products within industries in Sectors 31–33 as coded by the North American Industry Classification System (2002 Edition) published by the Executive Office of the President, Office of Management and Budget.

(k) *United States*. The term *United States* shall include the several States, the territories, possessions, and commonwealths of the United States, and the District of Columbia.

(l) *Commerce*. The term *commerce* shall have the meaning ascribed to that term in section 1 of the Clayton Act, 15 U.S.C. 12, or section 4 of the Federal Trade Commission Act, 15 U.S.C. 44.

(m) *The act*. References to ''the act'' refer to Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by section 201 of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. 94–435, 90 Stat. 1390, and as amended by Pub. L. 106–553, 114 Stat. 2762. References to ''Section 7A( )'' refer to subsections of Section 7A of the Clayton Act. References to ''this section'' refer to the section of these rules in which the term appears.

(n) (*as adjusted*). The parenthetical ''(as adjusted)'' refers to the adjusted values published in the FEDERAL REGISTER notice titled ''Revised Jurisdictional Threshold for Section 7A of the Clayton Act.'' This FEDERAL REGISTER notice will be published in January of each year and the values contained therein will be effective as of the effective date published in the FEDERAL REGISTER notice and will remain effective until superseded in the next calendar year. The notice will also be available at *http://www.ftc.gov*. Such adjusted values will be calculated in accordance with Section 7A(a)(2)(A) and will be rounded up to the next highest $100,000.

(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 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.

[43 FR 33537, July 31, 1978, as amended at 48 FR 34429, July 29, 1983; 52 FR 20063, May 29, 1987; 66 FR 8687, Feb. 1, 2001; 66 FR 23565, May 9, 2001; 68 FR 2430, Jan. 17, 2003; 70 FR 4990, Jan. 31, 2005; 70 FR 11510, Mar. 8, 2005; 70 FR 73372, Dec. 12, 2005; 70 FR 77313, Dec. 30, 2005; 76 FR 42479, July 19, 2011; 78 FR 68712, Nov. 15, 2013]

§ 801.2 Acquiring and acquired persons.

(a) Any person which, as a result of an acquisition, will hold voting securities or assets, either directly or indirectly, or through fiduciaries, agents, or other entities acting on behalf of such person, is an acquiring person.

Example: Assume that corporations A and B, which are each ultimate parent entitles of their respective ''persons,'' created a joint venture, corporation V, and that each holds half of V's shares. Therefore, A and B each control V (see § 801.1(b)), and V is included within two persons, ''A'' and ''B.'' Under this section, if V is to acquire corporation X, both ''A'' and ''B'' are acquiring persons.

(b) Except as provided in paragraphs (a) and (b) of § 801.12, the person(s) within which the entity whose assets or voting securities are being acquired is included, is an acquired person.

Examples: 1. Assume that person ''Q'' will acquire voting securities of corporation X held by ''P'' and that X is not included within person ''P.'' Under this section, the acquired person is the person within which X is included, and is not ''P.''

2. In the example to paragraph (a) of this section, if V were to be acquired by X, then both ''A'' and ''B'' would be acquired persons.

(c) For purposes of the act and these rules, a person may be an acquiring person and an acquired person with respect to separate acquisitions which comprise a single transaction.

(d)(1)(i) Mergers and consolidations are transactions subject to the act and shall be treated as acquisitions of voting securities.

(ii) In a merger, the person which, after consummation, will include the corporation in existence prior to consummation which is designated as the surviving corporation in the plan, agreement, or certificate of merger required to be filed with State authorities to effectuate the transaction shall be deemed to have made an acquisition of voting securities.

(2)(i) Any person party to a merger or consolidation is an acquiring person if, as a result of the transaction, such person will hold any assets or voting securities which it did not hold prior to the transaction.

(ii) Any person party to a merger or consolidation is an acquired person if, as a result of the transaction, the assets or voting securities of any entity included within such person will be held by any other person.

(iii) All persons party to a transaction as a result of which all parties will lose their separate pre-acquisition identities or will become wholly owned subsidiaries of a newly formed entity shall be both acquiring and acquired persons. This includes any combination of corporations and unincorporated entities consolidating into any newly formed entity. In such transactions, each consolidating entity is deemed to be acquiring all of the voting securities (in the case of a corporation) or interests (in the case of an unincorporated entity) of each of the others.

Examples: 1. Corporation A (the ultimate parent entity included within person ''A'') proposes to acquire Y, a wholly-owned subsidiary of B (the ultimate parent entity included within person ''B''). The transaction is to be carried out by merging Y into X, a wholly-owned subsidiary of A, with X surviving, and by distributing the assets of X to B, the only shareholder of Y. The assets of X consist solely of cash and the voting securities of C, an entity unrelated to ''A'' or ''B''. Since X is designated the surviving corporation in the plan or agreement of merger or consolidation and since X will be included in ''A'' after consummation of the transaction, ''A'' will be deemed to have made an acquisition of voting securities. In this acquisition, ''A'' is an acquiring person because it will hold assets or voting securities it did not hold prior to the transaction, and ''B'' is an acquired person because the assets or the voting securities of an entity previously included within it will be held by A as a result of the acquisition. B will hold the cash and voting securities of C as a result of the transaction, but since § 801.21 applies, this acquisition is not reportable. ''A'' is therefore an acquiring person only, and ''B'' is an acquired person only. ''B'' may, however, have a separate reporting obligation as an acquiring person in a separate transaction involving the voting securities of C.

2. In the above example, suppose the consideration for Y consists of $8 million worth of the voting securities of A. With regard to the transfer of this consideration, ''B'' is an acquiring person because it will hold voting securities it did not previously hold, and ''A'' is an acquired person because its voting securities will be held by B. Since these voting securities are worth less than $50 million (as adjusted), the acquisition of these securities is not reportable. ''A'' will therefore report as an acquiring person only and ''B'' as an acquired person only.

3. In the above example, suppose that, as consideration for Y, A transfers to B a manufacturing plant valued in excess of $50 million (as adjusted). ''B'' is thus an acquiring person and ''A'' an acquired person in a reportable acquisition of assets. ''A'' and ''B'' will each report as both an acquiring and an acquired person in this transaction because each occupies each role in a reportable acquisition.

4. Corporations A (the ultimate parent entity in person ''A'') and B (the ultimate parent entity in person ''B'') propose to consolidate into C, a newly formed corporation. All shareholders of A and B will receive shares of C, and both A and B will lose their separate pre-acquisition identities. ''A'' and ''B'' are both acquiring and acquired persons because they are parties to a transaction in which all parties lose their separate pre-acquisition identities

5. Partnership A and Corporation B form a new LLC in which they combine their businesses. A and B cease to exist and partners of A and shareholders of B receive membership interests in the new LLC. For purposes of determining reportability, A is deemed to be acquiring 100 percent of the voting securities

of B and B is deemed to be acquiring 100 percent of the interests of A. Pursuant to § 803.9(b) of this chapter, even if such a transaction consists of two reportable acquisitions, only one filing fee is required.

(e) Whenever voting securities or assets are to be acquired from an acquiring person in connection with an acquisition, the acquisition of voting securities or assets shall be separately subject to the act.

(f)(1)(i) In an acquisition of non-corporate interests which results in an acquiring person controlling the entity, that person is deemed to hold all of the assets of the entity as a result of the acquisition. The acquiring person is the person acquiring control of the entity and the acquired person is the pre-acquisition ultimate parent entity of the entity.

(ii) The value of an acquisition described in paragraph (f)(1)(i) of this section is determined in accordance with § 801.10(d).

(2) Any contribution of assets or voting securities to an existing unincorporated entity or to any successor thereof is deemed an acquisition of such voting securities or assets by the ultimate parent entity of that entity and is not subject to § 801.50.

Examples: 1. A, B and C each hold 33⅓ percent of the interests in Partnership X. D contributes assets valued in excess of $50 million (as adjusted) to X and as a result D receives 40 percent of the interests in X and A, B and C are each reduced to 20 percent. Partnership X is deemed to be acquiring the assets from D, in a transaction which may be reportable. This is not treated as a formation of a new partnership. Because no person will control Partnership X, no additional filing is required by any of the four partners.

2. LLC X is its own ultimate parent entity. A contributes a manufacturing plant valued in excess of $200 million (as adjusted) to X which issues new interests to A resulting in A having a 50% interest in X. A is acquiring non-corporate interests which confer control of X and therefore will file as an acquiring person. Because A held the plant prior to the transaction and continues to hold it through its acquisition of control of LLC X after the transaction is completed no acquisition of the plant has occurred and LLC X is therefore not an acquiring person.

(3) Any person who acquires control of an existing not-for-profit corporation which has no outstanding voting securities is deemed to be acquiring all of the assets of that corporation.

Example: A becomes the sole corporate member of not-for-profit corporation B and accordingly has the right to designate all of the directors of B. A is deemed to be acquiring all of the assets of B as a result.

(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.

[43 FR 33537, July 31, 1978, as amended at 48 FR 34431, July 29, 1983; 66 FR 8688, Feb. 1, 2001; 70 FR 4990, Jan. 31, 2005; 70 FR 11510, Mar. 8, 2005; 78 FR 68713, Nov. 15, 2013]

§ 801.3 Activities in or affecting commerce.

Section 7A(a)(1) is satisfied if any entity included within the acquiring person, or any entity included within the acquired person, is engaged in commerce or in any activity affecting commerce.

Examples: 1. A foreign subsidiary of a U.S. corporation seeks to acquire a foreign business. The acquiring person includes the U.S. parent corporation. If the U.S. corporation, or the foreign subsidiary, or any entity controlled by either one of them, is engaged in commerce or in any activity affecting commerce, section 7A(a)(1) is satisfied. Note, however, that §§ 802.50–802.52 may exempt certain acquisitions of foreign businesses or assets.

2. Even if none of the entities within the acquiring person is engaged in commerce or in any activity affecting commerce, the acquisition nevertheless satisfies section 7A(a)(1) if any entity included within the acquired person is so engaged.

[43 FR 33537, July 31, 1978; 43 FR 36054, Aug. 15, 1978]

§ 801.4 Secondary acquisitions.

(a) Whenever as the result of an acquisition (the ''primary acquisition'')