

FTC Finalizes Amendments to the Premerger Notification Rules Related to the Transfer of Exclusive Patent Rights in the Pharmaceutical Industry

Amendments Expand the Scope of Exclusive Rights Transfers that May Be Reportable

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The Federal Trade Commission (“**FTC**”) has [finalized amendments](#) to the Hart-Scott-Rodino (“**HSR**”) Premerger Notification Rules (the “**Rules**”) aimed at clarifying – and effectively expanding – the scope of transactions involving the transfer of rights to a patent in the pharmaceutical, biologics, and medicine manufacturing industries that may be subject to the notification and waiting period requirements of the HSR Act. The amendments *do not* alter the scope of transactions potentially reportable under the HSR Act in any other industry, including technology industries. Parties dealing with exclusive patent rights transfers in other industries should consult the Premerger Notification Office of the FTC (the “**PNO**”) on a case-by-case basis. These amendments were originally [published in a notice of proposed rulemaking](#) in August 2012, with public comments to the proposed Rules accepted until October 25, 2012. The final rulemaking notice was issued on November 6, 2013 and will be effective 30 days after the date of publication in the Federal Register, which should occur this week.

The HSR Act requires parties to mergers and acquisitions of assets and/or voting securities that exceed certain jurisdictional thresholds to make filings with the FTC and Department of Justice, Antitrust Division (“**DOJ**”) and to observe a waiting period before closing, during which the antitrust agencies may conduct an initial review of a transaction. While patents have always been viewed as “assets,” it previously had not always been clear when an exclusive patent license qualified as an acquisition of an asset for HSR filing purposes.

The PNO historically analyzed intellectual property transactions of this type by focusing on whether the exclusive rights to “make, use and sell” under a patent were being transferred. Only when the full bundle of rights was transferred did the PNO view the transaction as a transfer of an “asset” potentially reportable under the HSR Act. Specifically, if a licensor retained the right to manufacture a product or compound, even if exclusively for the licensee, the PNO viewed the transaction as akin to a non-reportable distribution agreement rather than an asset acquisition.

The final amendments to the Rules specifically change this view and require reporting under the HSR Act of exclusive patent rights transfers, even when the licensor retains certain manufacturing and/or co-development, co-promotion, and co-marketing rights. The amendments are summarized below.

Concept of “All Commercially Significant Rights”

As finalized, the transfer of patent rights will constitute an asset acquisition potentially reportable under the HSR Act if “all commercially significant rights” to a patent “for any therapeutic area (or specific indication within a therapeutic area)” are transferred. The term “all commercially significant rights” is defined in the amended Rules 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).”

As the Rule explains, “[a] therapeutic area covers the intended use of a patent, such as for cardiovascular or neurological use, and includes all indications.” An indication covers a segment of a therapeutic area;

the FTC's final Rule provides the example of Alzheimer's disease falling within the neurological therapeutic area.

The transfer of "all commercially significant rights" to a patent is now a potentially reportable event regardless of whether the transfer is called an exclusive license, assignment, or something else.

Limited Rights Retained by Patent Holder

The amendments make clear that "all commercially significant rights" are transferred even when the patent holder retains what is further defined as "limited manufacturing rights" and/or "co-rights."

The term "limited manufacturing rights" means rights retained by the patent holder to manufacture the product(s) covered by a patent when all other exclusive rights have been transferred, and "solely to provide the recipient of the patent rights with product(s) covered by the patent."

Therefore, the amendments treat as a potentially reportable asset acquisition the grant of an exclusive license to use and sell a product where the licensor retains the right to manufacture exclusively for the licensee. The published examples to the amended Rules also clarify that a transaction may still be reportable even if a licensor retains the right to manufacture the same licensed compound or product for use by a third party in a different therapeutic area. If a licensor agrees to manufacture solely for the use of the licensee within the particular therapeutic area (or specific indication within a therapeutic area) which is the scope of the license, this agreement would be viewed as substantively the same as an agreement giving the licensee the exclusive right to manufacture, use, and sell the product(s) covered by the license.

Similarly, a transfer of patent rights may be reportable even when the patent holder retains other "co-rights," either alone or in combination with "limited manufacturing rights." "Co-rights" include "co-development, co-promotion, co-marketing, and co-commercialization." Specifically, the Statement of Basis and Purpose of the final amendments contemplates "co-commercialization" to cover situations where the licensor "retains co-rights to assist the licensee in maximizing its sales of the licensed product" but where "all sales are typically booked by the licensee." Under existing PNO policy, the retention of these rights does not alone render a license non-exclusive, as long as the co-rights do not give the licensor the right to commercially use the patent. As such, the portion of the amendments defining co-rights and stating their effect on HSR reporting obligations is a codification of the PNO's current approach.

Exclusive distribution agreements, under which a party receives no exclusive patent rights and is only handling the logistics of distributing an approved pharmaceutical product, are still not reportable under the HSR Act.

Effect of the Amendments

According to the FTC, the final amendments aim to both clarify for the business community the analysis of whether or not a transfer of patent rights in the pharmaceutical industry is HSR reportable and provide the FTC and the DOJ a better opportunity to review such transactions for competitive concerns. The FTC estimates that the amendments will result in approximately 30 new HSR filings per year.

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