D.C. Circuit Upholds FTC Premerger Notification Rules Related to the Transfer of Exclusive Patent Rights in the Pharmaceutical Industry

Rules Expanded the Scope of Exclusive Rights Transfers That May Be Reportable

In November of 2013, the Federal Trade Commission ("**FTC**") promulgated a rule that required a Hart-Scott-Rodino Antitrust Improvements Act ("**HSR Act**") filing when a transaction resulted in the transfer of "all commercially significant rights" to a pharmaceutical patent. Previously, no HSR filing was required if the licensor retained certain rights, such as the right to manufacture solely for the licensee. The FTC's new rule reflected its conclusion that for purpose of evaluating the impact on competition of the transfer of pharmaceutical patent rights, the critical focus should be on whether the licensee received the right to direct all sales of and marketing efforts for the licensed product. On June 9, 2015, a D.C. Circuit panel held that the agency had acted within the scope of its authority in promulgating a rule which applied only to a particular industry. The court further held that the FTC had not acted in an "arbitrary and capricious" manner as had been alleged by the Pharmaceutical Research and Manufacturers of America ("**PhRMA**") in its challenge to the new rule.

Background

The HSR Act requires parties to mergers and acquisitions of assets and/or voting securities that exceed certain jurisdictional thresholds to make filings with the FTC and Department of Justice, Antitrust Division ("**DOJ**"), and to observe a waiting period before closing, during which the antitrust agencies may conduct an initial review of a transaction. While patents have always been viewed as "assets," it had not always been clear when an "exclusive" patent license qualified as an acquisition of an asset for HSR filing purposes.

The Premerger Notification Office of the FTC ("**PNO**") historically analyzed intellectual property transactions of this type by focusing on whether the exclusive rights to "make, use and sell" under a patent were being transferred. Only when the full bundle of rights was transferred did the PNO view the transaction as a transfer of an "asset" potentially reportable under the HSR Act. Specifically, if a licensor retained the right to manufacture a product or compound, even if exclusively for the licensee, the PNO viewed the transaction as akin to a non-reportable distribution agreement rather than an asset acquisition.

The final amendments to the Rules specifically changed this view and require reporting under the HSR Act of exclusive patent rights transfers involving "all commercially significant rights," even when the licensor retains certain manufacturing and/or co-development, co-promotion, and co-marketing rights, notably rights to manufacture solely for the licensee. However, the amendments were otherwise not a major shift from prior informal guidance received from the PNO, and they affect relatively few transactions.

Changes Implemented by the Amendments to the Rules

The PNO studied the structure of license transactions over several years. Following that review, it concluded that its previous guidance did not serve to capture all transactions that ought to be subject to HSR Act reporting and review, specifically those in which the licensor retained the right to manufacture a product or compound solely for the licensee and/or limited co-promotion or marketing rights, but where the licensee essentially directed all sales of and marketing efforts for the licensed product. The FTC stated in its rulemaking:

> "In recent years . . . it has become more common for pharmaceutical companies to transfer most but not all of the rights to "make, use, and sell" under an exclusive license, such that the "make, use and sell" approach is no longer adequate in evaluating the

> reportability of exclusive licenses in the pharmaceutical industry for HSR purposes. A licensor will often, for example, retain the right to manufacture under the patent, but under the agreement the licensor can only manufacture for the licensee.
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> The "all commercially significant rights" test in the rule captures more completely what the "make, use, and sell" approach was a proxy for, namely whether the license has transferred the exclusive right to commercially use a patent or a part of a patent . . . in a particular therapeutic area or specific indication within a therapeutic area.[1]

Exclusive distribution agreements, under which a party receives no exclusive patent rights and is only handling the logistics of distributing an approved pharmaceutical product, are still not reportable under the HSR Act.

The D.C. Circuit's Decision

The majority opinion, written by Senior Circuit Judge Harry Edwards, notes that the HSR Act was enacted to give the antitrust enforcement agencies a tool to identify problematic transactions before they are consummated, and that "[n]othing in the plain meaning, context, or legislative history of the Act unambiguously precludes the FTC from promulgating a rule, the substance of which is clearly within its delegated authority, merely because the rule focuses on a specific industry that is the sole source of the problem being addressed." In the court's view, PhRMA wrongly assumed that Congress intended the FTC to issue only rules of general applicability except when crafting exemptions from HSR Act filing for certain industries (e.g., oil and gas reserves and real estate).

In rejecting PhRMA's argument that the FTC's rulemaking was "arbitrary and capricious," the court acknowledged the FTC's review of filings over a five-year period, during which the agency received notifications for 66 transactions involving exclusive patent licenses. All involved pharmaceutical patents. In addition, the FTC reported that guidance sought from practitioners on the HSR treatment of license deals have generally been limited to the pharmaceutical industry. The rules thus focused on the pharmaceutical industry because that was the only industry in which the FTC had seen the types of commercial arrangements at issue. Further, the court pointed out that the FTC "repeatedly explained that if such arrangements arise in other industries, they too will be potentially reportable under the Act."

Key Takeaways

- The court's decision confirms the FTC's authority to promulgate industry-specific rules as to the applicability of HSR reporting obligations.

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[1] The term "all commercially significant rights" is defined in the amended HSR rules 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" are transferred even when the patent holder retains what is further defined as "limited manufacturing rights" and/or "co-rights."

The term "limited manufacturing rights" means rights retained by the patent holder to manufacture the product(s) covered by a patent when all other exclusive rights have been transferred, and "solely to provide the recipient of the patent rights with product(s) covered by the patent."

Similarly, a transfer of patent rights may be reportable even when the patent holder retains other "co-rights," either alone or in combination with "limited manufacturing rights." "Co-rights" include "co-development, co-promotion, co-marketing, and co-commercialization." Specifically, the Statement of Basis and Purpose of the final amendments contemplates "co-commercialization" to cover situations where the licensor "retains co-rights to assist the licensee in maximizing its sales of the licensed product" but where "all sales are typically booked by the licensee."

- The exclusive licensing of all commercially significant rights with respect to a pharmaceutical patent may trigger an HSR filing obligation, even if the licensor retains manufacturing, co-development, co-promotion, and/or co-marketing rights.

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