DC District Court Upholds New HSR Rules Expanding Reporting Requirements for Pharmaceutical Patent Licenses

On May 30, 2014, the Federal District Court for the District of Columbia upheld recent amendments to the Hart-Scott-Rodino Antitrust Improvements Act ("HSR" or the "Act") that apply the Act's reporting and waiting period requirements to certain transfers of exclusive pharmaceutical patent rights. The Court's ruling resolves a challenge to the new rules filed on December 12, 2013, by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association representing biopharmaceutical researchers and biotechnology companies.

The District Court denied PhRMA's challenge to the industry-specific nature of the new rules.

The new rules, which became effective on December 16, 2013, require firms operating in the pharmaceutical industry to comply with the Act's reporting and waiting period requirements before transferring "all commercially significant rights" to a patent where the Act's jurisdictional tests also have been met. The new rules define "all commercially significant rights" 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)."

Under the traditional FTC Premerger Notification Office ("PNO") approach, if a license grants the exclusive right to use a patent to develop a product, manufacture a product, and sell that product, then the license is considered to be the transfer of an asset potentially subject to reporting under the Act. Under this "make, use and sell" approach, the grant of only marketing and distribution rights ("use and sell" rights), even if granted on an exclusive basis and even if coupled with a grant of exclusive rights to a trade name, is considered a distribution agreement; the entry into a distribution agreement is not an acquisition of an asset and thus is not subject to the reporting requirements of the Act.

The new test modifies the long-standing PNO position on reporting exclusive licenses in two respects. First, it limits the relevance of manufacturing rights in determining whether the grant of an exclusive license is an HSR reportable transaction. Under the new test, "all commercially significant rights" are transferred even if the patent holder retains some manufacturing rights — specifically, the right to manufacture so as to provide only the recipient of the patent rights with product(s) covered by the patent. Second, and of primary importance to PhRMA's challenge, the new test applies only to the transfer of patents that cover products whose manufacture and sale would generate revenues in NAICS Industry Group 3254 (Pharmaceutical and Medicine Manufacturing). Although the new test is limited to the pharmaceutical industry, exclusive patent licensing transactions in other industries may trigger HSR reporting under the traditional PNO "make, use and sell" approach.

In its suit to set aside the new rules, PhRMA argued that the Federal Trade Commission ("FTC") (1) lacked statutory authority to issue industry-specific rules rather than rules of general application; (2) failed to establish a rational basis for such industry-specific rules; and (3) failed to comply with legally required procedures. In particular, PhRMA argued that the limited application of the new rules to the pharmaceutical industry exceeded the FTC's statutory authority under the Act and was arbitrary and capricious. PhRMA further argued that the FTC failed to include in the rulemaking record the factual basis for its decision as required by law.

The FTC will closely scrutinize exclusive licensing arrangements in the pharmaceutical industry to ensure that they comply with HSR requirements.

The District Court, however, found that because the statute, legislative history and purpose of the HSR Act to prevent anticompetitive mergers do not foreclose the FTC from issuing industry-specific rules, the FTC's promulgation of the new rules did not exceed its statutory authority. Additionally, the Court found that the new rules were not arbitrary and capricious because the FTC relied on its expertise, past HSR filings, and publicly-available data in promulgating the new rules. In particular, the Court noted that since 2008, the PNO reported receiving HSR filings for 66 transactions involving exclusive patent licenses, all of which related to pharmaceutical patents. Finally, the Court determined that the FTC's notice and comment periods provided adequate opportunity for PhRMA (and others) to participate in the rulemaking process. On cross-motions for summary judgment, the Court rejected PhRMA's claims and granted the FTC's motion.

The FTC's vigorous defense against and eventual victory in the PhRMA lawsuit indicates how broadly the FTC interprets its mandate to require premerger notification for transactions that it believes may raise competitive concerns. It also indicates that the FTC will closely scrutinize exclusive licensing arrangements in the pharmaceutical industry. Consequently, biotech and pharmaceutical companies will need to review carefully their proposed licensing arrangements to assure compliance with HSR requirements prior to entering into such arrangements.

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