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D.C. Circuit Court Approves Hart-Scott-Rodino Regulation Applicable to Only One Industry: Pharmaceuticals

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On May 30, 2014, the U.S. District Court for the District of Columbia upheld the Federal Trade Commission's ("FTC") authority to issue rules under the **Hart-Scott-Rodino Act's** ("HSR") premerger notification program that apply to one industry only. The summary judgment ruling came in a challenge by PhRMA (Pharmaceutical Research and Manufacturers of America) to new HSR rules that made certain exclusive licenses in the pharmaceutical industry — but in no other industry — subject to HSR filing requirements. The ruling directly affects companies in the pharmaceutical industry and puts companies in other industries on notice that the FTC has the power to implement rules specific to their industries as well.

HSR requires that parties to certain large acquisitions or mergers file certain information and documents with the FTC and the Department of Justice Antitrust Division, and obtain approval before closing the transaction. While both agencies receive the filings, it is the FTC's Premerger Notification Office that establishes and implements the rules regarding reportability. Those rules are intricate and have changed several times since the initial 1978 version, however, the pharmaceutical industry-specific rules that took effect in December 2013 were the first to affect a single industry.

HSR normally only applies to acquisitions, not licenses. The FTC, however, has long interpreted HSR to cover exclusive licenses as a reportable acquisition (assuming all other requirements are met) if the licensor did not retain any rights to "make, use or sell" under the patent. The recent change was to consider a patent license a reportable acquisition even if the licensor retains the right to manufacture — but solely for the licensee — or if the licensor retains the right to co-market, but again, solely with the licensee. That new rule applies only to transfers of patent rights by entities reporting revenues within the U.S. Census Bureau's NAICS Industry Group 3254: the pharmaceutical industry.

The FTC's rationale for making these licenses potentially reportable is that, despite the retention of limited rights, the licensor essentially is transferring "all commercially significant rights" to the patent and so the license is akin to an acquisition. The FTC limited this new rule to only the pharmaceutical industry because, in the FTC's experience, only that industry used these types of license provisions. The FTC did say in its *Federal Register* notice of the new rule that it "will continue to assess the appropriateness of a rule for other industries." PhRMA formally and informally objected during the

rulemaking process, even meeting with the FTC Commissioners. When the rule was finalized anyway, PhRMA filed suit, claiming the FTC lacked statutory authority to issue an industry-specific rule and did not have a rational basis for this one.

After reviewing the statutory language and legislative history, the court found that the HSR Act "does not mandate that the FTC only promulgate rules of general applicability and does not foreclose the FTC's issuance of an industry-specific rule." The court also found that the FTC had articulated a rational basis for the rule, given that all of the numerous requests for informal guidance and the dozens of HSR filings came from companies in the pharmaceutical industry.

As of this writing, PhRMA has not made public any plans to appeal. Pharmaceutical companies have been complying with this rule for months and will need to continue to do so. Companies in other industries can seek informal guidance from the FTC about whether their similar transactions might be reportable. And while the FTC has changed HSR rules only infrequently and only after formal and informal discussions with the antitrust community, this court ruling confirms that it has the authority to make industry-specific rules even if the reactions to its proposed changes are negative.

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