP) and if other exemptions are not applicable. The determination of whether a filing is required for a particular license thus raises a number of issues, including the method of valuing the license, that are beyond the scope of this memorandum.

2 All 66 HSR filings for exclusive patent licenses during 2008-12 were for pharmaceutical patents. The FTC distinguished exclusive patent licenses from exclusive distribution agreements, common in many other industries, which convey only the right to distribute the patented product.

The new rule will become effective for transactions closing thirty days after it is published in the Federal Register, which should occur shortly.

* * *

Please do not hesitate to contact us with any questions.

November 8, 2013