FTC Announces Amendments to HSR Rules Regarding the Transfer of Pharmaceutical Patent Rights

The Federal Trade Commission has announced an amendment to the premerger notification rules under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "Act"), which will require increased reporting of transfers of patent rights in the pharmaceutical industry. The final rule, expected to take effect in December, provides that a transfer of "all commercially significant rights" with respect to a patent will potentially subject parties to the premerger reporting and waiting periods under the Act; this will be the case regardless of whether manufacturing rights are retained by the licensor.

The final rule changes a long-standing but uncodified position of the Premerger Notification Office of the FTC on what constitutes an "exclusive" license, and therefore a potentially reportable asset transfer, under the Act. Prior to the final rule, whether a license was considered to be "exclusive" focused on the conveyance of a bundled right to exclusively use a patent to develop, manufacture and sell a product without restriction. As such, a licensor's retention of limited manufacturing rights typically rendered a license non-exclusive. Under the new rule, however, a license will be deemed to be "exclusive" when *all commercially significant rights* are conveyed, even if *limited manufacturing rights* or *co-rights* are retained by the licensor. The rule provides that an exclusive transfer of rights occurs if a license allows only the licensee to commercially use the patent as a whole or in part in a certain therapeutic area or for a specific indication within a therapeutic area. The rule also addresses the retention of co-rights, which include shared rights by the licensor and the licensee in developing and commercializing the product (including but not limited to co-development, co-promotion, co-marketing and co-commercialization), confirming that such a retention does not render the license non-exclusive.

The rules only impact the reportability of pharmaceutical patent licenses (products whose manufacture and sale would generate revenues in the areas of medical and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing, and biological product manufacturing); all other licenses, including those for medical devices, will be considered on a case-by-case basis.

The FTC identified several examples of situations which would become HSR reportable under the rules, assuming the jurisdictional thresholds of the Act are met, including:

- Where A obtains exclusive right to all of B's patent rights, and B retains limited manufacturing rights for certain ingredients to be sold by A under the agreement.
- Where B grants A an exclusive license of all patents for certain enumerated indications and B retains all patent rights for separate and distinct indications.
- Where B grants A an exclusive license to all of B's patent rights in all therapeutic areas, but A and B also enter into co-development and co-commercialization agreements.
- Where B grants A an exclusive license to use a certain compound in order to manufacture and sell a finished product in a certain therapeutic area, while B retains the right to manufacture the same or similar products in separate and distinct therapeutic areas.

Exclusive arrangements that do not include the transfer of exclusive rights to use a patent or a part thereof, such as an exclusive distribution agreement, are not subject to the rules and will not constitute the acquisition of an asset under the Act.

The new rules, available here, amend sections of 16 C.F.R. §801.1 and §801.2 and will become effective 30 days after the final rule is published in the Federal Register. Publication is expected to occur within the next week.

For additional information regarding this rule change or regarding HSR in general, please feel free to contact any member of Ropes & Gray's Antitrust Practice Group.