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Antitrust

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New FTC Rule to Increase Reportability of Exclusive Pharma Patent Rights Transfers

The US Federal Trade Commission ("FTC") proposes to adopt a new rule designed to increase the likelihood that transfers of pharmaceutical patent rights including biologics will be reportable under the Hart-Scott-Rodino Act ("HSR Act") pre-merger notification regime. The FTC's new rule would replace the current "make, use and sell" standard for analyzing the transfers with a new "all commercially significant rights" standard. The proposed rulemaking will increase the number of pharmaceutical exclusive rights transfers which will be reportable under the HSR Act (or if not reported, then subject to the harsh daily penalty for non-reporting). The principal practical change is that the transfer of exclusive manufacturing rights no longer is required to make the transfer potentially reportable under the new standard.

The FTC is inviting public comments on this new rule. **The deadline for providing comments to the FTC is October 25, 2012.** The proposed rule can be viewed on the FTC's website at http://ftc.gov/os/2012/08/120813hsr-ipnprm.pdf. We provide a brief description of the contrast between the FTC's current rule and its new rule, and describe how to comment on the FTC's proposed rule.

FTC Current Approach to Exclusive Rights Transfers: "Make, Use and Sell"

Under the current HSR Act and regulations, transfers of exclusive patent rights (e.g., licenses) may under certain circumstances be considered asset acquisitions and, therefore, potentially reportable transactions. Historically, the FTC's Premerger Notification Office ("PNO") analyzed patent transfers by looking to whether the transfer involved the exclusive right to "make, use *and* sell" the product covered by the patent.[1] If the transaction involved the transfer of the exclusive right to ***all three*** benefits (a trilogy of rights), then the transaction was potentially reportable. If the transaction did not involve all three aspects—for example, if the transfer involved the exclusive right only to use and sell the product, but not to manufacture the product—then the FTC viewed the transfer as more similar to a distribution agreement and not an asset acquisition, and therefore it was typically viewed as non-reportable under HSR. The prior guidance from the FTC's PNO repeatedly has been that patent rights transfers where the transferee did not receive exclusive manufacturing rights did not give rise to HSR Act reporting obligations. This was the longstanding and authoritative public PNO staff position, but was never codified in the HSR Act or regulations.

1 77 Fed. Reg. 50058.

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According to the FTC's Notice of Proposed Rulemaking, the "make, use and sell" standard framework failed to capture many pharmaceutical patent transfers. In the FTC's experience, pharmaceutical companies at times entered into license agreements in which the licensor licensed the right to "use and sell," but often retained the manufacturing rights in order to supply the product to the licensee. The net result is that pharmaceutical patent transfers involving the licensor's retention of manufacturing rights generally have not been reportable in the past, regardless of whether the transactions otherwise would have satisfied the HSR notification thresholds.

The FTC's Notice also points out that pharmaceutical patent owners often reserved "co-rights" in certain patent license arrangements. These reserved "co-rights" can include co-development and co-marketing rights, under which the licensor retains the right to assist the licensee by co-developing and co-promoting or otherwise co-commercializing the product. Under current FTC PNO policy, the FTC does not view these "co-rights" as precluding a conclusion that a license is otherwise exclusive, and, therefore, potentially a reportable transaction. The FTC's new proposed rule codifies that position.

The non-reporting of transactions subject to the HSR Act can subject a firm to a penalty of up to $16,000 per day.[2]

Proposed New FTC Rule: "All Commercially Significant Rights"

The FTC proposes to capture the pharmaceutical patent rights transfers by expanding the reach of its reporting obligations on pharmaceutical companies which transfer patent rights from "make, use and sell" to "all commercially significant rights."

The FTC defines "all commercially significant rights" in its newly proposed definitional paragraph in Section 801, 16 C.F.R. § 801.1(o):

> (o) All commercially significant rights. For purposes of paragraph (g) of § 801.2, the term all commercially significant rights means 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).

As the FTC explains in its public notice, this new definition does not make any reference to "licenses." That is intentional; the FTC acknowledges that pharmaceutical patent rights transfers most frequently are achieved through licenses, but "intend[s] to keep the focus on the substance of what is being transferred, not the form of the transfer." The FTC also addressed the licensor's retention of manufacturing rights for the purposes of manufacturing product for the licensee, proposing to add a new 16 C.F.R. § 801.1(p) that would define such retention as "limited manufacturing rights." Retention of "limited manufacturing rights" would not exempt an otherwise reportable transaction.

The new proposed rule also focuses on "therapeutic areas"—a term intended to "cover[] the intended use for the patent... and includes all indications."[3] The proposed rule would define an "indication" as "encompass[ing] a narrower segment of a therapeutic area."[4] Importantly, as described in the FTC's examples of the application of the new rule, transfers of rights to use a patent only as to an indication (or set of indications) still could trigger the rule and result in an HSR Act notification requirement. *See*, e.g., 77 Fed. Reg. 50061-62 (giving, as an example, that the transfer of exclusive rights to a patent for all veterinary applications would be an asset acquisition for HSR Act purposes, even if the licensor retained rights to other indications under the patent, such as rights to human indications).

Finally, the FTC proposes to define "co-rights" in a new provision, 16 C.F.R. § 801.1(q). As stated above, however, under the FTC's current policy, the FTC may consider a patent rights transfer to be "exclusive" regardless of the inclusion of "co-rights" provisions. Thus, this definition is more in the nature of a clarification than an introduction of an entirely new concept.

Impact on Transactions in the Pharmaceutical Industry

As intended, the proposed new "all commercially significant rights" rule would increase the likelihood that pharmaceutical patent rights transfers that otherwise meet the HSR Act's notification thresholds would be reportable under the HSR Act. For pharmaceutical patent rights transfers, the new rule:

- Eliminates the FTC's longstanding policy that the licensee must receive all three rights exclusively (make, use and sell), i.e., including the exclusive manufacturing rights in the patent rights transfer in order for a transaction to be reportable;
- Codifies that the transfer of patent rights of "all commercially significant rights" is reportable under certain circumstances;
- Codifies the FTC's position that indication-specific patent licenses are potentially reportable;

2 15 U.S.C. §18a(g)(1), as amended.

3 77 Fed. Reg. 50059.

4 77 Fed. Reg. 50059.

- Codifies the position that retention by the patent owner of "co-rights" in the patent do not negate the exclusivity of the rights transferred, such that the transaction remains potentially reportable;
- Bottom line: The proposed rule will likely expand the types of pharmaceutical industry transactions that would be potentially reportable under the HSR Act (and thus subject to fines for non-compliance). Certain formulations such as "commercially significant rights" seems less a bright line than the current trilogy formulation.

The proposed rule makes it clear that exclusive licenses will be potentially reportable even if the patent owner retains manufacturing rights or if it retains "co-rights," and even if the license is limited to only a specific indication or set of indications. The proposed rule's applicability to other common transactions, such as exclusive distribution agreements (which may or may not include an express patent license), is less clear. In any event, the proposed new rule not only subjects more transactions to FTC scrutiny, but also will increase the cost and time-to-implementation of a larger pool of pharmaceutical transactions.

Submitting Comments

The FTC will accept both online and paper comments concerning this proposed new rule. All comments are presumptively public, and will be kept confidential only if (i) submitted in paper form; (ii) the filer follows the FTC procedure in FTC Rule 4.9(c) (16 C.F.R. § 4.9(c)); and (iii) the FTC's general counsel grants the request for confidentiality. The FTC has provided the following advice for submitting comments:

Online Comments

Parties interested in submitting comments online must file them at https://ftcpublic.commentworks.com/ftc/hsripnprm, or at http://www.regulations.gov/#!home. The FTC will then publish the comment, along with the commenter's name and state, on the "public record," including, where possible, at http://www.ftc.gov/os/publiccomments.shtm. The FTC, "as a matter of discretion," will attempt "to remove individuals' home contact information from comments before placing them on the Commission website."

Paper Comments

If a party intends to submit a comment on paper, the FTC suggests that the party use an overnight or courier service. The commenting party should note "HSR IP Rulemaking, Project No. P989316" on the comment. The comment should be sent to the following address:

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex Q)
600 Pennsylvania Ave., NW
Washington, DC 20580

Deadline

The deadline for submitting comments is **October 25, 2012**. This means that the FTC must ***receive*** the comments by that date.