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Hart-Scott-Rodino Act Rules Expand For Pharmaceutical Licensing Agreements

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Rules from the Federal Trade Commission include new requirements for reporting pharmaceutical patent transfers.

On November 6, the **Federal Trade Commission (FTC)** released finalized amendments to the premerger notification rules (the Rule), which clarify when the transfer of pharmaceutical (including biological) patent rights is reportable to the FTC as an asset sale under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR Act).[1] The finalized Rule did not alter the proposed Rule, which was initially released by the FTC for public comment in August 2012. As a result of the rule change, any transfer of exclusive pharmaceutical patent rights is potentially reportable under the HSR Act, even when the patent owner retains certain manufacturing rights or certain "co-rights"—generally rights to co-develop or co-market the pharmaceutical product.

The Rule will go into effect 30 days after its publication in the *Federal Register*, which should be imminent. Deals that are expected to close following the effective date and that are reportable under the Rule will require HSR Act approval prior to closing.

The Rule at a Glance

Under the Rule, a license or other transfer of pharmaceutical patent rights will be potentially reportable under the HSR Act if the patent owner transfers all "commercially significant rights" to a patent, meaning the transfer of exclusive patent rights to the licensee or transferee where only the licensee or transferee is allowed to use the patent in a particular therapeutic area (e.g., neurological use) or specific indication within a therapeutic area (e.g., Alzheimer's disease within the neurological therapeutic area). This transfer will be potentially reportable even if (i) either the patent owner alone or both the patent owner and licensee/transferee have the right to manufacture the product covered by the patent being transferred solely for the transferee/licensee or (ii) the patent owner retains "co-rights" to develop and commercialize the product covered under the patent (e.g., through co-development and co-commercialization agreements).

For such arrangements to be deemed reportable, however, the proposed transaction would still need

to meet the size-of-person and size-of-transaction thresholds established by the HSR Act. Early-stage pharmaceutical collaboration arrangements often are not reportable under the HSR Act because one party fails to meet the $14.2 million (adjusted annually) size-of-person test or because the fair market value of the license at issue does not exceed the above $70.9 million (adjusted annually) size-of-transaction test. (There are complex rules regarding valuing payments contemplated by such collaborations, but often many of the later-stage milestone payments—e.g., payments triggered by advancing to a new stage in the Food and Drug Administration process, filing the new drug application, or payments of commercial royalties—can be discounted to zero due to the uncertainty of the milestone ever being reached.)

FTC Objectives

The FTC's objectives in enacting the Rule were threefold: (i) the Rule closes a perceived HSR Act loophole that previously applied when a licensor/transferor retained manufacturing rights; (ii) the Rule facilitates the FTC's HSR Act preclosing review of developmental-stage pharmaceutical product collaborations that may involve potential competitors; and (iii) the Rule simplifies a body of complex Premerger Notification Office (PNO) interpretations surrounding the reportability of pharmaceutical transfer arrangements under the HSR Act.

Previously, under the PNO's informal precedent, pharmaceutical patent transfers were generally exempt from the HSR Act if the patent owner retained the right to manufacture the underlying product, even if solely for sale to the licensee or transferee. The PNO viewed these arrangements as nonreportable distribution agreements rather than potentially reportable asset acquisitions.

The FTC had concerns that pharmaceutical companies engaged in product development could transfer to rivals all commercially significant patent rights to an underlying pipeline product, thereby potentially eliminating possible competition between the parties in the event that the licensee/transferee already owned a competing marketed or pipeline product. Following the PNO's informal guidance, parties could close these transactions without waiting for HSR Act approval simply by having the licensor/transferor retain manufacturing rights to the underlying product for the licensee/transferee.

Although such transactions are uncommon due to the uncertainty of whether a pipeline product will ever launch as well as the low probability that a licensee already has a directly competing pipeline or marketed product, these transactions do occur and raise substantive antitrust concerns. For example, in June 2013, Questcor Pharmaceuticals, which markets a drug used to treat various immune-related ailments, acquired the exclusive rights to a drug from another pharmaceutical company in the same field. The drug had not yet been marketed in the United States, and the value of the transaction, valued at $135 million, exceeded the HSR Act threshold. The licensor, however, retained the rights to manufacture the rival product, which made the license transfer exempt from the HSR Act. This type of transaction, which some observers suggested might eliminate Questcor's only potential competitive entrant into the United States, was one of the motivations for the FTC's introduction of the new Rule.

Licensor's Retention of "Co-Rights"

The Rule does not change the PNO's long-held position that exclusive patent transfers are potentially reportable even when the transferor/licensor retains certain "co-rights" to co-develop and co-commercialize the exclusively licensed patent. Parties to exclusive license agreements sometimes set forth the terms of each party's participation in the development and commercialization of the

exclusively licensed patent through ancillary co-development and co-commercialization agreements.

The FTC contends that these “co-rights” granted to or retained by a licensor do not render the license nonexclusive for HSR Act purposes. Instead, the “co-rights” merely reflect the licensor’s efforts to support development, sales, and marketing in order to maximize its future royalty stream, and the rights do not change the fact that the licensee/transferee will still acquire the exclusive right to commercially use a patent. Accordingly, the retention of these “co-rights” would still render the transaction HSR Act reportable.

Co-Exclusive License Agreements

The FTC did not explain in the Proposed Rule whether co-exclusive licenses, in which both the licensor and licensee share equally the IP rights in the patent, are still non-HSR Act reportable, as addressed in several PNO informal opinions.[2] Because the licensor in a co-exclusive license agreement would necessarily retain “co-rights” to the patent, practitioners expressed confusion regarding whether co-exclusive licenses would be deemed “co-rights” under the final Rule, making such co-exclusive licenses potentially HSR Act reportable.

In the final Rule’s Statement of Basis and Purpose, the FTC clarified that co-exclusive license grants are not HSR Act reportable and are distinguishable from “co-rights.” The FTC explained that, in an exclusive license arrangement, the licensor grants the licensee rights to a patent (or part of a patent) “to the exclusion of all others, **including the licensor**.” Although the grant of an **exclusive** license is potentially HSR Act reportable even when the licensor retains certain “co-rights” (e.g., through ancillary co-development/commercialization agreements), the grant of a co-exclusive license is not HSR Act reportable.

Examples of HSR Act Applicability

- **Retention of Co-Rights and Limited Manufacturing Rights:**Licensor owns a patent that will be used in a forthcoming product indicated to treat heart disease and brain disease. Licensor grants Licensee an exclusive license to develop and commercialize the patent but only for use in the heart disease therapeutic area. Licensor retains the right to manufacture the forthcoming heart disease product for Licensee only. Licensor and Licensee enter into ancillary co-developmental and co-commercialization agreements, pursuant to which the two parties will share certain developmental and marketing responsibilities for the forthcoming heart disease product. Licensee will book the sales of the biological patent and will pay Licensor royalties.
  HSR Act Applicability Under the Rule: The transaction is potentially HSR Act reportable under the Rule, despite Licensor’s retention of “co-rights,” limited manufacturing rights, and rights to use the patent in other therapeutic areas.

- **Grant of Co-License to Pharmaceutical Patent:** Company A owns the patent rights to Molecule A. Company B owns the patent rights to Molecule B. Company A and Company B seek to collaboratively develop, commercialize, and co-promote certain pharmaceutical products that will use Molecules A and B. To facilitate this collaboration, Company A and Company B will grant each other co-exclusive licenses to the underlying patents to develop and commercialize Molecule A and Molecule B. Each party will pay the other party up-front payments and royalties related to the co-exclusive patent rights.
  HSR Act Applicability Under the Rule: Both currently and under the new Rule, no HSR Act

filing is required because neither party is granting the other party exclusive patent rights.

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[1]. View the final Rule here.

[2]. *See, e.g.*, Informal Opinion 0806009, *available* here.

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