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Federal Trade Commission Enacts Changes to Reporting Requirements under the HSR Act for the Transfer of Exclusive Patent Licenses in the Pharmaceutical Industry

The U.S. Federal Trade Commission (FTC), with the concurrence of the Assistant Attorney General, Antitrust Division, Department of Justice (Antitrust Division) has amended the Premerger Notification Rules (Rules) promulgated under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR Act) that apply to proposed acquisitions of exclusive patent rights by companies in the pharmaceutical industry. The amendments are due to become effective 30 days after publication in the Federal Register.

The HSR Act and Rules require companies proposing to acquire voting securities, non-corporate interests or assets above certain thresholds to notify the FTC and the Antitrust Division and wait a specified period of time before closing. The HSR Act permits the FTC and Antitrust Division to review such transactions to determine whether they may violate the antitrust laws if consummated.

The amendments to the Rules apply to the transfer of patent rights in the pharmaceutical and medicine manufacturing industry, including biologics. Previously, the acquisition of a patent license was potentially reportable as an asset acquisition only where the license covered all three exclusive rights to "make, use and sell" the product covered by the patent for a specified geographic area or field of use. Under the amended Rules, the reportability of the transfer of a patent license is no longer based on strict exclusivity to make, use and sell a product covered by the patent, but on a newly-defined concept of "all commercially significant rights."

A grantor will have been deemed to have transferred "all commercially significant rights" to a license in the pharmaceutical industry even where the patent holder retains "limited manufacturing rights" – that is, the right to manufacture the product for the licensee – provided that the other exclusive rights to the patent within a specific therapeutic area or indication have been transferred. Previously, the license was not deemed to be exclusive if the grantor retained any rights to manufacture the product and thus, no potentially reportable asset acquisition occurred. The amended Rules also make clear that all commercially significant rights will be deemed transferred where the grantor retains "co-rights" to assist the licensee in developing and commercializing the product covered by the patent. It is the long standing position of the FTC's Premerger Notification Office (PNO) that the retention of co-rights by the grantor does not serve to make a license non-exclusive, so this amendment simply codifies a long standing interpretation.

The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group to which many major pharmaceutical companies belong, strongly objected to the

Contacts

Timothy Cornell
Counsel
T: +1 202 912 5220
E: timothy.cornell
@cliffordchance.com

Elizabeth Chen
Associate
T: +1 202 912 5028
E: elizabeth.chen
@cliffordchance.com

proposed changes on the basis that a specific industry should not be singled out for increased burdens under the HSR Act and Rules. The FTC responded that it was appropriate to enact changes solely for the pharmaceutical industry because in its experience, such types of exclusive patent license agreements that transfer all commercially significant rights occur primarily in this industry, and have not been seen by the PNO in other industries. Such types of licenses are becoming increasingly common, and the new test of "all commercially significant rights" more closely approximates the meaningful test for competition purposes – namely, whether the license has transferred the exclusive right to commercially use a patent, or part of a patent.

The FTC cautioned that while the amended Rules apply solely to the pharmaceutical industry, other industries that engage in similar exclusive patent right transfers should consult with the PNO to determine whether notification under the HSR Act and Rules is required. Further, the FTC stated that it will "continue to assess the appropriateness of a rule for other industries."

The amendments to the Rules were approved by the Commission by a 4-0 vote.

Clifford Chance, 31 West 52nd Street, New York, NY 10019-6131, USA