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New HSR Rules for Pharmaceutical Patent Licenses

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The Federal Trade Commission ("FTC") this week adopted a significant change to the notification rules under the Hart Scott Rodino ("HSR") Act that will increase the number of pharmaceutical patent licenses covered by the Act. The amendments apply explicitly only to pharmaceutical patent licenses. They likely will have the largest impact on those arrangements where the licensor retains only a limited right to manufacture for the licensee under the licensed patent, which previously had been non-reportable under the FTC's interpretation of the HSR Act.

The rule of thumb for the application of the HSR Act to patent licenses is that a license is not reportable if it is *non-exclusive*, but may be reportable if it is *exclusive* and otherwise meets the requirements for reportability, including being valued above a minimum threshold that is adjusted annually (currently $70.9 million). The amendments leave this basic principle intact, but clarify —and partially modify—what constitutes an exclusive license for the purpose of the HSR Act in the pharmaceutical industry. Notably, under the FTC's previous interpretations of the HSR Act, an exclusive patent license was one that gave the licensee the right to make, use and sell under the patent or part of the patent to the exclusion of everyone else, *including the licensor*. Under this approach, if the licensor retained the right to manufacture, even if only for the licensee, the license arrangement was non-

reportable.

Under the amended rules, a license of pharmaceutical patent rights is potentially reportable if the transaction conveys "all the commercially significant rights to a patent . . . for any therapeutic area (or specific indication within a therapeutic area)." The relevant question under this test is whether the transaction allows "only the recipient of exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)." The amendment codifies existing guidance that the grant of an exclusive license does not escape reportability under the HSR Act merely because the patent owner retains "co-rights," such as the right to "co-development, co-promotion, co-marketing, and co-commercialization." However, as noted above, the amendment changes the FTC's approach to exclusive licenses in which the patent owner retains the right to manufacture exclusively for the licensee. Under the amended rules, these licenses will be reportable assuming the other HSR Act requirements (such as the $70.9M size-of-transaction threshold) are met.

Although the new rule only covers the pharmaceutical industry, the FTC advises that similar types of licenses in other industries may be reportable under the Act, and suggests that parties consult with the FTC's Premerger Notification Office on a case-by-case basis to determine whether particular arrangements require HSR notification.

The FTC estimates that 30 additional transactions per year will require notification under the HSR Act as a result of the amended Rules. A failure to make a required notification subjects the parties to penalties of up to $16,000 per day until the filing is made.

The amendments will become effective 30 days after publication in the

Federal Register, which is expected in the near future.

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