[Billing Code: 6750-01S]

FEDERAL TRADE COMMISSION

16 CFR Part 801

Premerger Notification; Reporting and Waiting Period Requirements

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is proposing amendments to the premerger notification rules ("the Rules") to provide a framework for determining when a transaction involving the transfer of rights to 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" or "HSR"). The Act and Rules require the parties to certain mergers and acquisitions to file reports with the Federal Trade Commission ("the Commission") and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice ("the Assistant Attorney General") (collectively, "the Agencies") and to wait a specified period of time before consummating such transactions. The reporting and waiting period requirements are intended to enable these enforcement 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. This proposed rulemaking uses the concept of "all commercially significant rights" as the basis to determine whether there is a transfer of exclusive

rights to a patent in the pharmaceutical industry resulting in an asset acquisition that may be reportable under the Act.

DATES: Comments must be received on or before October 25, 2012.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "HSR IP Rulemaking, Project No. P989316" on your comment, and file your comment online at https://ftcpublic.commentworks.com/ftc/hsripnprm, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex Q), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Robert L. Jones, Deputy Assistant Director, Premerger Notification Office, Bureau of Competition, Room 302, Federal Trade Commission, Washington, DC 20580. Telephone: (202) 326-3100.

SUPPLEMENTARY INFORMATION:

Invitation to Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 25, 2012. Write "HSR IP Rulemaking, Project No. P989316" on your comment. Your comment – including your name and your state – will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

https://ftcpublic.commentworks.com/ftc/hsripnprm, by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "HSR IP Rulemaking, Project No. P989316" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex Q), 600 Pennsylvania Avenue, NW, Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 25, 2012. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

Statement of Basis and Purpose

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.

In this proposed rulemaking, the Commission proposes amending §801.1 and §801.2 to reflect the longstanding staff position that a transaction involving the transfer of exclusive rights to a patent in the pharmaceutical industry, which typically takes the form of an exclusive license, is potentially reportable under the Act. The proposed rules define and apply the concepts of "all commercially significant rights," "limited manufacturing rights," and "co-rights" in determining whether the rights transferred with regard to a patent in the pharmaceutical industry constitute a potentially reportable asset acquisition.

PART 801 - COVERAGE RULES

Section 801.2 Acquiring and Acquired Persons.

I. Background

The Act applies to reportable acquisitions of voting securities, controlling non-corporate interests,[2] and assets. Determining whether a transaction is reportable requires applying the statute, supporting regulations, formal interpretations, and informal staff interpretations. As the

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

Act covers asset acquisitions, and a patent is an asset,[3] it is usually a straightforward process to determine whether the acquisition of a patent triggers a reporting obligation under the Act.[4]

Determining whether the transfer of rights to a patent is an asset acquisition, and thus potentially reportable, is usually a more challenging analysis. From an early point, the Premerger Notification Office ("PNO") analyzed these transactions by focusing on whether the exclusive rights to "make, use and sell" under a patent were being transferred by the license. That is, the focus was on the transfer of the bundle of rights to use a patent to exclusively manufacture a product, develop the product for all potential uses, and sell that product without restriction. The transfer of this bundle of rights is seen as a potentially reportable asset acquisition under the Act. If the licensor retains the right to manufacture, the deal is, in most instances, non-reportable. For instance, some licensing agreements involve the exclusive use and sale of a patent, but typically allow the licensor to retain manufacturing rights for the patent. Under the current PNO approach, these exclusive licenses are not reportable since, without the right to manufacture, they are viewed as distribution agreements rather than asset acquisitions.

Although this basic approach was never codified, it became well-known throughout the HSR bar and is reflected in the letters and emails from practitioners in the PNO's informal interpretation database. While each situation in the database is factually unique, the questions

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[3] Indeed, 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).

[4] This rulemaking proposes to define when the transfer of rights to a pharmaceutical 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.

from practitioners overwhelmingly focus on exclusive licenses in the pharmaceutical industry where the licensor grants some rights but retains others. In those situations, PNO staff was asked to analyze the retained rights to determine if an asset acquisition was taking place. The retained rights typically fall into two categories: manufacturing rights and co-rights.

(a) Retention of Manufacturing Rights

As mentioned above, if the licensee was not granted the right to manufacture, but only the rights to use and sell, PNO staff viewed this as a non-reportable event because the license appeared essentially to be a distribution agreement. Yet, in licensing arrangements in the pharmaceutical industry, the right to manufacture is far less important than the right to commercialize. In fact, the right to manufacture is often retained by the licensor who has the relevant manufacturing expertise and facilities. As a result, pharmaceutical companies often enter into licenses in which the licensee receives the exclusive right to use and sell under the license, but the licensor retains the right to manufacture exclusively for the licensee. As the licensor is manufacturing solely for the use of the licensee, this is substantively the same as giving the licensee the exclusive right to manufacture, use and sell the product(s) covered by the license.

The proposed rule would treat this kind of exclusive license agreement as a potentially reportable asset acquisition. This aspect of the rule is a significant change in the weight given to manufacturing rights in determining whether or not exclusive rights to a patent are being transferred. Under the proposed rules, if the licensor retains the right to manufacture exclusively for the licensee, it is a potentially reportable asset acquisition because all commercially significant rights, as discussed below, will still have passed to the licensee.

(b) Retention of Co-Rights

In the pharmaceutical industry, a licensor also often retains co-rights in granting an exclusive license. Co-rights cover the shared responsibility for seeing the licensed product through the Food and Drug Administration ("FDA") approval process and then marketing and promoting the product. For example, the licensee is granted the exclusive right to make, use and sell a product, but the patent holder retains the right to co-develop and co-market the product along with the licensee. The licensor generally retains co-rights to assist the licensee in maximizing the licensee's sales of the licensed product so that the licensor might have a more robust royalty revenue stream or other revenue sharing arrangement.

Under current policy, the retention of these rights does not render the license non-exclusive. In the PNO's experience, when the licensor retains co-rights, typically only the licensee can use the patent rights as it strives to gain FDA approval for the pharmaceutical product, and any eventual royalty stream or other revenue sharing mechanism flows from this exclusivity. So, 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 use the patent. This approach will not change under the proposed "all commercially significant rights" concept.

(c) Limitation to the Pharmaceutical Industry

PNO staff has extensive experience providing advice regarding the transfer of rights to a patent through exclusive licenses in the pharmaceutical industry. In the PNO's view, the pharmaceutical industry presents unique incentives for the use of exclusive licenses. For example, in a scenario the PNO has seen quite frequently, an innovator discovers a compound,

but that innovator does not have the financial resources to shepherd the compound through the approval process required by the FDA, nor to effectively market or promote it in drug form after FDA approval. Thus, the innovator will enter into an exclusive licensing agreement with a (typically much larger) pharmaceutical company to provide the financial resources for the FDA approval process and the eventual marketing and promotion of the drug. There is a great deal of uncertainty involved, as neither party to the exclusive licensing agreement knows whether the compound will actually become an approved drug and be commercially successful. But if the drug is successful, the licensee will be able to book enormous profits, some of which will be shared with the licensor through royalties or other revenue sharing arrangements. Given its financial investment, the licensee wants the exclusive right to as much of these profits as possible to recoup its costs. The result is an exclusive license agreement that is, in the PNO's experience, unlike that seen in any other industry.

As a result of these unique incentives and because, in the PNO staff's experience, these arrangements have been limited to the pharmaceutical industry, the Commission has limited the proposed rule to analyzing the transfer of rights to a patent in the pharmaceutical industry. Thus, the proposed rule is limited to those specific NAICS codes that involve the pharmaceutical industry. Although the proposed rule is limited to the pharmaceutical industry, the transfer of exclusive rights to a patent in other industries remains a potentially reportable event under the Act. Parties dealing with exclusive rights to a patent in other industries should consult PNO staff, which will consider such questions on a case-by-case basis.

II. All Commercially Significant Rights

Although the typical mechanism used to transfer exclusive rights to a patent in the pharmaceutical industry is a license, the proposed rule does not use this term and instead focuses on the broader concept of exclusive rights to a patent in defining the key concept of "all commercially significant rights." This broad language is intended to keep the focus on the substance of what is being transferred, not the form of the transfer. Thus, any transfer of exclusive rights to a patent in the pharmaceutical industry is a potentially reportable event, regardless of whether this transfer is called an exclusive license or something else.

The proposed rule focuses on the transfer of exclusive rights to a pharmaceutical patent in a particular therapeutic area. A therapeutic area covers the intended use for 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. As discussed above, the proposed rule emphasizes the substance of what is being transferred, not the form that this transfer takes, even though the transfer will most often occur in the form of an exclusive license. When the recipient, typically a licensee, receives the exclusive rights to the patent in a therapeutic area, it is receiving the exclusive right to use the patent in that therapeutic area.

"All commercially significant rights," as defined in proposed §801.1(o), flow from the exclusive rights to a patent. As a result of these exclusive rights, only the recipient has the right to use the patent in a particular therapeutic area, or specific indications within that therapeutic area, to generate eventual profits (some of which will be shared with the licensor through

royalties or other revenue sharing arrangements). The recipient alone gains all commercially significant rights to the patent through the transfer of the exclusive rights to it.

In transferring exclusive rights to a patent in the pharmaceutical industry, the patent holder will often retain "co-rights," as defined by proposed §801.1(q). As discussed above, in the PNO's experience, a licensor will often grant the licensee an exclusive license to make, use and sell a product, but retain co-rights to assist the licensee in maximizing its sales of the licensed product. All sales are booked by the licensee, but the licensor benefits as a result of a more robust royalty revenue stream or other revenue sharing arrangements. The key is that, in retaining these kinds of rights, the licensor does not retain the right to use the patent in the same therapeutic area.

Under current policy, the patent holder's retention of these rights does not render the license non-exclusive, and under the proposed rule, will not affect the transfer of all commercially significant rights to the licensee. As a result, the all commercially significant rights test reflects the PNO staff's existing position on the reportability of exclusive licenses in which the patent holder retains co-rights.

The proposed all commercially significant rights test does, however, establish a new approach to the analysis of manufacturing rights under an exclusive license. Under the proposed rule, when the licensor retains the right to manufacture exclusively for the licensee, it will retain "limited manufacturing rights," as defined by proposed §801.1(p). In retaining these rights, the licensor does not retain the right to use the patent in the same therapeutic area. As in the case of co-rights, the licensor retains limited manufacturing rights to aid the licensee's efforts to market and sell the product and generate royalties in that therapeutic area. Thus, when it retains limited

manufacturing rights, the licensor is still transferring all commercially significant rights to the licensee and a potentially reportable asset acquisition is taking place.

In sum, the proposed all commercially significant rights test should greatly simplify the question of whether an asset acquisition is occurring as the result of the transfer of rights to a patent in the pharmaceutical industry. In addition, the proposed test makes clear that the retention of certain rights, such as "limited manufacturing rights" and "co-rights," does not affect whether the transfer of all commercially significant rights has occurred. The proposed rule thus clarifies the analysis of the reportability of transfers of pharmaceutical patent rights while providing the Agencies with a better opportunity to review the transfers of exclusive rights to a patent in the pharmaceutical industry for competitive concerns. The Commission believes these benefits outweigh any additional burden on filing parties.

Communications by Outside Parties to Commissioners and Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor will be placed on the public record. 16 CFR 1.26(b)(5).

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601-612, requires that the agency conduct an initial and final regulatory analysis of the anticipated economic impact of the proposed amendments on small businesses, except where the Commission certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605.

Because of the size of the transactions necessary to invoke an HSR filing, the premerger notification rules rarely, if ever, affect small businesses. The 2000 amendments to the Act exempted all transactions valued at $50 million or less, with subsequent automatic adjustments to take account of changes in GNP resulting in a current threshold of $68.2 million. Further, none of the proposed rule amendments expands the coverage of the premerger notification rules in a way that would affect small business. Accordingly, the Commission certifies that these proposed rules will not have a significant economic impact on a substantial number of small entities. This document serves as the required notice of this certification to the Small Business Administration.

Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501-3521, 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 information collection requirements in the HSR rules and Form have been reviewed and approved by OMB under OMB Control No. 3084-0005. The current clearance expires on August 31, 2014. Because the rule amendments proposed in this NPR would change existing reporting requirements, the Commission is submitting a Supporting Statement for Information Collection Provisions to OMB.

To estimate the impact of this proposed rulemaking on the number of filings, PNO staff reviewed letters from outside counsel discussing non-reportable transactions that would be reportable under this proposal. The average annual number of letters over the past five years was 21. Consultations with several outside practitioners who are heavily involved in analyzing HSR

reportability for patent licensing in the pharmaceutical industry indicate that there are an estimated 9 additional transactions per year that fall into this category and are not confirmed by letter with staff.

Consequently, PNO staff estimates that there will be an increase of 30 transactions per year requiring non-index HSR filings due to the proposed rule change.[5] The outside practitioners who were contacted by staff agreed that this is a reasonable estimate. Based on the FTC's projection of 1,500 total transactions per year, this represents a 2% increase due to the proposed rules, averaged from annual expected filings in FY2012-2014 (30 ÷ 1500 = .02 or 2%). As a result, staff estimates that the total burden hours under the HSR rules as revised will be 56,420 hours, an increase of 2,664 hours from the staff's estimate of 53,756 hours for the current Rules.[6] Similarly, staff estimates the labor costs under the proposed rules will be $25,953,000

[5] "Index" filings pertain to banking transactions, and thus would not be affected by the proposed amendments. Index filings are incorporated, however, into the FTC's currently cleared burden estimates (the FTC has jurisdiction over the administration of index filings). They are mentioned here to distinguish them from and to further explain what a "non-index" filing is. 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 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), as illustrated by the calculations in footnote 6 below.

[6] The currently cleared estimate was calculated as follows: [(1428 non-index filings x 37 hours) + (22 transactions requiring more precise valuation x 40 hours) + (20 index filings x 2 hours) = 53,756 hours]. See 76 FR 42471, 42479 (July 19, 2011). Staff estimates that the proposed rules will increase by 30 the number of transactions that require non-index filings, resulting in an estimate of 1,500 filings per year, averaged from FY2012 to FY2014, coinciding closely with the current clearance duration. Accordingly, staff estimates the hours burden for the proposed rule as follows: [(1,500 non-index filings x 37 hours) + (22 transactions requiring more precise valuation x 40 hours) + (20 index filings x 2 hours) = 56,420 hours.]. Associated labor costs: 56,420 hours x $460/hour for executives and attorneys' wages = $25,953,000.

(rounded to the nearest thousand), an increase of approximately $1,225,000 from the estimate of $24,728,000 for the current rules.

PNO staff believes that any incremental capital/non-labor costs presented by the proposed amendments would be marginal. Businesses subject to the HSR Rules generally have or would obtain necessary equipment for other business purposes. Staff believes that the existing requirements (and proposed extension to certain additional transactions) necessitate ongoing, regular training so that covered entities stay current and have a clear understanding of federal mandates. This should constitute a small portion of and be subsumed within the ordinary training that employees receive apart from that associated with the information collected under the HSR Rules and the corresponding Notification and Report Form.

The Commission invites comments that will enable it to: (1) evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collections of information on those who must comply.

Comments on any proposed reporting requirements that are subject to OMB review under the PRA should additionally be submitted to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Federal Trade Commission.

Comments should be submitted via facsimile to (202) 395–5167 because U.S. postal mail at the OMB is subject to lengthy delays due to heightened security precautions.

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) above 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) above and paragraph (g) of §801.2, the term *co-rights* means shared rights retained by the patent holder to assist the recipient of the exclusive

patent rights in developing and commercializing the product covered by the patent. 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 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 distribution agreement is not an asset acquisition.

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By direction of the Commission.

Donald S. Clark,
Secretary.