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Antitrust

ALERT

OCTOBER 2012

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New FTC/DOJ Position Will Require Heightened Regulatory Reporting of Pharma, Biological and Diagnostic Licenses

October 25, 2012, Deadline for Comments by Companies Affected

The Federal Trade Commission and Department of Justice recently announced revisions to the Hart-Scott-Rodino (HSR) Act's premerger notification rules to require enhanced reporting of transactions (including licenses) relating to patents involving pharmaceutical, biological and diagnostic products.[1] In the past, these "pharma" patent licenses were not reportable under HSR if the licensor retained either (i) manufacturing rights, even if only to manufacture for the licensee, or (ii) certain other forms of "co-exclusivity." These rules precluded the need to assess HSR valuation issues on many transactions that might otherwise have met "size of transaction" thresholds for reporting. As the historical carve-outs are now disappearing, valuation will take on much greater importance, and more pharma patent licenses will need to be filed under the HSR Act.[2] This alert discusses the background of HSR's application in this arena, the nature of the proposed changes, and areas requiring further clarification.

Background. The HSR Act requires filing a "premerger notification form" to both the FTC and DOJ for acquisitions meeting a "size" threshold of $68.2 million and not qualifying for certain exemptions. Exclusive licenses of intellectual property are considered asset acquisitions subject to the HSR Act, with most precedents analyzing whether the bundle of rights granted is sufficient to treat the license as "exclusive," and if so, whether its valuation meets the size threshold.

If filing is required, it triggers a 30-day waiting period (15 days for a cash tender offer or a bankruptcy sale), during which closing or other steps implementing the proposed acquisition cannot occur. The waiting period can be extended significantly if a "second request" is issued investigating the transaction. On the other hand, expiration of the waiting period without incident is not a regulatory "clearance" per se — a transaction can still be challenged even after the HSR filing is completed, the waiting period expires and the deal closes.

Historical Effect of Licensor Manufacture, and Proposed Change. In the past, the Agencies consistently held that licenses in any industry where the licensor retained manufacturing rights, even if only to manufacture for the licensee, were not "exclusive" and thus not asset acquisitions

[1] Notice of Proposed Rulemaking, Premerger Notification; Reporting and Waiting Period Requirements, 77 Fed. Reg. 50,057 (August 13, 2012) (http://ftc.gov/os/2012/08/120813hsr-ipnprm.pdf). The scope of the new rules actually extends broader than traditional "pharma"; it affects "patents covering products whose manufacture and sale would generate revenues in NAICS Industry Group 3254, including:

325411 Medical and Botanical Manufacturing

325412 Pharmaceutical Preparation Manufacturing

325413 In-Vitro Diagnostic Substance Manufacturing

325414 Biological Product (except Diagnostic) Manufacturing".

Id. at 50,061. Just the first of these categories — Medical and Botanical Manufacturing — includes a broad range of products outside the pharma arena, such as fish oils, herbal supplements and vitamins. Thus the new changes could have a much broader impact beyond traditional manufacturers of pharmaceutical products. However, because the Agencies' announcement consistently focuses solely on "pharma" in its explanations, we have adopted that same terminology herein.

[2] The Agencies acknowledge that the proposed rule will "provid[e] the Agencies with a better opportunity to review the transfers of exclusive rights to a patent in the pharmaceutical industry for competitive concerns." Id. at 12. Separately, the Agencies also require notification of drug patent litigation settlements between branded innovators and generics, and even between generics, under the Medicare Modernization Act of 2003 (MMA). The FTC has also been enforcing MMA requirements more aggressively in recent years, as part of an overall heightened focus on perceived "pay for delay" settlements. Thus, the HSR changes targeting pharma licenses are a continuation of the FTC's expansion of its reach as to pharmaceutical companies.

subject to the HSR Act. Under the proposed changes, this position is reversed, but only for the pharmaceutical industry. Going forward, the Agencies will treat manufacture of pharma products by the licensor for the licensee (termed "limited manufacturing rights") as irrelevant, and if "all commercially significant rights" are being transferred, will require valuing the transaction and filing an HSR notification form if "size"" thresholds are met. "All commercially significant rights" are defined as "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)." Notice of Proposed Rulemaking, 77 Fed. Reg. at 50,061.

Historical Effect of Licensor "Co-Exclusive," and Proposed Clarification. The Agencies have also historically treated certain "co-exclusive" licenses whereby the "licensor retains rights to the IP" as granting insufficient exclusivity to require reporting. A number of elaborate discussions of whether the package of rights licensed or retained is sufficient to trigger HSR reporting can be found in the FTC's "informal interpretations" database, but the "co-exclusive" rule has not been flatly rejected, nor a different "co-rights" rule clearly adopted. In any case, going forward, the Agencies state a "current policy" that retention of "co-rights" does NOT render a license non-exclusive, and thus that such arrangements can also be subject to HSR reporting. Id. at 50,059.

Statistics on Increased Burden. The Agencies estimate the new rules will require 30 more filings per year, and then divide that by the total number of projected HSR filings (1,500 per year) to reach an increase of just 2 percentage points. Id. at 50,060-50,061. Arguably, a more relevant denominator would be the projected number of filings in the pharma industry, which would be below 75, the total number where the target was in either the pharma or chemical industries in 2011. HSR Annual Report, FY2011, Table XI (www.ftc.gov/os/2012/06/2011hsrreport.pdf) (providing statistics for NAICS Industry Group 325, Chemical Manufacturing, which includes the categories targeted by the proposed change – see note 1, supra). On this basis, 30 more pharma filings could easily represent a 100 percent year-on-year increase in filings within that industry attributable to this change. This potentially significant increase is itself noteworthy, but there are several other important questions left to be addressed.

Open Issues. The proposed changes raise three important questions for pharma/biological/diagnostic companies — and hopefully the Agencies — to consider during the comment stage.

(1) "Co-Rights": The treatment of "co-rights" is in theory a codification of existing rules, but in practice will likely result in increased reporting. "Co-rights" are defined as "shared rights retained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent," including but not limited to "co-development, co-promotion, co-marketing and co-commercialization."

The Agencies state that such "co-rights" have not precluded a need to file in the past, and thus purport for this to be more codification than change. Id. at 50,059. However, a situation in which the rights were described as "co-exclusives" involving "research, development and commercialization of licensed products undertaken jointly" by the parties obviated the need to file, despite sounding suspiciously close to "co-rights." Informal Interpretation Number 0203001 (www.ftc.gov/bc/hsr/informal/opinions/0203001.htm) (March 6, 2002)[3] If the Agencies intended no change as to co-exclusives, HSR practitioners and their clients are still left with a need for further clarification to parse whether a proposed allocation of rights commonly used in the industry or at issue in a proposed transaction falls within the non-reportable "co-exclusive" category or reportable "co-rights" category. Perhaps more likely, the Agencies intended a change of the former carve-out for co-exclusives described in Interpretation No. 0203001 and elsewhere, but that could use clarification as well.

(2) Experimental/Research Indications: One question many companies may struggle with is how to treat licenses granted for experimental or research indications — *i.e.*, with the license to become effective and exclusive upon an experimental indication becoming an approved indication. The changes clearly intend to grasp exclusive grants for (i) "all uses," (ii) an entire therapeutic area, or (iii) a specific indication, which (especially given the absence of definition) some companies may interpret as approved indications. They do not specifically address, and upon information and belief the Agencies did not consider, situations where the license focuses on testing the compound in an experimental or research indication. "All commercially significant rights" may be too far down the horizon for licenses involving these experimental indications to trigger the new rule, but this deserves further clarification, in particular as to whether experimental/research indications perhaps deemed non-reportable at present could require

[3] *See also* Informal Interpretation Number 0806009 (www.ftc.gov/bc/hsr/informal/opinions/0806009) (June 10, 2008) (no reporting required where "A would grant to B the co-exclusive right … to develop and co-promote Product A. B would grant to A the co-exclusive right … to develop and co-promote a product combining Product A with Product B (hereafter, the "Combination Product"). A and B would agree to collaborate exclusively worldwide with each other to develop, manufacture, and commercialize Product A and the Combination Product"); ABA Section of Antitrust Law, Premerger Notification Practice Manual (PNPM), Interpretation No. 27 (4th ed. 2007) (citing Interpretation No. 0203001 for the rule that "a co-exclusive license where the licensor retains rights to the intellectual property is not considered by the PNO to be an exclusive license").

valuation and reporting if greater exclusivity "kicks in" once FDA approval of an indication is received.[4]

(3) Valuation: Valuation of pharma licenses takes on vastly greater significance going forward. Currently valuation is easily avoided if the licensor retains manufacturing rights, even if only for the licensee. As this quasi-exemption from valuation requirements disappears — and given the obvious heightened focus on pharma transactions more generally — companies engaging in pharma licenses will need to pay closer attention to whether the "acquisition price" or "fair market value" of exclusive rights acquired reaches the minimum HSR threshold of $68.2 million.

An "acquisition price" can be determined where the licensee is able to "reasonably estimate" the gross amount of royalties it expects over the life of the license, in which case those payments are typically required to be taken at full value, rather than discounted to present value. However, the speculative nature of many pharma licenses often allows for "acquisition price" to be avoided in favor of "fair market value" calculations, historically enabling discounting of projected royalties or other payments to present value (interpretations also refer to the "current fair market value of a fully paid-up license"). Id., Interpretation No. 86. This determination must be made by the licensee's board of directors or its delegee within 60 days prior to filing (or consummation if no filing is required).

The key issue will be whether the rules allowing discounting in "speculative" pharma situations stand, especially given that the Agencies' express rationale for targeting the pharma industry — its "unique incentives for the use of exclusive licenses" — also focused on uncertainty:

> [I]n a scenario … seen quite frequently, an innovator discovers a compound, but that innovator does not have the financial resources to shepherd the compound through the approval process required by the FDA, nor to effectively market or promote it in drug form after FDA approval. Thus, the innovator will enter into an exclusive licensing arrangement with a (typically much larger) pharmaceutical company to provide the financial resources for the FDA approval process and the eventual marketing and promotion of the drug. *There is a great deal of uncertainty involved, as neither party to the exclusive licensing agreement knows whether the compound will actually become an approved drug and be commercially successful*. But if the drug is successful, the licensee will be able to book enormous profits, some of which will be shared with the licensor through royalties or other revenue sharing arrangements. Given its financial investment, the licensee wants the exclusive right to as much of these profits as possible to recoup its costs. The result is an exclusive license agreement … unlike that seen in any other industry. Notice of Proposed Rulemaking, 77 Fed. Reg. at 50,059 (emphasis added).

By using this as a key example, the Agencies clearly intend to require increased reporting in this scenario. Yet the proposed changes also purport to leave valuation rules essentially untouched, and a long-standing valuation precedent provides that:

> [I]n … circumstances [involving] milestone payments subject to achieving various levels of [FDA] approval for a to-be-developed product, [a reasonable basis for estimating contingent consideration] could be highly speculative. If a reasonable estimate cannot be made, the acquisition price is not determined. Although the value of the contingency cannot be deemed to be zero merely because the amount of the future payment cannot reasonably be estimated, if the future payment is unlikely, its value could approach zero. PNPM, supra, Interpretation No. 94.

An obvious tension exists between desiring increased reporting of deals involving "a great deal of uncertainty" surrounding FDA approval, and maintaining a valuation precedent recognizing that if milestone payments based on FDA approval are deemed "unlikely" their "value could approach zero." Whether the valuation rule stands — and if so, whether certain facts presented in a given situation suggest that future milestone or royalty payments are sufficiently "unlikely" to justify low valuations – or a more refined valuation analysis applies, requires clarification.

Practical Caveats. Among other practical caveats that may result from this heightened focus on valuation, internal company documents assessing valuations under various scenarios may take on greater importance in the analysis on HSR reporting. Also and relatedly, pharma companies may find themselves increasingly required to present fair market valuation questions to the board or its delegee. Therefore, the

[4] One precedent that, if applied under the new rules, could require reporting in this instance involved nonexclusive licenses for research into technology for generating human antibody production, with exclusivity for commercial exploitation conditioned on "future identification" of specific antibodies and antigen targets products. Informal Interpretation Number 0205006 (May 13, 2002) (www.ftc.gov/bc/hsr/informal/opinions/0205006.htm). Importantly, while acknowledging the conditions to exclusivity, the writer seeking the HSR interpretation emphasized other key facts: (i) "the exclusive licenses granted by each party to the other are intended to be legally binding" and "present grants of license rights, rather than options"; and (ii) before the effective date, one party "will have identified … one or more antibodies generated against antigen targets as to which it … will be able to exercise the exclusive rights." Based on these facts, the interpretation confirmed that the agreement "would be viewed for HSR reporting purposes as granting all of the exclusive license rights at the time the [agreement] became effective, whether or not the relevant antigens or antibodies are identified at that time or at some time later during the term of the agreement." This precedent may be highly fact-specific, but deserves revisiting in the context of the new rules.

need to reconcile the position taken in early documents with the valuation believed appropriate for the board's determination may require careful consideration.

Due Date for Comments. The Agencies require comments on the proposed changes to be provided in writing by October 25, 2012. Notice of Proposed Rulemaking, 77 Fed. Reg. at 50,058 (providing detailed instructions).

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