

## Antitrust Alert

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### FTC Proposes Amendments to HSR Rules Targeting Certain Pharmaceutical Licensing Arrangements

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The Federal Trade Commission (FTC) recently announced proposed amendments to the Premerger Notification Rules (HSR Rules) to clarify reporting requirements under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the HSR Act), for transactions involving the transfer of patent rights in the pharmaceutical industry. The proposed rule is largely a codification of the FTC's current treatment of exclusive licenses, with one significant change regarding the weight given to manufacturing rights retained by the licensor in pharmaceutical transactions.

The HSR Act requires parties engaged in certain transactions (involving the acquisition of voting securities, assets, or controlling non-corporate interests) to file a notification with the FTC and the Antitrust Division of the Department of Justice (DOJ), and to observe the statutorily prescribed waiting period prior to closing. The *acquisition* of a patent is treated as an asset acquisition, and thus a potentially reportable transaction under the HSR Act. However, whether the *transfer of rights* to a patent is also deemed an asset acquisition commonly involves a complex analysis focused on whether the transferred rights grant the licensee the *exclusive* right to "make, use and sell."

#### Commercially Significant Rights

The proposed amendments would codify the reporting requirement under the HSR Act for any transaction within the pharmaceutical industry that involves the transfer of "all commercially significant rights." These rights are defined as the exclusive patent rights to use the patent in a particular therapeutic area or in a specific indication within a therapeutic area.

The FTC has defined the pharmaceutical industry for purposes of this amendment by specifying NAICS (North American Industry Classification System) code 3254, which includes medical and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing, and biological product manufacturing. Importantly, the FTC's proposed amendments are limited to the pharmaceutical industry and do not change the current HSR Act reporting requirements related to exclusive licenses in other industries.

#### Retained Manufacturing Rights

Under current FTC practice, transactions where the licensor retains the right to *manufacture* are generally deemed non-exclusive and thus non-reportable under the HSR Act, even if the licensee obtains exclusive rights to *use* and *sell* under the patent. These transactions historically have been viewed as distribution agreements, rather than asset acquisitions.

The FTC, however, has determined that the right to manufacture in pharmaceutical licensing arrangements is far less important than the right to commercialize (use and sell) the product. Therefore, the FTC's proposed amendment treats these types of exclusive arrangements in the pharmaceutical industry — where the licensee obtains the exclusive right to use and sell but the licensor retains the right to manufacture — as the transfer of "all

commercially significant rights” and thus potentially reportable under the HSR Act. This change would represent a significant departure from the FTC’s current practice.

## Retained “Co-Rights”

In certain licensing arrangements, the licensor often retains “co-rights” when granting an otherwise exclusive license. For example, in the pharmaceutical industry, co-rights provide for the shared responsibility between the licensor and the licensee to see the licensed product through the Food and Drug Administration (FDA) approval process, and the subsequent marketing and promotion of the product (often referred to as “co-development” and “co-marketing” rights). Under current FTC practice, the retention of these co-rights by the licensor does not render the license non-exclusive, therefore they remain potentially reportable licensing arrangements under the HSR Act. The proposed amendments would simply codify this approach without making any change to current practice.

The proposed amendments would modify the HSR Rules contained in 16 C.F.R. §801.1 and §801.2. [Click here for the text of the Federal Register Notice, and the full language of the proposed amendments.](#) Comments regarding the proposed amendment must be submitted to the FTC by October 25, 2012.

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