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 warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC, on October 25, 2013.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12/12/13	AK	Venetie	Venetie	3/5254	10/15/13	Takeoff Minimums and (Obstacle) DP, Orig.
12/12/13	AK	Minchumina	Minchumina	3/5335	10/15/13	NDB RWY 3, Amdt 3A.
12/12/13	AK	Minchumina	Minchumina	3/5336	10/15/13	RNAV (GPS) RWY 3, Orig.
12/12/13	AK	Minchumina	Minchumina	3/5340	10/15/13	RNAV (GPS) RWY 21, Orig.
12/12/13	WA	Everett	Snohomish County (Paine Fld).	3/5409	10/15/13	Takeoff Minimums and (Obstacle) DP, Amdt 2.
12/12/13	AK	Northway	Northway	3/6133	10/15/13	RNAV (GPS) RWY 23, Amdt 1.
12/12/13	AK	Gustavus	Gustavus	3/6328	10/15/13	RNAV (GPS) RWY 29, Amdt 2.
12/12/13	IL	Effingham	Effingham County Memorial.	3/7065	10/15/13	RNAV (GPS) RWY 29, Orig.
12/12/13	MT	Scobey	Scobey	3/7755	10/15/13	RNAV (GPS) RWY 12, Orig.
12/12/13	FL	Tampa	Tampa Intl	3/9215	10/15/13	RNAV (GPS) RWY 10, Amdt 1A.
12/12/13	AZ	Fort Huachuca Sierra Vista.	Sierra Vista Muni-Libby AAF.	3/9530	10/15/13	RNAV (GPS) RWY 8, Amdt 1.
12/12/13	CA	Chico	Chico Muni	3/9848	10/15/13	Takeoff Minimums and (Obstacle) DP, Amdt 6.

[FR Doc. 2013–26719 Filed 11–14–13; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 801

RIN 3084–AA91

Premerger Notification; Reporting and Waiting Period Requirements

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''Commission'' or ''FTC''), with the concurrence of the Assistant Attorney General, Antitrust Division, Department of Justice (the ''Assistant Attorney General'' or the ''Antitrust Division'') (together the ''Agencies''), is amending the Hart-Scott-Rodino Premerger Notification Rules (the ''Rules'') in order to provide a framework for determining when a transaction involving the transfer of rights to a patent or part of a patent in the pharmaceutical, including biologics, and medicine manufacturing industry (North American Industry Classification System Industry Group 3254) (''pharmaceutical industry'') is reportable under the Hart Scott Rodino Act (''the Act,'' ''HSR Act'' or ''HSR''). This final rule defines and applies 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.

DATES: *Effective Date:* These final rule amendments are effective on December 16, 2013.

FOR FURTHER INFORMATION CONTACT: Robert L. Jones, Deputy Assistant Director, Premerger Notification Office, Bureau of Competition, Room H–303, Federal Trade Commission, Washington, DC 20580, (202) 326–3100, *rjones@ftc.gov.*

SUPPLEMENTARY INFORMATION:

Statement of Basis and Purpose

Section 7A of the Clayton Act requires the parties to certain mergers or acquisitions to file with the Agencies and to wait a specified period of time before consummating such transactions. The reporting requirement and the waiting period that it triggers are intended to enable the Agencies to determine whether a proposed merger or acquisition may violate the antitrust laws if consummated and, when appropriate, to seek a preliminary injunction in federal court to prevent consummation, pursuant to Section 7 of the Act.

Section 7A(d)(1) of the Act, 15 U.S.C. 18a(d)(1), directs the Commission, with the concurrence of the Assistant Attorney General, in accordance with the Administrative Procedure Act, 5 U.S.C. 553, to require that premerger notification be in such form and contain

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) (10/25/2012)[2]
3. Antonio Burrell. (10/26/2012)

Comments 1 and 3 supported the proposed rule. Comment 2 did not support the proposed rule, objecting to the adoption of rules limited to the pharmaceutical industry.

After carefully considering the comments, the Commission has determined that the proposed rule is appropriately limited to the pharmaceutical industry. Thus, the Commission is adopting the rule as proposed.

Although the rule is limited to the pharmaceutical industry, to the extent that other industries engage in similar exclusive licensing transactions, such transactions remain potentially reportable events under the Act and existing rules implementing the Act. Parties dealing with the transfer of exclusive rights to a patent or part of a patent in other industries should consult with Premerger Notification Office (''PNO'') staff to determine whether the arrangement at issue is reportable under the Act and Rules. The Commission will continue to assess the appropriateness of a rule for other industries.

Background

The Act applies to reportable acquisitions of voting securities, controlling non-corporate interests,[3] and assets. A patent is an asset under the Act.[4] The acquisition of a patent gives the buyer the right to commercially use that patent to the exclusion of all others. The same is true of an exclusive license to a patent. In an exclusive patent licensing arrangement, the licensor gives the licensee the right to commercially use the patent, or a part of the patent,[5] to the exclusion of all others, including the licensor.[6] An exclusive license is substantively the same as buying the patent or part of the patent outright, and carries the same potential anticompetitive effects. Thus, the granting of an exclusive right to commercially use a patent or part of a patent is a potentially reportable asset acquisition under the Act.

In determining reportability, the parties must analyze what the licensor is transferring to the licensee and determine whether the license conveys the exclusive rights to commercially use the patent or part of a patent. For years, this analysis was straightforward as evidenced by the questions and filings received by the PNO about exclusive patent licenses in the pharmaceutical industry that expressly included the rights to ''make, use, and sell'' under the patent or part of the patent.[7] For such licenses, the PNO had only to verify that the transfer involved the exclusive right to use a patent or part of a patent to develop a product, manufacture the product, and sell that product without restriction. Although never codified, the ''make, use and sell'' approach became well-known throughout the HSR bar and is reflected in the numerous letters and emails from practitioners in the PNO's informal interpretation database on its Web site.[8]

In recent years, however, 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. In such a case, under the PNO's ''make, use, and sell'' approach, the retention of the right to manufacture would render the transaction non-reportable even though the licensor would not be manufacturing for its own commercial use, but exclusively for the licensee. In addition, the PNO has seen with increasing frequency licensors retaining the right to co-develop, co-promote, co-market and co-commercialize the product along with the licensee, and the retention of these ''co-rights'' also raises questions about the adequacy of using the ''make, use, and sell'' approach to determine reportability. Practitioners who represent clients in the pharmaceutical industry have often sought guidance from the PNO about transactions where the licensor grants the licensee the exclusive right to commercially use a pharmaceutical patent or part of a patent but retains the right to manufacture for the licensee and/or to co-develop, co-promote, co-market and co-commercialize the product along with the licensee. This

[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.

an exclusive patent license in the pharmaceutical industry. Exclusive patent licensing arrangements have evolved such that, in many instances, an exclusive patent license in the pharmaceutical industry no longer includes the exclusive right to manufacture; typically the licensor grants the licensee exclusive rights to the patent but retains the right to manufacture solely for the licensee. Under the prior ''make, use, and sell'' approach, the retention of such manufacturing rights renders the arrangement non-reportable because not all of the rights to ''make, use, and sell'' under the patent or part of a patent transfer to the licensee. This has been the PNO's approach even though the arrangement has the same effect as a transfer to the licensee of all patent rights. The final rule ensures that transactions in which the licensor retains only the right to manufacture exclusively for the licensee, and thus retains ''limited manufacturing rights,'' as defined by § 801.1(p), will be reported if the relevant HSR statutory thresholds are met.

Comment 2 asserts that there are agreements in other industries that involve the retention of manufacturing rights.[16] The Commission does not disagree. There are many kinds of exclusive licensing agreements in other industries that involve the retention of manufacturing rights. But, the rule is not focused on all exclusive licensing agreements where the licensor retains manufacturing rights; it is focused on exclusive patent licenses that transfer all rights to a patent or part of a patent but where the licensor retains rights to manufacture solely for the licensee. The agreements cited by Comment 2 are not the kind of agreements that are the subject of the rule. They are exclusive distribution agreements, which convey to the licensee only the exclusive right to distribute the patented product. In exclusive distribution agreements, the licensor retains not just the right to manufacture but all commercially significant rights to the patent, such that no reportable asset acquisition takes place. Based on HSR filings and requests for advice on the reportability of transactions, the PNO has found that exclusive patent licensing agreements that transfer all of the rights to commercially use a patent or part of a patent almost solely occur in the pharmaceutical industry.

Comment 2 also takes issue with the NPRM's statement that, in licensing arrangements in the pharmaceutical industry, the right to manufacture is less important than the right to commercialize. Comment 2 asserts that the right to manufacture is integral to the pharmaceutical industry and that the NPRM discounts the importance of manufacturing in this industry.[17] The statement in the NPRM, however, was not a general assessment of the value of manufacturing in the pharmaceutical industry but was intended only to provide a possible explanation as to why the PNO sees exclusive patent licenses in the pharmaceutical industry structured the way they are structured, namely more and more frequently without the transfer of manufacturing rights.

Limitation to the Pharmaceutical Industry

The Commission is limiting the rule to the pharmaceutical industry because, as stated in the NPRM, this is where the need for clarification arises and where the Commission has experience with the relevant transactions. For the five-year period ending December 31, 2012, the PNO received filings for 66 transactions involving exclusive patent licenses, and all were for pharmaceutical patents. The PNO has not found other industries that rely on these types of arrangements. Although it is possible for other industries to engage in the kind of exclusive licensing that typifies the pharmaceutical industry, the PNO has not processed filings related to these kinds of exclusive licenses in any other industry in the past five years. In addition, requests for guidance on the treatment of exclusive patent licensing transactions have generally been limited to the pharmaceutical industry. Accordingly, the Commission has not found a need for a rule applicable to other industries. Moreover, the Commission's experience with such transactions in the pharmaceutical industry allows it to develop a rule that is tailored to exclusive patent licenses in the pharmaceutical industry, defining the relevant scope of the transfer of part of a patent by reference to the therapeutic area or specific indication within a therapeutic area.

As noted above, the PNO typically does not see exclusive transfers of rights to a patent or part of a patent outside the pharmaceutical context, and this is likely a result of the incentives that characterize the industry. The PNO quite frequently sees situations in which an innovator discovers and patents a pharmaceutical or biomedical compound, but that innovator does not have the financial resources to shepherd the compound through the FDA approval process, nor to effectively market or promote it in drug form after FDA approval. Thus, the innovator will enter into an exclusive licensing agreement transferring all the rights to the patent or part of the patent with a (typically, although not always, 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 because the transfer takes place very early in the development of the product covered by the patent and neither party to the exclusive licensing agreement knows whether the compound will actually become an approved drug and achieve commercial success. If the drug is successful, however, the licensee will book enormous profits, some of which will be shared with the licensor through royalties or other revenue sharing arrangements. As a result, there is a tremendous incentive for the pharmaceutical innovator to enter into an exclusive licensing arrangement rather than a patent sale.

By contrast, in many other industries, the products are generated pursuant to the exercise of a patent or part of a patent at a much later stage in development, and the patent owner can simply sell the patent for its proven value.[18] Where companies in other industries do enter into patent licensing agreements, the incentives for licensors typically lie in engaging as many licensees as possible and not in the exclusivity that characterizes patent licenses in the pharmaceutical industry.

Comment 2 argues that the pharmaceutical industry incentives and market structure are not unique.[19] The comment points to several other industries as encountering regulatory hurdles similar to those presented by the FDA in the pharmaceutical industry. It also asserts that the royalty rates in the pharmaceutical industry are similar to those in other industries and appears to claim that, therefore, the incentives to maximize future profits are no different in the pharmaceutical industry.[20] The rule is limited to the pharmaceutical industry not because of the uniqueness of the incentives in that industry but because it is the only industry to the

[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 industry.

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 specified in the rule will have a significant impact on these businesses. A business falling within the SBA thresholds that is subject to a reporting obligation as a result of the rule would in most instances be filing under the Act as the acquired person in the context of an asset transaction and would therefore be submitting less information. For example, an acquired person in an asset acquisition is not required to complete Item 6 of the Form. In addition, the acquired person in the types of licensing transactions covered by the rule would typically not report any revenues in Item 5 of the Form because the product has not yet generated any revenues, and this would mean no requirement to report overlaps in Item 7 of the Form. The acquired person would thus be required to submit only annual financial statements in Item 4(b) of the Form (assuming it is not publicly traded) and relevant transaction documents in Items 4(c) and 4(d) of the Form. Although there is some burden associated with gathering documents responsive to Items 4(c) and 4(d) of the Form, most of that burden will fall on the buyer with whom these kinds of documents typically reside. The buyer also typically pays the filing fee associated with the notification requirement.

Although the Commission continues to certify under the RFA, as it did in the NPRM, that the amendments would not, if promulgated, have a significant impact on a substantial number of small entities, the Commission has determined, nonetheless, that it is appropriate to publish an FRFA in order to explain the impact of the amendments on small entities as follows:

A. Need for and Objectives of the Final Rule Amendments

Section 7A(d)(1) of the Act, 15 U.S.C. 18a(d)(1), directs the Commission, with the concurrence of the Assistant Attorney General, in accordance with the Administrative Procedure Act, 5 U.S.C. 553, to require that premerger notification be in such form and contain such information and documentary

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.

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. The objective of the rule is to clarify when transactions involving the transfer of exclusive rights to a pharmaceutical patent are reportable under the Act.

B. Significant Issues Raised by Public Comments, Summary of the Agency's Assessment of These Issues, and Changes, if Any, Made in Response to Such Comments

The Commission received three comments on the proposed pule, two of which addressed possible small business impacts. Comments 2 and 3 asserted that small businesses would be impacted by the rule because of the costs associated with a HSR filing. However, as discussed above, any business falling within the SBA threshold would likely be the acquired person in the transaction, while most of the costs associated with a filing required by the Rules would be borne by the acquiring person.

C. Description and Estimate of the Number of Small Entities Subject to the Final Rule or Explanation Why No Estimate Is Available

Under the Small Business Size Standards issued by the Small Business Administration, the standards for the pharmaceutical industry are 750 or 500 employees, depending on the specific NAICS code. Based on an assessment of prior filings, the Commission estimates that of the 60 additional filings expected annually as a result of the rule, roughly 20 of the filers will qualify as small businesses, although these businesses will typically have revenues or assets large enough to meet the minimum HSR filing thresholds.

D. Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Final Rule Amendments, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Rule and the Type of Professional Skills That Will Be Necessary To Comply

The Commission recognizes that the rule will involve some burdens on affected entities and related fees. However, the amendments should not have a significant impact on entities falling within the SBA thresholds that are acquired persons. As discussed above, such acquired entities required to submit HSR filings as a result of the rule would submit an HSR form along with yearly financials and related deal documents, but less information than acquiring entities.

E. Steps the Agency Has Taken To Minimize Any Significant Economic Impact on Small Entities, Consistent With the Stated Objectives of the Applicable Statute

As discussed above, the Agencies have minimized the filing burden for acquired persons because the current Rules allow acquired persons to submit less information than the acquirer. Any entities newly covered by the final rule amendments that fall within the SBA thresholds would likely be acquired persons and have reduced filing burdens.

Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501–3521 (''PRA''), requires agencies to submit ''collections of information'' to the Office of Management and Budget (''OMB'') and obtain clearance before instituting them. Such collections of information include reporting, recordkeeping, or disclosure requirements contained in regulations. The existing information collection requirements in the Rules and Form have been reviewed and approved by OMB under Control No. 3084–0005. In accordance with the PRA, the FTC submitted the proposed rule [33] and supporting statement to OMB. The currently cleared burden hours total is 53,759. Comment 2 and its Supplemental Letter addressed the PRA estimates.

A. Necessity for the Rule Amendments

The PRA requires that an agency's collection of information be necessary for the proper performance of the agency's function, and that the information collected have ''practical utility.'' [34] According to the PRA, ''practical utility'' is the ability of an agency to use information, particularly the ability to process such information in a timely and useful fashion.[35]

Comment 2 questions the need for the rulemaking to further the purposes of the HSR Act.[36] The HSR Act is intended to allow the Agencies to review significant transactions to determine, prior to consummation of a transaction, if it is anticompetitive. Like patent sales, exclusive patent licenses prevalent in the pharmaceutical industry are asset acquisitions that may produce anticompetitive effects. This rule ensures that exclusive patent licensing transactions in the pharmaceutical industry are reported when they meet the requisite minimum thresholds, enabling the agencies to assess under the HSR Act the competitive impact of these transactions. Thus, the amended reporting requirements are necessary to effectuate the purposes of the HSR Act and have practical utility.

B. Filing Requirements, Including Form Preparation and Document Collection

Commenter 2 submitted two cost estimates. In its original submission, the commenter stated that the cost associated with preparation and completion of HSR forms for a ''straightforward'' transaction is at least $15,000 per party. Subsequently, however, the commenter submitted a Supplemental Letter stating that, on average, the cost associated with preparation of HSR forms, including collection and review of documents, is between $40,000 and $60,000 for each party to a transaction, with more straightforward transactions costing in the $15,000–$20,000 range. This assessment is higher than the Agencies' assessment, which is based on an hourly cost estimate derived after consultation with practitioners from the private bar. The FTC's estimate for a standard non-index filing [37] is $16,650 (based on an

[33] 76 FR 42471 (July 19, 2011).

[34] 44 U.S.C. 3508: Determination of necessity for information; hearing

Before approving a proposed collection of information, the Director [of the Office of Management and Budget] shall determine whether the collection of information by the agency is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility. Before making a determination the Director may give the agency and other interested persons an opportunity to be heard or to submit statements in writing. To the extent, if any, that the Director determines that the collection of information by an agency is unnecessary for any reason, the agency may not engage in the collection of information.

[35] 44 U.S.C. 3502(11). In determining whether information will have ''practical utility,'' OMB will consider ''whether the agency demonstrates actual timely use for the information either to carry out its functions or make it available to third-parties or the public, either directly or by means of a third-party or public posting, notification, labeling, or similar disclosure requirement, for the use of persons who have an interest in entities or transactions over which the agency has jurisdiction.'' 5 CFR 1320.3(l).

[36] Cmt. 2 at 13.

[37] Clayton Act Sections 7A(c)(6) and (c)(8) exempt from the requirements of the premerger notification program certain transactions that are subject to the approval of other agencies, but only if copies of the information submitted to these other agencies are also submitted to the FTC and the Assistant

Continued

assumed 37 hours per filing multiplied by $460/hour), and for filings requiring more precise valuation for fee determination purposes, it is $18,400 (based on an assumed 40 hours per filing, multiplied by $460/hour).

In the PNO's experience, Comment 2's Supplemental Letter substantially overestimates the costs of preparing an HSR filing. First, Comment 2's estimate suggests that the cost of preparing the HSR filing would depend in substantial part on the number of people involved in investigating, assessing, negotiating, and approving licensing transactions. In the PNO's experience, however, the competitive impact documents required by the HSR Rules usually reside with a core team of individuals, as not every person with some involvement in the transaction will have the specific documents that must be produced. Indeed, in the PNO's experience, HSR filings for exclusive licensing transactions typically contain fewer documents than company-wide acquisitions or mergers. Moreover, by not differentiating between the acquiring and acquired person, Comment 2's estimate suggests that both parties to a transaction would incur comparable costs. However, the acquired person's costs would be significantly lower, as that person does not have to supply as much information for the HSR form.[38]

In addition, Comment 2's original estimate appears to include the costs of valuing the transactions.[39] Parties to an exclusive patent licensing agreement, however, are very likely to conduct a patent valuation as part of their due diligence for the transaction; accordingly, this is not an additional cost of rule compliance. While in some circumstances a more precise valuation would assist in determining whether a filing is required or the appropriate filing fee, such a more precise estimate would be needed only where the existing estimate is a range that straddles the minimum filing threshold or two filing fee categories.

While the FTC's per transaction estimate is lower than the estimates in Comment 2's Supplemental Letter, the FTC's estimate of the industry-wide incremental costs of filing due to the rule is roughly comparable to Comment 2's original estimate. Comment 2's original estimate stated that the proposed rule amendments would increase the costs of form preparation and document collection, cumulatively, by more than $1,000,000.[40] By comparison, in the NPRM, the FTC stated that, rounding upward the number of expected new filings, this rule would increase the cost burden of the existing Rules by a total of $1,225,000. Without such upward rounding, the estimated burden increase is smaller. Calculating the burden under the assumption that the rule will result in the filing of 30 additional transactions per year, or 60 additional filings, with 10 filings requiring a more precise valuation, the estimated increase in the industry-wide burden is 2,250 hours per year,[41] or $1,035,000 using a rate of $460 per hour.[42] Nevertheless, out of an abundance of caution and in light of the comments, the Commission retains the larger burden increase estimate of 2,664 hours, or $1,225,000.

C. Filing Fees

Comment 2 asserts further that filing fees associated with reporting a transaction covered by the HSR Act should be included in the PRA cost estimates.[43] Filing fees, however, are not part of a respondent's burden of a PRA ''collection of information'' as they are not resources expended ''to generate, maintain, or provide information'' regarding the transactions to the Agencies, *see* 44 U.S.C. 3502(2), but rather are paid pursuant to an accompanying, additional statutory requirement in order to offset the Agencies' expenses. *See* Public Law 106–553, 114 Stat. 2762.

D. Second Requests

Comment 2 also asserts that the costs of responding to additional information requests (''second requests'') should also be included in the PRA estimates.[44] ''Second requests,'' however, are not a ''collection of information'' subject to the PRA because they are issued ''during the conduct of an . . . investigation . . . involving an agency against specific individuals or entities.'' *See* 44 U.S.C. 3518(c)(1)(B)(ii); 5 CFR 1320.4(a)(2).

Accordingly, the FTC retains its previously published estimates that the amendments will yield an additional 2,664 burden hours and approximately $1,225,000 in associated labor costs (based on an assumed hourly rate of $460 per hour).

List of Subjects in 16 CFR Part 801

Antitrust.

For the reasons stated in the preamble, the Federal Trade Commission amends 16 CFR part 801 as set forth below:

PART 801—COVERAGE RULES

■ 1. The authority citation for part 801 continues to read as follows:

Authority: 15 U.S.C. 18a(d).

■ 2. Amend § 801.1 by adding paragraphs (o), (p) and (q) to read as follows:

§ 801.1 Definitions.

* * * * *

(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).

(p) *Limited manufacturing rights.* For purposes of paragraph (o) of this section and paragraph (g) of § 801.2, the term limited manufacturing rights means the rights retained by a patent holder to manufacture the product(s) covered by a patent when all other exclusive rights to the patent within a therapeutic area (or specific indication within a therapeutic area) have been transferred to the recipient of the patent rights. The retained right to manufacture is limited in that it is retained by the patent holder solely to provide the recipient of the patent rights with product(s) covered by the patent (which either the patent holder alone or both the patent holder and the recipient may manufacture).

(q) *Co-rights.* For purposes of paragraph (o) of this section and paragraph (g) of § 801.2, the term co-rights means shared rights retained by

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 × 40 burden hours) = 2,250 burden hours]. Even assuming, however, that two thirds of the transactions would require a more precise valuation, the total estimated burden hours are not significantly higher. [(40 filings × 37 burden hours) + (20 filings requiring a more precise valuation × 40 burden hours) = 2280].

[42] As noted above, because the acquired person (or licensor) would be submitting less information for the HSR form than the acquiring person (or licensee), it would have a smaller burden than the acquiring person. Nevertheless, for purposes of this rulemaking, the FTC will assume that, like the acquiring person, the acquired person will incur a burden of 37 hours per filing.

[43] Cmt. 2 at 14.

[44] *Id* at 14–15.

the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent. These co-rights include, but are not limited to, co-development, co-promotion, co-marketing and co-commercialization.

■ 3. Amend § 801.2 by adding paragraph (g) to read as follows:

§ 801.2 Acquiring and acquired persons.

* * * * *

(g) Transfers of patent rights within NAICS Industry Group 3254.

(1) This paragraph applies only to 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

(2) The transfer of patent rights covered by this paragraph constitutes an asset acquisition; and

(3) Patent rights are transferred if and only if all commercially significant rights to a patent, as defined in § 801.1(o), for any therapeutic area (or specific indication within a therapeutic area) are transferred to another entity. All commercially significant rights are transferred even if the patent holder retains limited manufacturing rights, as defined in § 801.1(p), or co-rights, as defined in § 801.1(q).

Examples: Although these examples refer to licenses, which are typically used to effect the transfer of pharmaceutical patent rights to a recipient of those rights, other methods of transferring patent rights, by assignment or grant, among others, are similarly covered by these rules and examples.

1. B holds a patent relating to an active pharmaceutical ingredient for cardiovascular use. A will obtain a license from B that grants A the exclusive right to all of B's patent rights except that both A and B can manufacture the active pharmaceutical ingredient to be sold by A under the exclusive license agreement. B retains limited manufacturing rights as defined in § 801.1(p) because it retains the right to manufacture the product covered by the patent for cardiovascular use solely to provide the product to A. A is still receiving all commercially significant rights to the patent, and the transfer of these rights via the license constitutes an asset acquisition. Further, even if B retained all rights to manufacture (so that A could not manufacture), B would still retain limited manufacturing rights, and A would still receive all commercially significant rights to the patent. Thus, the transfer of these rights via the license would also constitute an asset acquisition.

2. B holds a patent for an in-vitro diagnostic substance relating to arthritis. B will grant A an exclusive license to all of B's patent rights for all veterinary indications. B retains all patent rights for all human indications. The exclusive license to all commercially significant rights for all veterinary indications is an asset acquisition because A is receiving all rights to the patent for a therapeutic area.

3. B holds a patent relating to a biological product. B will grant A an exclusive license to all of B's patent rights in all therapeutic areas. A and B are also entering into a co-development and co-commercialization agreement under which B will assist A in developing, marketing and promoting the product to physicians. B cannot separately use the patent in the same therapeutic area as A under the co-development and co-commercialization agreement. A will book all sales of the product and will pay B a portion of the profits resulting from those sales. Despite B's retention of these co-rights, A is still receiving all commercially significant rights. The licensing agreement is an asset acquisition. This would be an asset acquisition even if B also retained limited manufacturing rights.

4. B holds a patent relating to an active pharmaceutical ingredient and a bulk compound that contains that active pharmaceutical ingredient. B will grant A an exclusive license to use the bulk compound to manufacture and sell a finished product in the neurological therapeutic area. B cannot manufacture the active pharmaceutical ingredient or bulk compound for any other finished products in the neurological area, but it can manufacture either for use by another party in a different therapeutic area. Despite B's retention of manufacturing rights of the active pharmaceutical ingredient and bulk compound for therapeutic areas other than neurology, A is still receiving all commercially significant rights in a therapeutic area and the licensing agreement is the acquisition of an asset.

5. B holds a patent related to a pharmaceutical product that has been approved by the FDA. B will enter into an exclusive distribution agreement with A that will give A the right to distribute the product in the U.S. B will manufacture the product for A and will receive a portion of all revenues from the sale of the product. A receives no exclusive patent rights under the distribution agreement. A has not obtained all commercially significant rights to the patent because it is only handling the logistics of selling and distributing the product on B's behalf. Therefore, the exclusive distribution agreement is not an asset acquisition.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–27027 Filed 11–14–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2011–C–0878]

Listing of Color Additives Exempt From Certification; Spirulina Extract; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of September 13, 2013, for the final rule that appeared in the **Federal Register** of August 13, 2013. The final rule amended the color additive regulations to provide for the safe use of spirulina extract made from the dried biomass of the cyanobacteria *Arthrospira platensis* (*A. platensis*), as a color additive in candy and chewing gum.

DATES: The effective date for the final rule published August 13, 2013 (78 FR 49117), is confirmed as September 13, 2013.

FOR FURTHER INFORMATION CONTACT: Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1264.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 13, 2013 (78 FR 49117), we amended the color additive regulations to add § 73.530 *Spirulina extract* (21 CFR 73.530) to provide for the safe use of spirulina extract made from the dried biomass of the cyanobacteria *A. platensis,* as a color additive in candy and chewing gum.

We gave interested persons until September 12, 2013, to file objections or