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Federal Trade Commission (FTC) Amendments to Premerger Notification Rules: The Who, What & Why

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On November 6, 2013, the **Federal Trade Commission** released final amendments to the Hart-Scott-Rodino Premerger Notification Rules to clarify when a transaction involving the transfer of rights to all or part of a pharmaceutical (including biologics) patent is reportable under the **Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act").**

The final rule, which is the same as the proposed rule circulated a year ago for public comment, codifies an "all commercially significant rights" test to determine whether a transfer of rights has occurred in an exclusive patent license agreement. Under that rule, if a patent licensor transfers all commercially significant rights to the patent, the transaction may be reportable. The final rule states that if "limited manufacturing rights" are retained by the licensor, then the transaction may also be reportable under the Act.

The final rule, which takes effect on December 16, 2013, is available here**.**

Patent Transfer Reporting Requirements and Reasons for Changes

The HSR Act requires the reporting of acquisitions of voting securities, controlling non-corporate interests, and assets to the Premerger Notification Office (PNO) to determine whether the transaction at issue will violate antitrust rules.*

Patents are considered assets under the Act, and acquiring a patent gives the buyer the exclusive right to use a patent without restriction. Prior to the issued amendments, the PNO followed a "make, use and sell" approach, whereby only agreements that gave an acquiring party the rights to use a patent or part of a patent to exclusively develop, manufacture, and sell a product were required to be reported.

However, the FTC explained that since the adoption of the "make, use and sell" approach, exclusive license agreements in the pharmaceutical industry have evolved to allow the licensee the right to use commercially all or part of a patent to the exclusion of all others, thus having an anticompetitive effect.

Certain patent transfer agreements, for example, allow the licensor to retain "limited manufacturing

rights" when the licensor manufactures the product exclusively for the licensee. Other agreements permit the retention of "co-rights." The FTC determined that these agreements were the same as buying the patent or part of the patent outright, carrying with them the same potential for anticompetitive effects. As such, the FTC considered the "make, use and sell" approach an inadequate way to evaluate whether such license agreements are reportable.

Summary of the New HSR Requirements

In light of the retention of "limited manufacturing rights" and "co-rights" in patent licensing agreements, the FTC revised the Act to adopt an "all commercially significant rights" test to clarify that an asset acquisition occurs when all commercially significant rights to a patent or part of a patent have been transferred, even if the licensor retains "limited manufacturing rights" or "co-rights" as defined by the Act.

1. "All Commercially Significant Rights" Test

16 C.F.R. §§ 801.1 and 801.2 were amended to adopt the "all commercially significant rights" test under the Act to determine whether a reportable asset transaction has occurred. The FTC stated in its adoption of the proposed rule that "[t]he 'all commercially significant rights' test in the rule captures more completely what the 'make, use, and sell' approach was a proxy for, namely*whether the license has transferred the exclusive right to commercially use a patent or part of a patent*." (emphasis added). An asset acquisition is reportable if "all commercially significant rights" to a patent, as defined in Section 801.1(o), are transferred to another entity.

16 C.F.R. § 801.1(o) defines "all commercially significant rights" to mean 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 a specific indication within a therapeutic area)." This section codifies the new approach to be used by the PNO in determining whether a particular transaction results in a transfer of assets.

The rule now makes it clear in 16 C.F.R. § 801.2(g) that when a licensee is granted all commercially significant rights to use a patent in a particular therapeutic area, a transfer of assets has occurred, which may be reportable under the Act.

2. "Limited Manufacturing Rights"

This is so even if the licensor retains "limited manufacturing rights," which are defined in 16 C.F.R. § 801.1(p). "Limited manufacturing rights" are those rights retained by the patent holder to manufacture the product exclusively for a licensee who has received all other exclusive rights within a particular therapeutic area. This agreement is viewed as a transfer of assets because the "limited" right retained by the licensor is exclusively for the benefit of the licensee.

3. "Co-Rights"

Likewise, if a licensor retains "co-rights" in a particular agreement, then a transfer of assets might have occurred. "Co-rights" are defined in 16 C.F.R. § 801.1(q) as "shared rights maintained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent." A transfer of assets has occurred where the co-rights retained by the licensor are to assist the licensee in maximizing the sales of the licensed product. The retention of co-rights is different from a co-exclusive license, in which both the licensor and licensee

have the right to commercially use all or part of a patent because “no exclusivity exists and the agreement would not be reportable.”

Application to Pharmaceutical Industry

1. PhRMA Comments Relating to Burden on Pharmaceutical Industry

On October 25, 2012, the Pharmaceutical Research and Manufacturers of America (PhRMA) submitted comments to the proposed rule challenging the FTC’s rule-making authority under the HSR Act to adopt a rule strictly limited to the pharmaceutical industry.

An attorney for PhRMA stated that “Congress nowhere granted the FTC authority to increase the HSR Act’s reporting burden only for a single industry, but instead limited the FTC’s power to differentiate between industries solely by granting exemptions from the Act to those ‘classes of persons’ who ‘are not likely to violate the antitrust rules.’”

PhRMA highlighted the commonality of exclusive license agreements in other industries and emphasized the financial impact the amendment will have solely on the pharmaceutical industry, explaining that “the proposed HSR rule amendments each year would be forced to expend between $1,350,000 to $8,400,000.”

The comment is available here.

2. FTC Response

Despite these arguments, the FTC, in its final rule, cited its industry-specific rulemaking authority, stating that “the Commission has broad authority to issue rules to facilitate the review of large transactions. Nothing in the HSR Act prevents the Commission from issuing such rules on an industry specific basis.” As further support for applying the new amendment solely to the pharmaceutical industry, the FTC reported that “[f]or the five-year period ending December 31, 2012, the PNO received filings for 66 transactions involving exclusive patent licenses, and all were for pharmaceutical patents.”

The Commission also disagreed with PhRMA’s cost estimation, claiming that in the PNO’s experience, PhRMA’s letter “substantially overestimates the costs of preparing an HSR filing.”

To address PhRMA’s argument that similar agreements occur in other industries, the FTC stated that if similar arrangements arise in other industries, the agencies can then assess whether a like rule will be appropriate. In the absence of a specific rule, similar exclusive licenses may be reportable and parties to transactions are advised to consult the PNO for guidance if such agreements are made.

The FTC further explained that, for the most part, the new rule treats the reportability of license agreements the same way the PNO has treated them for years. Specifically, the rule codifies the PNO’s position that the retention of co-rights does not make the patent license non-exclusive. Whether an asset acquisition occurs depends on whether the exclusive patent license allows only the licensee to commercially use all or part of a patent, not on the kind or scope of the co-right retained.

The exception under the new rule relates to when a licensor retains limited manufacturing rights, which was once viewed as a non-transfer of assets under the “make, use, and sell” approach. Now,

the retention of limited manufacturing rights is reportable under the Act.

Amendments Effective on December 16, 2013.

These adopted amendments will be effective **December 16, 2013**, thirty (30) days after they were published in the Federal Register, on November 15, 2013.

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* Once a company seeks to engage in an asset transfer that is reportable under the Act, it must notify the Commission and allow for a waiting period (usually 30 days) before consummating the transaction. The parties also must submit a filing fee, which ranges from $45,000 to $280,000 depending on the size of the transaction. The consequences of non-compliance can be financially significant, for 15 U.S.C. § 18(a)(g)(1) imposes civil penalties of up to $10,000 for each day a person is in violation of the Act.

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