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E-ALERT | Antitrust

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FTC ADOPTS NEW RULES CLARIFYING HSR FILING REQUIREMENTS FOR TRANSFERS OF PHARMACEUTICAL PATENT RIGHTS

On November 6, the Federal Trade Commission ("FTC") amended the implementation rules of the Hart Scott Rodino Antitrust Improvements Act (the "HSR Act") to specify when parties to pharmaceutical patent license agreements must observe the HSR Act's notification and pre-closing waiting period requirements. Under the new rules, pharmaceutical patent licenses that transfer "all commercially significant rights to a patent . . . for any therapeutic area (or specific indication within a therapeutic area)" will be considered asset acquisitions reportable under the Act if the notification thresholds are met and no exemption applies. The FTC developed the new rules in conjunction with the Antitrust Division of the Department of Justice. The new rules were presented for public comment in August 2012 and have been adopted as initially proposed.

The amendments, which may be found here, may have a significant impact on pharmaceutical companies by making more licensing deals subject to pre-closing review by the antitrust agencies. Pharmaceutical companies considering such transactions should consult with antitrust counsel to ensure that they comply with these new rules.

BACKGROUND

The HSR Act

Under the HSR Act, parties to transactions that satisfy certain thresholds must file notifications with the U.S. antitrust agencies and observe a waiting period. This gives the antitrust agencies time to investigate the deal's potential effects on competition before the parties close.

There are two notification thresholds, both of which are adjusted early each year based on changes in GNP.

- *Size-of-transaction.* A transaction is potentially reportable if the acquiring person will hold more than $70.9 million worth of the acquired person's voting securities, assets, or non-corporate interests as a result of the acquisition.
- *Size of person.* If the size of the transaction exceeds $70.9 million but not $283.6 million, the transaction is reportable if either of the parties has total assets or annual worldwide net sales of at least $141.8 million and the other has assets or sales of at least $14.2 million. If the size of the transaction exceeds $283.6 million the acquisition is reportable, regardless of the size of the persons involved, if no exemption applies.

The HSR waiting period, during which the acquiring person may not exercise beneficial ownership of the securities or assets it proposes to acquire, is 30 calendar days for most transactions. The waiting period may be terminated early at the agencies' discretion if the parties request it, or extended significantly if either antitrust agency issues a request for additional information (referred

to as a "Second Request") before the end of the period, which occurs in roughly 4 percent of filed transactions each year. Failure to observe the requirements of the HSR Act can subject parties to civil penalties of up to $16,000 per day of non-compliance.

The FTC's Prior Approach to Pharmaceutical Patent Licenses

The FTC has long interpreted the HSR Act to cover the sale of patents and other intangible assets. However, the circumstances under which a patent license can constitute a potentially reportable asset transfer under the Act have been less clear.

The FTC's prior approach was to treat only *exclusive* patent licenses—those in which the licensor gave the licensee the right to use the patent (or a part of the patent) in a designated field or for a particular use to the exclusion of all others, including the licensor—as potentially reportable asset sales under the HSR Act. Under this approach, agreements to co-develop or co-promote patented pharmaceutical products were not considered HSR-reportable asset acquisitions unless they included the transfer of "make, use, and sell" rights with respect to a particular field of use that were exclusive even as to the licensor. Similarly, the retention by the licensor of rights to use the patent, including in particular the right to manufacture for any purpose the product covered by the patent, could make the license "non-exclusive" and thus not reportable under the Act.

Pharmaceutical Patent Licenses Under the Amended HSR Rules

The FTC has determined that the "make, use, and sell" approach—which was widely understood within the antitrust bar but never codified—no longer adequately reflects licensing practices within the pharmaceutical industry. It has therefore amended the HSR Rules to clarify when the grant of a pharmaceutical patent license may require an HSR filing. Under the revised Rules:

- Transfers of rights to patents covering pharmaceutical or biological products (defined with reference to the North American Industrial Classification System codes) are considered asset acquisitions that are subject to the HSR Act.
- A pharmaceutical patent license will be considered an asset acquisition under the Act only if "all commercially significant rights" to the patent are transferred.
- The term "all commercially significant rights" is defined 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)."
- All commercially significant rights will be considered transferred even if the patent holder retains:
  - "limited manufacturing rights," which are defined as the right to manufacture the product(s) covered by the patent solely for the purpose of providing the product(s) to the licensee; or
  - "co-rights," which are defined as shared rights—such as co-development, co-promotion, co-marketing, or co-commercialization right—retained by the patent holder to assist the licensee in developing and commercializing the product covered by the patent.

(See: The FTC's Announcement.)

Potential Implications

The FTC acknowledges in its statement that the treatment of manufacturing rights under the amended HSR Rules is a departure from its prior practice. Whereas it had previously been clear that the retention of such rights by the licensor resulted in the license agreement being "non-exclusive" for HSR purposes, and thus non-reportable, it will now be necessary to review the terms of

pharmaceutical patent licenses carefully to determine whether they transfer "all commercially significant rights" to the licensee under the amended HSR Rules. The Antitrust practice group at Covington & Burling, which includes several senior attorneys well-versed in the application of the HSR Act to transactions in the pharmaceutical industry, stands ready to help clients understand and comply with the new rules.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

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