frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not

such information and documentary material as may be necessary and appropriate to determine whether the proposed transaction may, if consummated, violate the antitrust laws. In addition, Section 7A(d)(2) of the Act, 15 U.S.C. 18a(d)(2), grants the Commission, with the concurrence of the Assistant Attorney General, in accordance with 5 U.S.C. 553, the authority to define the terms used in the Act and prescribe such other rules as may be necessary and appropriate to carry out the purposes of Section 7A.

On August 13, 2012, the Commission posted a Notice of Proposed Rulemaking and Request for Public Comment (''NPRM'') on its Web site, and it was published in the Federal Register on August 20, 2012.[1] The comment period closed on October 25, 2012. The proposed rule recommended amendments to 16 CFR 801.1 and § 801.2 to reflect the longstanding staff position that a transaction involving the transfer of exclusive rights to a patent or a part of a patent in the pharmaceutical industry, which typically takes the form of an exclusive license, is potentially reportable under the Act and to clarify the treatment of retained manufacturing rights. The proposed rule defined and applied the concepts of ''all commercially significant rights,'' ''limited manufacturing rights,'' and ''co-rights'' in determining whether the rights transferred with regard to a patent or a part of a patent in the pharmaceutical industry constitute a potentially reportable asset acquisition under the Act. Under the proposed rule, the retention of limited manufacturing rights and co-rights does not affect whether the transfer of all commercially significant rights has occurred.

The Commission received three public comments addressing the proposed rule. The comments are published on the FTC Web site at http://ftc.gov/os/comments/premergeriprights/index.shtm.

The following submitted public comments on the proposed rule:

1. Clyde Dinkins. (8/13/2012)
2. Pharmaceutical Research and Manufacturers of America. (Baker Botts LLP, Stephen Weissman) (10/ Tm (8)Tj as may be necessae0sgrr1J 111 Ttd mang (10c.002 0 0 5.85 111.20624 158.63i Notice oe

[1] 77 FR 50057 (August 20, 2012).

[2] PhRMA also provided additional information to the Commission in a letter dated June 7, 2013 (''Comment 2's Supplemental Letter'').

[3] Acquisitions of non-corporate interests must confer control in order to be reportable.

[4] As the Second Circuit explained in SCM Corp. v. Xerox Corp., ''[s]ince a patent is a form of property . . . and thus an asset, there seems little reason to exempt patent acquisitions from scrutiny under [Section 7 of the Clayton Act].'' 645 F.2d 1195, 1210 (2d Cir. 1981).

[5] In this rule, the phrase ''part of the patent'' refers to a subset of potential uses under the patent. For example, in the pharmaceutical industry, the phrase refers to a therapeutic area or a specific indication within a therapeutic area. See discussion in the all commercially significant rights section.

[6] A patent holder may choose to enter into a licensing arrangement instead of an outright sale because a license provides for a royalty revenue stream over many years and may better allow parties to agree on a method of valuing an unproven patent. See discussion of limitation to the pharmaceutical industry.

[7] The pharmaceutical industry has been making HSR filings for exclusive licenses that trigger the reporting requirements of the Act since the early 1980s.

[8] http://ftc.gov/bc/hsr/informal/index.shtm.

rule addresses when an exclusive patent license to a pharmaceutical patent or part of a patent constitutes an asset transfer under the HSR Act.

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. § 801.2(g)(3) of the rule provides that the transfer of exclusive rights to a patent or a part of a patent in the pharmaceutical industry is a reportable asset transfer if it allows only the recipient to commercially use the patent as a whole, or a part of the patent in a particular therapeutic area or specific indication within a therapeutic area.[9] The rule codifies the PNO's long-standing position that the retention of co-rights does not render a license to the patent or part of the patent as non-exclusive. The rule also provides that such a reportable asset transfer may occur even if the licensor retains the limited right to manufacture under the patent or part of a patent for the licensee.[10]

All Commercially Significant Rights

As noted above, due to the evolution of pharmaceutical patent licenses, the ''make, use, and sell'' approach is no longer adequate to evaluate the HSR reportability of exclusive patent licenses in the pharmaceutical industry.

In this rule, the ''all commercially significant rights'' test modifies the analysis to address the evolving structure of exclusive patent licenses in the pharmaceutical industry, providing the Agencies with a more effective means of reviewing exclusive patent licenses meeting the statutory requirements under the Act. [11] In effect, however, with the exception of the treatment of the right to manufacture exclusively for the licensee, the rule treats the reportability of exclusive licensing arrangements, including those where the licensor retains co-rights, in the same way that the PNO has for decades.

The ''all commercially significant rights'' test focuses on whether the licensee receives the exclusive right to commercially use the patent. [12] In such a case, only the recipient of the exclusive rights to the patent may generate revenue from those exclusive rights, even when some of those profits will likely be shared with the licensor through royalties or other revenue sharing arrangements.

An exclusive patent license may be reportable even if it transfers exclusive rights to only a part of the patent—that is, a subset of potential uses under the patent—because only the recipient of the exclusive rights to a part of a patent may generate revenue from those exclusive rights. The rule clarifies that, in the pharmaceutical industry, a patent licensing arrangement constitutes an asset acquisition if it transfers all commercially significant rights to the patent in a particular therapeutic area or specific indication within a therapeutic area. The terms ''therapeutic area'' and ''indication'' should provide clear guidance to the pharmaceutical industry, as these terms are well-known in the industry and frequently appear in exclusive patent licenses. A therapeutic area covers the intended use for a part of the patent, such as for cardiovascular use or neurological use, and includes all indications. An indication encompasses a narrower segment of a therapeutic area, such as Alzheimer's disease within the neurological therapeutic area.

Retention of Co-Rights

In transferring exclusive rights to a patent or a part of a patent in the pharmaceutical industry, the licensor often retains ''co-rights.'' This term, as defined by § 801.1(q), refers to shared rights to assist the licensee in developing and commercializing the patented product and includes rights to co-develop, co-promote, co-market, and co-commercialize. In the PNO's experience with exclusive patent licensing transactions in the pharmaceutical industry, the licensor grants the licensee an exclusive license to ''make, use, and sell'' under a patent or part of a patent, but retains co-rights to assist the licensee in maximizing its sales of the licensed product. In such cases, all sales are typically booked by the licensee, but the licensor often benefits from sharing in a more robust royalty revenue stream or other revenue sharing arrangement.

''Co-rights'' do not include the right of the licensor to commercially use the patent or part of the patent. Therefore a transfer of ''all commercially significant rights'' has occurred even when the grantor retains co-rights. Accordingly, this rule reflects the PNO staff's established position that exclusive licenses in which the licensor retains co-rights are asset acquisitions and potentially reportable under the Act. While Comment 2 asserts that the PNO's treatment of co-rights has been unclear and/or inconsistent, [13] the PNO has consistently taken this approach for many years, as illustrated by numerous informal interpretations available on the PNO's Web site in its informal interpretations database. We note that in the case of a co-exclusive license, no exclusivity exists and the agreement would not be reportable. [14]

Comment 2 also asserts that the rule does not differentiate between the kinds, magnitude, or scope of co-rights being retained and that blanket treatment of co-rights is inconsistent with the Act's coverage. [15] When a licensee obtains the exclusive right to commercially use a patent or part of a patent, a potentially reportable asset transfer occurs regardless of the kind or magnitude of co-right retained by the licensee. In the PNO's experience, the existence of a co-right is indicative of an effort on the part of the licensor to support the sales and marketing of the licensee in order to create a more lucrative royalty stream. Whether an asset transfer has occurred does not hinge on the kind, magnitude, or scope of co-right retained, but on whether the exclusive patent license allows only the licensee to commercially use the patent or part of the patent. Even though both the licensee and licensor will share any eventual profits, the profits result from a potentially reportable transfer to the licensee of the exclusive right to commercially use the patent or part of the patent.

Retention of Limited Manufacturing Rights

The ''all commercially significant rights'' test in the rule also clarifies the analysis of manufacturing rights under

[9] This rulemaking defines when the transfer of exclusive rights to a pharmaceutical patent or part of a patent constitutes the acquisition of an asset. It in no way delimits the much broader definition of an asset for purposes of Sections 7 and 7A of the Clayton Act in any other context.

[10] The focus of the rule is exclusive patent licenses that transfer the rights to use the patent or part of a patent to the exclusion of all others, even the licensor. Exclusive licenses that do not involve the transfer of exclusive rights to use the patent or part of the patent, such as an exclusive distribution agreement, are not covered by the rule.

[11] 15 U.S.C. 18a. See also http://ftc.gov/bc/hsr/stepstofile.shtm

[12] Although the transfer of exclusive rights to a patent or part of a patent in the pharmaceutical industry typically occurs through a license, the rule does not use this term and instead focuses on the broader concept of exclusive rights to a patent or part of a patent in defining ''all commercially significant rights.'' This is intended to keep the focus on the exclusivity of the rights being transferred and not on the form of the transfer.

[13] Cmt. 2 at 11.

[14] Comment 2 cited an informal interpretation from 2008, number 0806009, as inconsistent with the PNO's position in the rule. Id. In fact, this interpretation is not inconsistent because it concerns a case where the IP at issue was co-exclusively licensed. As a result, no filing was required because no transfer of exclusive patent rights occurred. The co-rights do not factor into the analysis.

[15] Cmt. 2 at 12.

[16] Cmt. 2 Varner Decl. at 11–14.

[17] Cmt. 2 Varner Decl. at 15.

[18] For example, the electronics, semiconductor, and chemicals industries.

[19] Cmt. 2 Varner Decl. at 9–11.

[20] Comment 2 also cites to the prevalence of ''know how'' to argue that co-rights are ubiquitous, appearing in numerous industries. Cmt. 2 Varner Decl. at 10. The NPRM did not state that the retention of co-rights is unique to the pharmaceutical industry. It stated only that the retention of such co-rights is common in that

PNO's knowledge in which exclusive patent licenses are prevalent. The incentives are discussed because they may help explain why the mechanism for transferring patent rights in the pharmaceutical industry takes the form of an exclusive license instead of an outright sale. However, even if there are other industries that may encounter similar regulatory hurdles or share certain other structural similarities with the pharmaceutical industry, this does not change the fact that the exclusive patent licenses frequently seen in the pharmaceutical industry have not been seen by the PNO in other industries. As discussed above, Comment 2 has not identified any other industry in which exclusive patent licenses, as opposed to exclusive distribution agreements, are common. [21]

In sum, in the PNO's experience, the pharmaceutical industry is the only industry in which parties regularly enter into exclusive patent licenses that transfer all commercially significant rights. If the PNO finds that such arrangements occur in other industries, the Agencies can then assess the appropriateness of a similar rule for those other industries. Even in the absence of a specific rule concerning other industries, however, such exclusive patent licenses remain potentially reportable.

Rulemaking Authority Under the HSR Act

As mentioned above, the HSR Act requires the Agencies to review asset acquisitions meeting certain size of transaction and size of party thresholds. The Act provides the Commission, with concurrence of the Assistant Attorney General, rulemaking authority to implement this requirement. Section 18(a)(d)(2)(A) gives the Commission authority to define terms, which allows it to determine which types of patent rights constitute reportable assets under the Act. In addition, Section 18a(d)(2)(C) gives the Commission authority to prescribe rules ''as may be necessary and appropriate to carry out the purposes of this section.''

Comment 2 has argued that the Commission does not have authority to issue a rule under the HSR Act that expands the Act's requirements with respect to only a single industry. [22] First, the Commission is not expanding the HSR requirements to parties or transactions not covered by the Act. The Commission is simply clarifying the types of transactions that constitute asset transfers for which the Act requires prior notification. [23] Second, the Commission has broad authority to issue rules to facilitate the review of large transactions. [24] Nothing in the HSR Act prevents the Commission from issuing such rules on an industry-specific basis. Section 18(a)(d)(2)(B), which grants the Commission authority to exempt from the filing requirement classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws, does not limit the broad and discretionary rulemaking authority granted in Sections 18a(d)(2)(A) and (C). [25] The authority to exempt specific industries or transactions from the Act's filing requirements is not inconsistent with the authority to implement these requirements on an industry-specific basis prior to consummation of these agreements.[26]

The licensing arrangements covered by this rule are functionally equivalent to patent transfers and are thus properly viewed as asset acquisitions under the Act. Allowing such transactions to go unreported would deprive the Commission of an opportunity, consistent with the purpose of the Act, to review these significant asset acquisitions that, like other reportable asset acquisitions, are potentially anticompetitive. [27]

Consistency With the APA

Comment 2 has also argued that the rule is arbitrary and capricious because there is no basis to limit the rule to the pharmaceutical industry. [28] The rule is limited to the pharmaceutical industry because the PNO has not received filings over the past five years for exclusive patent licensing arrangements in other industries and requests for guidance on the treatment of exclusive patent licensing arrangements have nearly always come from practitioners in the pharmaceutical industry. Moreover, the PNO's experience with such arrangements in the pharmaceutical context allows the Commission to tailor the rule to the pharmaceutical industry by covering exclusive patent rights to use the patent in a therapeutic area or for a specific indication within a therapeutic area. While the PNO's experience with exclusive patent licensing arrangements has indicated a need for a rule for the pharmaceutical industry, at this time the Commission has not yet determined that a specific rule is necessary with respect to other industries. Nevertheless, to the extent they occur, transfers of exclusive rights to patents in other industries remain potentially reportable under the Act and existing HSR rules. Parties to such a transaction should contact the PNO, which will advise whether the arrangements are reportable under the Act.

Agencies may limit rules to those areas where they have observed a problem to be addressed. [29] As noted

[21] In addition, Comment 2 references technology licenses, but these are not the kinds of exclusive patent licenses covered by the final rule. Cmt. 2 Varner Decl. at 9. Technology licenses grant the use of technology covered by a patent and do not involve the potentially reportable transfer of patent rights.

[22] Cmt. 2 at 1, 3–6.

[23] Indeed, with the exception of agreements in which the licensor retains limited manufacturing rights, the pharmaceutical industry has been filing the exclusive patent licenses at issue for decades.

[24] Citing H.R. Rep. No. 94–1372 (July 28, 1976), Comment 2 has argued that, in order to issue a rule under the FTC's authority to issue regulations necessary and appropriate to carry out the purposes of the Act, the FTC must show that the transactions at issue are ''the most likely to substantially lessen competition and the most difficult to unscramble.'' Cmt 2 at n. 23. The cited House Report excerpt merely explains Congress's rationale for including only large mergers and asset acquisitions in the HSR Act. It does not purport to alter the Commission's authority to implement rules carrying out the purpose of the Act, which is to ensure that large transactions are reported. Moreover, the language of the HSR Act is controlling, and that statutory language requires premerger reporting of asset acquisitions based on size thresholds, without limitation to transactions that might prove particularly difficult to untangle.

[25] See, e.g., Texas Oil & Gas Ass'n v. EPA, 161 F.3d 923, 938–39 (5th Cir. 1998) (holding that particularized exemption authority did not speak to the scope of agency's plenary rulemaking authority to differentiate among groups of covered parties).

[26] Nor does the legislative history of the HSR Act suggest that the Commission may not use its broad rulemaking authority to issue industry-specific rules. Comment 2 has asserted that Congress's exclusion of a provision that would have permitted the Commission to require pre-merger notification from persons or categories of persons not otherwise required to file (namely, parties below the minimum size thresholds) indicates Congress's intent not to allow the Commission to impose requirements on an industry-specific basis. See Cmt. 2 at 3. However, the omission of a provision allowing the Commission to expand the Act's coverage beyond the minimum thresholds says nothing about the Commission's authority to issue industry-specific rules for parties or transactions that meet the thresholds.

[27] See 122 Cong. Rec. 29342 (statement of Sen. Hart) (''The whole purpose of [the Pre-Merger Notification section] is to provide antitrust authorities with a meaningful opportunity to study the potential antitrust consequences of significant mergers and acquisitions prior to consummation.''); The Antitrust Improvements Act of 1975, S. 1284, 94th Cong. (1975) (''It is the purpose of the Congress in this Act to support and invigorate effective and expeditious enforcement of the antitrust laws, to improve and modernize antitrust investigation and enforcement mechanisms, to facilitate the restoration and maintenance of competition in the marketplace, and to prevent and eliminate monopoly and oligopoly power in the economy.'').

[28] Cmt. 2 at 2, 7–13.

[29] See, e.g., Illinois Commercial Fishing Ass'n v. Salazar, 867 F.Supp.2d 108 (D.D.C. 2012) (upholding rule banning take of certain fish by commercial fishermen but not recreational fisherman, where evidence indicated that greatest risk to endangered fish was posed by commercial

Continued

above, the Agencies will continue to assess the appropriateness of a similar rule for other industries, but they need not take an all-or-nothing approach. In promulgating regulations, agencies may proceed incrementally. Like legislatures, they are not required to resolve a problem that may occur more broadly ''in one fell regulatory swoop.'' [30]

Effect on Pharmaceutical Industry

Comment 3, although expressing support for the rule, indicated a concern that the administrative costs associated with HSR filings, as well as the cost of obtaining a patent valuation to determine whether a filing is required, could chill pharmaceutical transactions. Comment 2's Supplemental Letter raised a similar concern that the rule could chill pharmaceutical transactions or cause parties to alter the terms of such transactions. In the PNO's experience, the administrative costs of filing are very small compared to the profits at stake in the multi-million dollar transactions reportable under the Act and are unlikely to deter or materially distort these acquisitions. In an exclusive licensing transaction the parties would be very likely to conduct a patent valuation as part of their due diligence notwithstanding HSR. [31]

Conclusion

In sum, the ''all commercially significant rights'' test should provide clarity and consistency to the assessment of whether an asset acquisition is occurring as the result of the transfer of rights to a patent or part of a patent in the pharmaceutical industry. In addition, the test explains that even if there is a retention of ''limited manufacturing rights'' and ''co-rights'' the transfer of all commercially significant rights has occurred. The rule thus clarifies the analysis of the reportability of transfers of pharmaceutical patent rights while providing the Agencies with an opportunity to assess under the HSR Act the competitive impact of exclusive pharmaceutical patent licenses that may not have been reportable under PNO staff's prior approach. The Commission believes these benefits outweigh any potential additional burden on filing parties.

Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires that the Commission provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule, and a Final Regulatory Flexibility Analysis (''FRFA'') with the final rule, unless the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission does not anticipate that the rule will have a significant economic impact on a substantial number of small entities. The Act is designed to have minimal impact on small entities. First, for a transaction to trigger a reporting requirement under the Act, the transaction must be valued at more than $50 million (as adjusted). [32] Such a high transaction threshold will typically not catch most transactions involving small entities.

In addition, the Act requires that in cases where the transaction is valued at greater than $50 million (as adjusted) but $200 million or less (as adjusted), one party to the transaction must have at least $10 million (as adjusted) in sales or assets in order to trigger reporting requirements. This size of person test also ensures that the Act does not regularly reach small entities. Of the 6,487 transactions filed over the last five years, only 66 of this total number were related to exclusive licenses involving the pharmaceutical industry. Of these 66 transactions, only one involved an entity that did not have reportable sales or assets of $10 million or more (as adjusted).

The Commission recognizes that some of the affected manufacturers may qualify as small businesses under the relevant Small Business Administration (''SBA'') thresholds, which for the pharmaceutical industry are based on number of employees and not on annual receipts. However, the Commission does not expect that the requirements specifie, inan

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fishing rather than recreational fishing); Manufactured Housing Instit. v. EPA, 467 F.3d 391 (4th Cir. 2006) (upholding EPA regulation treating apartment buildings differently from manufactured home communities for purposes of determining whether submetering constituted a sale of water, effectively exempting apartment buildings from certain water safety requirements; although EPA had deemed the water distribution system to be safe in apartment houses, it could not categorically say the same for manufactured home communities, which would be exempted on a case-by-case basis); Investment Co. Inst. v. United States Commodity Futures Trading Comm'n, 891 F.Supp.2d 162, 187 (D.D.C. 2012) (upholding CFTC regulation requiring registration and reporting by some entities engaging in derivatives trading, but exempting others, where CFTC justified exempting these other entities on the basis that it was not aware of any such other entities engaging in derivatives trading).

[30] Investment Co. Inst., 891 F.Supp.2d at 201. See also City of Las Vegas v. Lujan, 891 F.2d 927, 935 (D.C. Cir. 1989) (''agencies have great discretion to treat a problem partially''); National Ass'n of Broadcasters v. FCC, 740 F.2d 1190, 1207–08 (D.C. Cir. 1984) (''agencies . . . need not deal in one fell swoop with the entire breadth of a novel development; instead, reform may take place one step at a time, addressing itself to the phase of the problem which seems most acute to the regulatory mind.'') (quotation, quotation marks, and brackets omitted).

[31] Comment 3 also argued that the rule would have a chilling effect stemming from companies' fears that the transaction will be challenged by the Agencies. The Agencies can challenge any transaction that is anticompetitive under the antitrust laws, regardless of whether it triggers the need for an HSR filing.

[32] The 2000 amendments to the Clayton Act require the Commission to revise certain reportability thresholds annually, based on the change in the level of gross national product. The minimum size of transaction threshold as of February 11, 2013, is $70.9 million with one person having sales or assets of at least $141.8 million and the other person having sales or assets of at least $14.2 million.

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Attorney General. Thus, parties must submit copies of these ''index'' filings, but completing the task requires significantly less time than non-exempt transactions which require ''non-index'' filings.

[38] For example, see Regulatory Flexibility section above.

[39] Comment 3 also expressed concern that the Rule would add administrative costs to pharmaceutical deals, including the costs of analyzing whether the transaction is reportable and the costs of conducting a valuation of the acquisition.

[40] Cmt. 2 at 14.

[41] Based on a review of valuations for prior licensing transactions, the FTC estimates that about one third of the 30 added transactions will require a more precise valuation, with one party per transaction conducting such valuation. [(50 filings × 37 burden hours) + (10 filings requiring a more precise valuation ×