IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. Federal Trade Commission, Defendant.	Case No. 13-cv-1974 (BAH)

DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant Federal Trade Commission ("Commission") hereby respectfully moves this Court to enter summary judgment pursuant to Fed. R. Civ. P. 56 for the Commission on all claims asserted in Plaintiff's Complaint. Pursuant to Local Rule 7(a) and (h)(2), this motion is supported by the accompanying Memorandum of Points and Authorities. Pursuant to Local Rule 7(f) and the Court's Standing Order 5(b), Defendant requests a hearing on this motion, should the Court deem it helpful for resolution of this case.

Respectfully Submitted,

JONATHAN E. NUECHTERLEIN, DC Bar # 442470
General Counsel

JOHN F. DALY, DC Bar No. 250217
Deputy General Counsel for Litigation

JOEL MARCUS, DC Bar No. 428680
Assistant General Counsel

MICHELE ARINGTON, DC Bar No. 434082
Attorney
600 Pennsylvania Avenue, N.W.
Washington, DC 20580
(202) 326-3157

Of Counsel:

J. Robert Kramer II
General Counsel

Nancy M. Olson
Deputy General Counsel-Civil
D.C. Bar No. 444801

U.S. Department of Justice
Antitrust Division
950 Pennsylvania Ave., NW
Washington, DC 20530

Dated: March 10, 2014

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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. Federal Trade Commission, Defendant.	Case No. 13-cv-1974 (BAH)

DEFENDANT FEDERAL TRADE COMMISSION'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

JONATHAN E. NUECHTERLEIN
General Counsel
DC Bar No. 442470

JOHN F. DALY
Deputy General Counsel for Litigation
DC Bar No. 250217

JOEL MARCUS
Assistant General Counsel
DC Bar No. 428680

MICHELE ARINGTON
Attorney
DC Bar No. 434082
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580
(202) 326-3157

Of Counsel:

J. Robert Kramer II
General Counsel

Nancy M. Olson
Deputy General Counsel-Civil
D.C. Bar No. 444801

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PRELIMINARY STATEMENT

In challenging the Commission's Rule identifying when transfers of exclusive patent rights constitute asset acquisitions under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"), Plaintiff principally complains that the Rule is too narrow. Plaintiff argues that the Commission exceeded the scope of its statutory authority in issuing a rule limited to the pharmaceutical industry, and that the Commission lacked adequate justification for an industry-specific rule. These arguments, however, do not call into question the substantive standard contained in the Rule. Nor do they call into question the Commission's authority, as a general matter, to impose HSR notification requirements on Plaintiff's members. The only question, then, is whether the Rule must apply to all industries and not just the one that Plaintiff represents. The Commission appropriately determined that it need not.

Congress delegated to the Commission broad authority to determine the rules for premerger notification reporting. Plaintiff asserts that Congress intended to prohibit the Commission from prescribing notification requirements on an industry-specific basis. But there is not a shred of support for that claim in either the text of the HSR Act or its legislative history. In contending otherwise, Plaintiff badly mischaracterizes the legislative history. The passages it cites show merely that Congress did not intend to allow the Commission to require particular companies or industries to report transactions falling *below the Act's minimum thresholds*. But all the transactions covered by the Rule will be *above* those thresholds. Because Congress never addressed the issue of industry-specific rules for transactions that meet the Act's monetary thresholds, the Commission's interpretation of the Act to permit such rules is entitled to *Chevron* deference. And the Commission's implementation of its authority is reasonable and fully comports with the well-established principle that, in promulgating regulations, 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.' " *Nat'l Ass'n of Broadcasters v. FCC*, 740 F.2d 1190, 1207 (D.C.Cir.1984) (quoting *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955)).

The Commission provided ample explanation for its adoption of the Rule and articulated a clear connection between its factual findings and its judgment that a rule addressing transfers of exclusive patent rights in the pharmaceutical industry is appropriate. In particular, the Commission explained its reasons for limiting the Rule's application to transactions occurring in that industry. The Commission carefully considered Plaintiff's comments, including the report of its expert, but found them unpersuasive. That decision was reasonable, and this Court should grant summary judgment for the Commission.

BACKGROUND

A. The Premerger Notification Program

The HSR Act, 15 U.S.C. § 18a, requires persons intending to "acquire, directly or indirectly, any voting securities or assets of any other person," to file notification with the Commission and the Antitrust Division of the Department of Justice ("DOJ") and wait a designated period of time before consummating such transactions. These reporting requirements apply to an "acquisition" that meets or exceeds certain monetary jurisdictional thresholds.[1] The

[1] The Commission is required to revise the reportability thresholds annually, based on the change in the level of gross national product. The minimum size of transaction threshold as of February 24, 2014, is $75.9 million with one person having sales or assets of at least $151.7 million and the other person having sales or assets of at least $15.2 million. *See* 79 Fed. Reg. 3814 (Jan. 23, 2014)

main purpose of the Act is to enable the antitrust enforcement agencies to evaluate the competitive implications of large acquisitions before they occur and to permit either agency to seek a preliminary injunction if, after investigation, the agency determines that the transaction is substantially likely to harm competition.[2]

The Act authorizes the Commission, with the concurrence of the DOJ, to prescribe rules implementing the premerger notification program, including to "define the terms used in" the Act, 15 U.S.C. § 18a(d)(2)(A), and "as may be necessary and appropriate to carry out the purposes of" the Act, 15 U.S.C. § 18a(d)(2)(C). The Commission issued initial rules, codified at 16 C.F.R. Parts 801 through 803 (the "HSR Rules"), in 1978, and it has amended those rules on numerous occasions since then to improve the program's effectiveness. The Commission, through its Premerger Notification Office ("PNO"), administers the premerger notification program and has the primary responsibility for explaining the HSR Rules and responding to questions from the public concerning their application. Each year, the PNO answers thousands of inquiries, providing informal guidance on the potential reportability of transactions. *See* Federal Trade Comm'n & U.S. Dep't of Justice, HART SCOTT RODINO ANNUAL REPORT – FISCAL YEAR 2012, at 3, available at http://www.ftc.gov/sites/default/files/documents/reports_annual/35th-report-fy2012/130430hsrreport_0.pdf.[3]

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[2] *See* S. Rep. No. 803, 94th Cong., 2d Sess. 61 (1976) ("The essence of [the premerger notification provision] is the creation of a mechanism to provide advance notification to the antitrust authorities of very large mergers prior to their consummation, and to improve procedures to facilitate enjoining illegal mergers before they are consummated.").

[3] *See also* http://www.ftc.gov/enforcement/premerger-notification-program/informal-interpretations/about-informal-interpretations.

B. Transfers of Exclusive Rights to a Patent

Patents are a type of property, *Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc*, 131 S. Ct. 2188, 2195 (2011), and plainly constitute "assets" under the HSR Act.[4] The transfer of patent rights from one entity to another can have important competitive effects—for example, by consolidating economic control over two competing technologies with the same function. *See SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981) (antitrust violation "will have occurred where . . . the dominant competitor in a market acquires a patent covering a substantial share of the same market that he knows when added to his existing share will afford him monopoly power"). The PNO has long taken the position that the transfer of exclusive rights to a patent is a potentially reportable asset acquisition under the HSR Act because the transaction is substantively the same as an outright sale of the patent and carries the same potential anticompetitive effects. 77 Fed. Reg. 50,057, 50,058 (Aug. 20, 2012);[5] 78 Fed. Reg. 68,705, 68,706 (Nov. 15, 2012);[6] s*ee also* ABA Section of Antitrust Law, PREMERGER NOTIFICATION PRACTICE MANUAL 38 (4th ed. 2007); U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 5.7 (1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 3,132 ("[t]he Agencies will apply a merger analysis to an outright sale by an intellectual property owner of all of its rights to that intellectual property and to a transaction in which a person obtains through grant, sale, or other transfer an exclusive license for intellectual

[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); *accord Crucible, Inc. v. Stora Kopparbergs Bergslags AB*, 701 F. Supp. 1157, 1162 (W.D. Pa. 1988) ("A patent, as a form of property, is an asset and not exempt from scrutiny under Section 7.").

[5] Ex. A to Plaintiff's Motion for Summary Judgment.

[6] Ex. D to Plaintiff's Motion.

property").[7] Under the PNO's approach, to warrant treatment as the acquisition of an asset, the transaction must make the license exclusive even against the licensor. 78 Fed. Reg. at 68,706.

Such exclusive licenses are commonly used in the pharmaceutical industry, which has been making HSR filings involving transfers of exclusive rights to a patent since the early 1980s. 78 Fed. Reg. at 68,706 n.7. Indeed, in the five years preceding this rulemaking, *all* of the 66 HSR filings received by the PNO involving exclusive patent licenses were for pharmaceutical patents. *Id*. at 68,708. And almost all of the requests to the PNO for guidance about the reportability of exclusive patent licenses have concerned transactions in the pharmaceutical industry. *Id*.; 77 Fed. Reg. at 50,059.

In establishing reportability, the parties must determine whether the license conveys the exclusive rights to commercially use the patent or part of a patent. For years, the PNO analyzed these transactions by focusing on whether the license transferred the full panoply of rights recognized under patent law—*i.e.*, the right to "make, use, and sell" under a patent. *See* 35 U.S.C. § 271(a). That is, the PNO's 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. If the patent holder retained any of these rights, PNO staff viewed the transaction as not constituting a reportable "acquisition" of an "asset." 77 Fed. Reg. at 50,058-59; 78 Fed. Reg. at 68,706.

[7] *See also Eastman Kodak Co. v. Goodyear Tire & Rubber Co*., 114 F.3d 1547, 1552 (Fed. Cir. 1997) ("section 7 may prohibit an acquisition, such as the acquisition of some patent licenses"), *overruled on other grounds* by *Cybor Corp. v. FAS Techs., Inc*., 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (*en banc*).

In recent years, however, exclusive patent licensing practices in the pharmaceutical industry have evolved from straightforward grants of the exclusive right to "make, use and sell" under a patent to include, more commonly, arrangements in which a pharmaceutical company transfers most, but not all, of the rights under a patent. For example, a licensor will often retain the right to manufacture under the patent—but may manufacture only for the licensee. 77 Fed. Reg. at 50,059; 78 Fed. Reg. at 68,706. Representatives of pharmaceutical companies have contacted the PNO for guidance about the reportability of licenses involving such terms. 77 Fed. Reg. at 50,059. Such an arrangement may be mutually beneficial as a business matter because of the licensor's manufacturing expertise or possession of a facility already vetted by the Food and Drug Administration ("FDA"). Yet such an arrangement nevertheless may still effect a full transfer, from licensor to licensee, of all competitively relevant rights in products covered by the patent, such as the sole right to decide if and when to commercialize the patent and how to market and price the product covered by the license. Under the PNO's "make, use, and sell" approach, the licensor's retention of manufacturing rights made the transaction non-reportable. *Id*. at 50,059; 78 Fed. Reg. at 68,706. Thus, pharmaceutical companies could enter such transactions without providing notification under the HSR Act and waiting the designated time before closing, regardless of any competitive concerns the transaction might raise, simply by having the licensor retain limited manufacturing rights.

The PNO also has often received questions about licenses in which the licensor retains certain "co-rights" to assist the licensee in maximizing its sales of the licensed product, such as the right to jointly co-develop, co-promote, co-market, and co-commercialize a product along with the licensee. *Id*.; 78 Fed. Reg. at 68,706. 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. Such retained co-rights, however, do not give the licensor the right to commercially use the patent or part of the patent. 78 Fed. Reg. at 68,707. The PNO has long advised that, if the license grants the rights to "make, use and sell" under the patent, the licensor's retention of such co-rights does not render the license non-exclusive, and the transaction is a reportable transfer of an "asset." *Id*.; 77 Fed. Reg. at 50,059.

C. The Commission's Rulemaking

1. The Notice and Comment Process

In August 2012, the Commission issued a Notice of Proposed Rulemaking ("NPR"), proposing to amend the HSR Rules to provide a framework for determining when the transfer of exclusive rights to a pharmaceutical patent is an acquisition under the HSR Act. The proposed rule adopted an "all commercially significant rights" test, which the Commission provisionally determined would better capture whether the license has transferred the exclusive right to commercially use a patent or part of a patent. 77 Fed. Reg. at 50,059-60. The Commission explained that a focus on "all commercially significant rights" reflects the evolving structure of exclusive patent licenses in the pharmaceutical industry, and would provide the antitrust agencies with a more effective means of reviewing exclusive patent licenses that meet the statutory requirements for HSR Act reportability. With the exception of the treatment of the right to manufacture exclusively for the licensee, the proposed rule treated the reportability of exclusive licensing arrangements, including those where the licensor retains co-rights, in the same way the PNO has for decades. The Commission further explained that the proposed rule was limited to transactions in the pharmaceutical industry because that is the only industry, to the PNO's knowledge, in which such exclusive patent licenses are prevalent. *Id*. at 50,059.

The Commission received three public comments: one in opposition from Plaintiff and two supporting the proposed rule.[8] After reviewing the comments, the Commission voted unanimously to approve the Rule, and the DOJ concurred.

2. The Final Rule

The Rule provides that, in the pharmaceutical industry, the "transfer of patent rights . . . constitutes an asset acquisition" within the meaning of the HSR Act when "all commercially significant rights to a patent … are transferred to another entity." 16 C.F.R. § 801.2(g)(2) and (3); 78 Fed. Reg. at 68,713. The Commission defines "all commercially significant rights" to mean "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." 16 C.F.R. § 801.1(o); 78 Fed. Reg. at 68,712. The Rule formalizes the longstanding position of PNO staff that a transaction involving the transfer of exclusive rights to a patent or a part of a patent in the pharmaceutical industry is potentially reportable under the Act and clarifies the PNO's current treatment of co-rights.[9] But it modifies the PNO's treatment of transactions in which the licensor retains the right to manufacture solely for the licensee. In the language of the Rule, "[a]ll commercially significant rights are transferred" even if the patent holder retains "co-rights" or "limited manufacturing rights," both of which are terms defined in Section 801.1(p), and (q) of the Rule. 78 Fed. Reg. at 68,712-13. The Rule provides various examples of the application of these concepts. *Id*. at 68,713.

[8] Exs. B, E, and F to Plaintiff's Motion.

[9] Although the PNO has long advised that a licensee's retention of co-rights does not render a license non-exclusive, the continuing questions from practitioners regarding co-rights indicated a need for guidance on this issue. *See* 78 Fed. Reg. at 68,706-07.

The Commission explained that the Rule is limited to the pharmaceutical industry because that is where the Commission has identified the need for clarification on the reportability of such transactions, based on filings made and questions posed to the PNO. But the Commission specified that, to the extent they occur, transfers of exclusive rights to a patent in other industries remain potentially reportable under the Act and existing HSR Rules, and that parties to such transactions should consult with the PNO for further guidance. *Id*. at 68,706, 68,709.

ARGUMENT

I. THE FTC REASONABLY INTERPRETED THE HSR ACT.

Plaintiff's leading argument is that the HSR Act "plainly" forbids the Commission from implementing a rule that applies only to a particular industry. Plaintiff's Mem. 16. In fact, the statute contains no such restriction.

"When a litigant challenges the Commission's interpretation of a statute that it administers," the Court's review "is governed by the familiar dictates" of *Chevron*. *Consumer Electronics Ass'n v. FCC*, 347 F.3d 291, 297 (D.C. Cir. 2003). The first question is "whether Congress has spoken to 'the precise question at issue.' " *Id*. (quoting *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837, 842 (1984)). If it has, the Court "must give effect to the unambiguously expressed intent of Congress." *Chevron,* 467 U.S. at 843. When the statute is silent or ambiguous on the precise question in dispute, the Court moves to *Chevron*'s second step, under which it will defer to the agency's interpretation if it offers a

"permissible construction of the statute." *Id.*[10] Under these principles, the FTC reasonably interpreted the HSR Act as authorizing adoption of the Rule.

The *Chevron* inquiry begins "with the plain language of the statute in question." *Consumer Electronics*, 347 F.3d at 297. The HSR Act provides that "except as exempted . . . no person shall acquire, directly or indirectly, voting securities or assets of any other person," if the "acquisition" meets certain monetary thresholds, unless the parties to the transaction file notification pursuant to rules prescribed by the Commission. 15 U.S.C. § 18a. Congress did not define the terms "asset, "acquire," or "acquisition," but instead gave the Commission, with the concurrence of the DOJ, the authority to "define the terms used in" the Act. 15 U.S.C. § 18a(d)(2)(A). Congress also gave the Commission, with the concurrence of the DOJ, the authority to "prescribe such other rules as may be necessary and appropriate to carry out the purposes of" the Act. 15 U.S.C. § 18a(d)(2)(C).

In the Rule at issue here, the Commission gave definition to the terms "asset" and "acquisition" as applied to transfers of exclusive patent rights in the pharmaceutical industry. Plaintiff does not question, or even address, the Commission's authority under the Act to define these terms. Instead, Plaintiff argues that, because the Act's notification requirements apply as a general matter to all "persons," "[e]xcept as exempted," 15 U.S.C. § 18a(a), the Commission may not issue industry-specific coverage rules requiring notification (and may issue industry-specific rules only to exempt parties or transactions from the filing requirements). *See* Plaintiff's Mem. 16. It is impossible, however, "to glean so much from the little that [the statute]

[10] As the Supreme Court has recently made clear, *Chevron* deference is warranted even where an agency has interpreted a statutory provision that could be said to delineate the scope of its jurisdiction. *City of Arlington v. FCC*, 133 S. Ct. 1863, 1874 (2013).

provides." *Mayo Foundation for Med. Educ. & Research v. United States*, 131 S. Ct. 704, 711 (2011).

In fact, the statute contains no support whatsoever for Plaintiff's argument. Contrary to Plaintiff's suggestion, there is no inconsistency between (1) requiring all parties in qualified transactions to file notification (unless exempted) and (2) allowing the Commission to implement the requirements of the Act on an industry-specific basis. Nothing in the text of the Act demonstrates that Congress intended to prohibit the Commission from issuing industry-specific coverage rules; certainly, Congress has not "directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842; *see 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); *see also Adirondack Medical Center v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014) ("[t]he *expressio unius* canon is a feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved") (internal quotation marks omitted).

Nor does the legislative history support Plaintiff's construction of the Act. The Senate bill provision to which Plaintiff refers, dropped from the final Act, would have allowed the Commission to require particular companies or industries to report transactions *falling below the Act's minimum thresholds*. *See* 122 Cong. Rec. 29,342 (Sept. 8, 1976) (Senate bill provision addressed "transactions between persons not meeting the minimum size criteria"); 122 Cong. Rec. 30,877 (Sept. 16, 1976) ("[t]he Senate bill permitted the FTC, with participation of the Department of Justice, to promulgate rules subjecting 'small' mergers . . . to the notification and waiting requirements"). Thus, when Rep. Rodino stated that "the coverage of this bill should be

decided by Congress—not the FTC and the Justice Department," *id*., he was talking about who gets to decide the size of the transactions that warrant mandatory pre-closing review. Nothing in this legislative history suggests that Congress intended to deprive the Commission of authority to issue industry-specific rules for parties or transactions that *meet* the Act's thresholds.

Chevron recognized that "[t]he power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." 467 U.S. at 843 (internal quotation marks omitted). Congress delegated to the Commission plenary authority to implement the HSR Act, and the Commission's policy choice here to implement the Act by means of an industry-specific rule merits deference. *Id*. at 843-44. Contrary to Plaintiff's suggestion, it is entirely appropriate for an agency to limit rules to those areas where it has observed a problem. As this Court has explained, "in promulgating regulations, agencies may proceed incrementally." *Investment Co. Inst. v*. *CFTC*, 891 F.Supp.2d 162, 187 (D.D.C. 2012), *aff'd* 720 F.3d 370 (D.C. Cir. 2013). "In classifying economic activity, 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.' " *Nat'l Ass'n of Broadcasters*, 740 F.2d at 1207 (quoting *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955)); *accord City of Las Vegas v. Lujan*, 891 F.2d 927, 935 (D.C. Cir. 1989) ("agencies have great discretion to treat a problem partially").[11]

[11] Thus, for example, in *Investment Co. Inst.*, this Court upheld a CFTC regulation requiring registration and reporting by some entities engaging in derivatives trading, but exempting others, where the CFTC justified exempting these other entities on the basis that it was not aware of any such other entities engaging in derivatives trading. 891 F.Supp.2d at 187. *See also Illinois Commercial Fishing Ass'n v. Salazar*, 867 F. Supp. 2d 108, 118-19 (D.D.C. 2012) (upholding

Particularly given this background principle of administrative law, Congress's silence in the HSR Act with respect to the permissibility of industry-specific implementing rules leaves ample room for the Commission's determination here that such a rule is both authorized and appropriate.

Plaintiff also argues that, because the Rule defines concepts ("all commercially significant rights," "limited manufacturing rights," and "co-rights") that do not appear in the HSR Act, the Commission has exceeded its authority to "define the terms used in" the Act, 15 U.S.C. § 18a(d)(2)(a). *See* Plaintiff's Mem. 20.[12] That makes no sense. The Rule gives meaning to (*i.e.*, defines) terms ("acquisition" and "asset") that *do* appear in the Act. As the Commission explained, section 18a(d)(2)(A) of the Act "allows [the Commission] to determine which types of patent rights constitute reportable *assets* under the Act," and "[t]his rulemaking *defines* when the transfer of exclusive rights to a pharmaceutical patent or part of a patent

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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 fishing rather than recreational fishing); *Manufactured Housing Instit. v. EPA,* 467 F.3d 391, 400-01 (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).

[12] None of the cases that Plaintiff cites remotely support its argument that the Commission improperly invoked its authority to define the terms of the Act. In *Am. Bankers Ass'n v. SEC*, 804 F.2d 739, 744-50 (D.C. Cir. 1995), Congress had delegated to other agencies, not the SEC, the authority to regulate the matter at issue—which is clearly not the case here. In *Comcast v. FCC*, 600 F.3d 642, 655 (D.C. Cir. 2010), the FCC itself conceded that Congress had not given it express authority over the matter at issue—whereas, here, Congress expressly delegated to the Commission the authority to implement the HSR Act. And in *Am. Civil Liberties Union v. FCC*, 823 F.2d 1554, 1567 (D.C. Cir. 1987), the FCC adopted a definition that was "at odds with a definition of that very term contained in the Act itself"—which is also not the case here (neither "asset" nor "acquisition" are defined in the HSR Act).

constitutes the *acquisition of an asset*." 78 Fed. Reg. at 68,707 n.9, 68,709 (emphasis added). Accordingly, the Rule identifies when "[t]he transfer of patent rights" in the pharmaceutical industry "constitutes an *asset acquisition*." *Id*. at 68,713 (section 801.2(g)(2), emphasis added). In the course of defining these terms of the Act, the Commission may of course use and define additional terms and concepts that do not themselves appear in the Act.[13]

Plaintiff also misses the mark in arguing that the Commission's authority to issue rules "as necessary and appropriate to carry out the purposes of" the Act, 15 U.S.C. § 18a(d)(2)(C), does not give the Commission authority to issue this Rule. *See* Plaintiff's Mem. 21. Plaintiff seeks to dismiss this authority as merely "ancillary," citing wholly inapposite cases.[14] As the D.C. Circuit has recognized, however, "[t]he alleged negative restriction on this power [to regulate 'as necessary and appropriate'] is at best ambiguous, if indeed it exists at all." *Associated Gas Distributors v. FERC*, 824 F.2d 981, 1001 (D.C. Cir. 1987) ("[u]nder these circumstances, *Chevron* binds [the court] to defer to Congress's decision to grant the agency . . . the primary authority and responsibility to administer the statute"). In substance, moreover,

[13] In fact, many of the terms included in the "definitions" section of the HSR Rules do not appear in the Act itself. *See*, *e.g.*, 16 C.F.R. § 801.1(a)(2) (entity); § 801.1(a)(3) (ultimate parent entity); § 801.1(b) (control); § 801.1(d)(2) (associate); § 801.1(f)(1)(ii) (non-corporate interest); §801.1(f)(3) (conversion).

[14] Plaintiff's argument finds no support in *Whitman v. American Trucking Ass'n, Inc.*, 531 U.S 457, 468 (2001), which (unlike the instant case) involved an agency regulation that was "unambiguously" at odds with the "text of [the statute], interpreted in its statutory and historical context." *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), did not address the issue of an agency's rulemaking authority, but instead involved an entirely distinct question concerning the subject matter covered by the relevant statute (whether a claimed invention was patentable under the Patent Act). And, unlike here, in *Am. Library Ass'n v. FCC*, 406 F.3d 689, 691 (D.C. Cir. 2005), "no specific statutory provision" gave the agency regulatory authority over the subject matter at issue.

Plaintiff's arguments regarding whether this Rule is "necessary" are arguments that the Rule is "arbitrary and capricious." We address those arguments in the following section.

II. THE COMMISSION COMPLIED WITH ALL ASPECTS OF THE APA.

In most respects, the Rule simply codifies the Commission's long-standing policy regarding transfers of patent rights in the pharmaceutical industry. An exclusive patent license that transfers all significant commercial rights is a reportable asset acquisition (if sufficiently large); a transaction in which a licensor retains unlimited manufacturing rights is non-reportable; and a licensor's retention of certain co-rights does not render an otherwise exclusive patent license non-reportable. The Rule also provides detailed guidance in terms that would not be pertinent to other industries, while leaving in place the Commission's general policy that the transfer of exclusive rights to a patent in other industries is a potentially reportable asset acquisition. *See* pp. 8-9, *supra*. Only in one discrete factual setting does the Rule impose new obligations on the pharmaceutical industry: where the licensor grants exclusive rights to the licensee but retains the right to manufacture solely for that licensee. And even in that setting, the Rule simply aligns the letter of reporting requirements with the economic rationale for those requirements.

With respect to all aspects of this Rule, the Commission provided a "reasoned explanation for its action," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514 (2009), articulating a "rational connection between the facts found and the choice made." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 626 F.3d 84, 90 (D.C. Cir. 2010) (internal quotation marks omitted). In particular, the Commission explained its reasons for modifying its treatment of transactions in which the licensor retains the right to manufacture

solely for the licensee, and for issuing a rule specifically addressed to transactions occurring in the pharmaceutical industry. And the Commission carefully considered Plaintiff's comments, including the report of its expert, but found Plaintiff's arguments and evidence unpersuasive.

Such "reasoned decisionmaking" is all that the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), requires. *See Investment Co. Inst.*, 720 F.3d at 376 ("Such reasoned decisionmaking is an acceptable way to change [the agency's] past rules . . . . The law requires no more.").[15] Under the APA's "deferential" standard, which "presumes the validity of agency action," *WorldCom Inc. v. FCC*, 238 F.3d 449, 457 (D.C. Cir. 2001) (internal quotation marks omitted), the Commission is entitled to summary judgment.

A. The Commission Provided a Reasoned Basis for the Rule.

The Commission thoroughly explained its reasoning for issuing a rule that identifies when a transaction involving the transfer of exclusive rights to a patent or part of patent in the pharmaceutical industry constitutes an asset acquisition under the HSR Act. "In recent years," the Commission observed, "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." 78 Fed. Reg. at 68,706. For example, the Commission found, it has become increasingly common for a pharmaceutical

[15] The Supreme Court has made clear that regulatory change is not subject "to more searching review." *Fox Television Stations*, 556 U.S. at 514. An agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and the agency *believes* it to be better, which the conscious change of course adequately indicates." *Id*. at 515 (emphasis in original).

licensor to retain the limited right to manufacture only for the licensee, which would make the transaction non-reportable under the "make, use and sell" approach, even though the licensor would not be manufacturing for its own commercial use. *Id*.; 77 Fed. Reg. at 50,059. Also, it has become more common for licensors of pharmaceutical patents to retain the right to co-develop, co-promote, co-market and co-commercialize the product along with the licensee. 78 Fed. Reg. at 68,706. In addition, the Commission noted, the PNO often receives questions from practitioners representing clients in the pharmaceutical industry, seeking guidance about the reportability of transactions where the licensor retains co-rights and/or the right to manufacture solely for the licensee. *Id*. at 68,708; 77 Fed. Reg. at 50,059. The Commission explained that the Rule is a response to these developments and is intended to "provide clarity and consistency to the assessment of whether an asset acquisition is occurring as the result of the transfer of right to a patent in the pharmaceutical industry." 78 Fed. Reg. at 68,710.

The Commission further explained that the "all commercially significant rights" test that the Rule adopts "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 part of a patent." *Id*. at 68,707. The Commission stated that the licensing arrangements covered by this Rule are "functionally equivalent to patent transfers and are thus properly viewed as asset acquisitions under the Act." *Id*. at 68,709. In the Commission's judgment, allowing such transactions to go unreported "would deprive [it] of an opportunity, consistent with the purposes of the Act, to review these significant asset acquisitions that, like other reportable asset acquisitions, are potentially anticompetitive." *Id*. And, in considering comments expressing concern that the Rule might chill certain types of pharmaceutical transactions, the Commission determined that because the administrative costs of filing are very small compared to the profits

at stake for the multi-million dollar transactions reportable under the Act, the Rule is unlikely to chill or materially distort these types of acquisitions. *Id*. at 68,710.

The Commission also explained its reasons for a rule limited to the pharmaceutical industry. The Commission noted that pharmaceutical industry is the only industry where, in the PNO's experience, exclusive patent licenses that transfer all commercially significant rights are prevalent. *Id*. at 68,708-09. Indeed, in the five years prior to the rulemaking, the PNO received filings for 66 transactions involving exclusive patent licenses, all of which were for pharmaceutical patents. *Id*. at 68,708. In addition, the Commission explained, the pharmaceutical industry is where the need for clarification has arisen. Requests for guidance from the PNO on the treatment of exclusive patent licensing transactions have nearly always come from practitioners in the pharmaceutical industry. *Id*. at 68,709. The Commission added that its experience with these transactions in this context allowed it to fashion a rule with sufficient specificity to provide meaningful guidance to industry, by 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. *Id*. at 68,707-08. All of these determinations were reasonable.

B. The Commission Was Justified in Limiting the Rule to Transactions in the Pharmaceutical Industry.

At bottom, Plaintiff argues that the Commission lacked justification for confining its Rule to transactions in the pharmaceutical industry, rather than applying it more broadly to all industries throughout the economy. That challenge disregards much of the Commission's rationale, ignores the Commission's empirical basis for its decisions, and vastly overstates the evidentiary value of Plaintiff's own expert's report.

1. The Commission had a strong empirical basis for the Rule.

The Commission's decision to issue a rule addressing transactions specifically in the pharmaceutical industry did not rest, as Plaintiff claims, on vague invocations of its institutional expertise. To the contrary, the Commission reasonably relied on the PNO's long experience in reviewing HSR filings involving exclusive patent licenses in the pharmaceutical industry and, in particular, on the fact that pharmaceutical patents accounted for every one of the 66 HSR filings for exclusive patent licenses submitted in the last five years. The Commission further explained that nearly all of the questions to the PNO seeking guidance on the reportability of exclusive patent licenses have come from the pharmaceutical industry, a fact that bolsters the case for an industry-specific rule.

This is more than a sufficient empirical basis for the Commission's action. Plaintiff implausibly criticizes the Commission for not having conducted an investigation to determine with certainty whether (contrary to the PNO's experience) other industries employ the types of exclusive patent licenses covered by the Rule. But the APA imposes no such requirement. *See Chamber of Comm. v. SEC*, 412 F.3d 133, 142 (D.C. Cir. 2005) (holding that agency's "decision not to do an empirical study does not make that an unreasoned decision"); *Nat'l Ass'n of Regulatory Util. Comm'rs v. FCC*, 737 F.2d 1095, 1124 (D.C. Cir. 1984) (failure to conduct independent study not violative of APA because notice and comment procedures "permit parties to bring relevant information quickly to the agency's attention"). Indeed, where, as here, "an agency is obliged to make policy judgments where no factual certainties exist or where facts alone do not provide the answer," the court's "role is more limited; we require only that the agency so state and go on to identify the considerations it found persuasive." *Chamber of Comm. v. SEC*, 412 F.3d at 142 (quoting *BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C.Cir.1999)).

The Commission made clear that its decision to adopt a Rule for transactions in the pharmaceutical industry did not require factual certainty regarding licensing practices in other industries. It recognized that it was possible that exclusive patent licenses of the type covered by this rule might be used in other industries. But it found no evidence to suggest that such licensing arrangements are common outside of the pharmaceutical industry, and went on to explain why a rule limited to the pharmaceutical industry is preferable at this juncture. Notably, no commenters below (except for Plaintiff) disputed the Commission's understanding that exclusive patent licenses of this type are not generally employed in other industries. Though the Commission would not expect parties to such transactions to invite antitrust scrutiny, neither did it hear from consumers or other interested parties who ordinarily would be expected to bring potentially anticompetitive transactions to the government's attention.

Relying on its expert's report, Plaintiff alone argued that various agreements in other industries resemble the types of pharmaceutical licenses at issue here and thus should also be encompassed within the Rule. The Commission reasonably rejected that contention.

The Rule applies to patent licenses that transfer all significant rights to commercially use the patent to the exclusion of all others, even the licensor. Such licenses "are functionally equivalent to patent transfers and are thus properly viewed as asset acquisitions under the Act." 78 Fed. Reg. at 68,709. As the Commission explained, "[e]xclusive 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." *Id*. at 68,707 n.10. The Commission further explained that the licensing agreements from other industries cited by Plaintiff's expert "are exclusive distribution agreements, which convey to the licensee only the exclusive right to distribute the patented product," but do not convey "all commercially significant rights to the

patent." *Id*. at 68,708. Indeed, distribution agreements are not commonly considered transactions in which one party "acquires" the "assets" of another. *See generally* VIII Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶ 1600 (3d ed. 2010) (discussing distribution restraints). Thus, the Commission reasonably concluded that the agreements cited by Plaintiff's expert "are not the kinds of agreements that are the subject of the Rule." 78 Fed. Reg. at 68,708.

The Court need not take the Commission's word for this; it need only look at the agreements that Dr. Varner cited:

- A "Master Distributorship Agreement" granting the exclusive right "to purchase, inventory, promote, and resell" the licensor's product incorporating patented technology (Varner Decl. ¶ 23 n. 33, citing Ex. 10.14 of http://www.sec.gov/Archives/edgar/data/880242/000119312507102934/dex1014.htm);[16]

- A "Market Development and Distributorship Agreement" specifying that the relationship between the parties "shall be that of a seller and buyer," and granting to the licensee "and its customers" a non-exclusive license "to practice" the patented technology (*id*. at n. 34, citing ex. 10.6 of http://sec.gov/Archives/edgar/data/1047175/0000950124-97-005153.txt);

- A "License and Supply Agreement" granting exclusive "limited" rights under the patents "solely to use and repair" a product incorporating patented technology, and providing that "the licenses granted herein do not include the right to make, have made, offer for sale, sell or import the Product" (*id*. at n.35, citing Ex. 10.35 of http://www.sec.gov/Archives/edgar/data/1366340/000095012310030701/b78730exv10w35);

- A "Patent and Trademark License Agreement" granting exclusive "Distribution Rights" to "market, promote, . . . sell and otherwise distribute products and services covered by the Intellectual Property," but providing that the licensor retains the right (rights are exclusive "except as to Licensor") to "modify, adapt, update, develop upgrades for and otherwise create derivative works and

[16] Ex. B to Plaintiff's Mot., at pp. B-28 to B-30.

improvements based or related to the Intellectual Property," and specifying that "Licensor owns all right . . . and interest in and to the Intellectual Property" (*id*. at n.36, citing Ex. 10.5 of http://www.sec.gov/Archives/edgar/data/868725/000119312504147170/dex105.htm);

- A "Distributorship Agreement" appointing the licensee the "exclusive distributor of" the licensor's products and granting a non-exclusive license "to use" the intellectual property "in furtherance of" the distribution agreement" (*id*. at n.37, citing Ex. 10.4 of http://www.sec.gov/Archives/edgar/data/808326/0000950144-99-006379.txt);

- A "Distribution Agreement" providing that the relationship between the parties is that of "seller" and "purchaser," and granting a license merely " to use the trademarks" within the intellectual property (*id*. at n.38, citing Ex. 10.7 of http://www.sec.gov/Archives/edgar/data/866291/000095013508001653/b65742a3exv10w7.txt);

- An "Exclusive License and Supply Agreement" providing that "[a]ll proprietary rights . . . with respect to the Patent Rights . . . shall at all times remain solely with" the licensor (*id*. at n.39, citing 10.4 of http://www.sec.gov/Archives/edgar/data/1016169/0001045969-00-000229.txt);

- A "Manufacturing, Supply and Distribution Agreement" providing that the grantor "shall retain all rights, title and interest in and to all intellectual property rights relating to the Products," and that "[n]o license to any trademark, patent, copyright or other property right . . . is granted under this Agreement," except as necessary to market the products under the terms of the distribution agreement (*id*. at n.40, citing Ex. 10.10 of http://www.sec.gov/Archives/edgar/data/1082249/000101968704001855/visijet_10qex10-10.txt);

- A "Distribution Agreement," providing that the licensee will "purchase such products sold by [the licensor] or distribution and resale," and granting "a limited, non-exclusive . . . license to use the [licensor's] trademarks" to the distributor and a non-exclusive license of Product Software to the distributor "and any end user customers" (*id*. at n.41, citing Ex. 99.1 of http://www.sec.gov/Archives/edgar/data/895380/0001045969-99-000562.txt); and

- A "License Agreement" entered into as part of a "Supply Agreement" for the licensor's supply of motors for use in wheelchairs produced by the licensee, providing that the licensor "reserves the right (i) to use and practice Licensed Technology in the manufacture of Licensed Motors . . . and (ii) to sell, offer to sell, ship, distribute, advertise and promote the Licensed Motors" (*id*. at n.42, citing Ex. 20.20 of

http://www.sec.gov/Archives/edgar/data/315449/000089973302000027/licensere dacted.htm).

None of those agreements transfer all significant rights to commercially use a patent (or part of a patent) to the exclusion of all others, including the patent holder. Indeed, some of them transfer no patent rights at all.

Those agreements stand in stark contrast to licensing agreements in the pharmaceutical industry—also cited by Dr. Varner (though for a separate point)—that illustrate the types of transfers of patent rights that the Rule addresses:.

- An "Agreement . . . For the Licensing and Development of Glufosfamide," granting an "exclusive license . . . under and using the Licensed Patents and Licensed Know-How . . . to develop, make, have made, use, supply, offer for sale, sell, import, export and otherwise distribute [the] Licensed Product" (Varner Decl. n.50, citing Ex. 10.2 of http://www.sec.gov/Archives/edgar/data/1183765/000119312504059933/dex106.htm);[17] and

- A "Licensing Agreement" granting "an exclusive (even as to NexMed) . . . license, under the NexMed Patent Rights and NexMed Know-How to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, offer for sale, sell, have sold and otherwise commercialize" the licensed products (*id*. at n. 63, citing Ex. 99.1 of http://www.sec.gov/Archives/edgar/data/1017491/000114420405028876/v025708_ex99-1.htm).[18]

In the first of these, though not the second, the licensor also retains limited manufacturing rights (it can manufacture the product only for the licensee). But, unlike the other agreements discussed above, both satisfy the Rule's definition of an asset acquisition: They transfer all significant rights to commercially use a patent (including the sole right to decide if and when to

[17] Ex. B to Plaintiff's Mot., at p. B-32.

[18] Ex. B to Plaintiff's Mot., at p. B-34.

commercialize the patent and, if the licensee commercializes the patent, how to market and price the product covered by the license).

The Commission did not by any means "disregard" Dr. Varner's study (or any other of the arguments made by Plaintiff), as Plaintiff contends. *See* Plaintiff's Mem. 25. The Commission simply found Plaintiff's arguments and evidence unpersuasive. And Plaintiff's further accusation that the Commission's rationale for a limited rule was "pretextual," *id*., is not only baseless but also in conflict with the "deferential" APA standard, which "presumes the validity of agency action." *WorldCom Inc. v. FCC*, 238 F.3d 449, 457-58 (D.C. Cir. 2001) (internal quotation marks omitted); *see also Chamber of Comm.*, 412 F.3d at 143 (agency " made clear enough the limitations of the study, and we have no cause to disturb its ultimate judgment that the study was 'unpersuasive evidence' ").

2. The Commission reasonably opted for the benefits of a narrow rule.

As already discussed, an agency "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." *Nat'l Ass'n of Broadcasters*, 740 F.2d at 1207 (D.C.Cir.1984) (internal quotation marks omitted). Here, the Commission reasonably decided to limit the Rule to exclusive patent licenses in the pharmaceutical industry because "this is where the need for clarification arises and where the Commission has experience with the relevant transactions." 78 Fed. Reg. at 68,708. The Commission further reasoned that cabining the Rule's scope in this manner allowed it to identify reportable transactions employing terminology that has precise meaning in the pharmaceutical industry but would be meaningless in other contexts. *Id*. Specifically, the Commission defined the relevant scope of the transfer of the exclusive rights to part of a patent by reference to "a

particular therapeutic area (or specific indication within a therapeutic area)." 16 C.F.R. § 801.1(o). *See* 78 Fed. Reg. at 68,708. This specificity serves to provide concrete practical guidance to practitioners in the pharmaceutical industry in a way that a more general rule would not. And it obviated any need for the Commission to undertake a time-consuming and needless detour into corresponding criteria for the transfer of patent rights in other industries.

Moreover, far from a shortcoming, the narrowness of the Rule is a strength. The Commission is appropriately cautious about intruding in areas of the economy where it has not had the opportunity to assess the impact of regulatory action. Although the Commission is quite familiar with exclusive patent transfers in the pharmaceutical industry, it has not witnessed similar exclusive licenses in other industries. As the Commission explained (and as discussed at pp. 12-13, *supra*), "[a]gencies may limit rules to areas where they have observed a problem to be addressed." 78 Fed. Reg. at 68,709. The Commission noted that the antitrust agencies "will continue to assess the appropriateness of a similar rule for other industries. *Id*. at 68,710. This is a policy judgment firmly within the antitrust agencies' discretion to make. *See City of Las Vegas v. Lujan,* 891 F.2d 927, 935 (D.C. Cir. 1989) ("agencies have great discretion to treat a problem partially").

Contrary to Plaintiff's argument, the Commission also had an adequate basis for concluding that the Rule promotes the pro-competitive purposes of the HSR Act. The Act requires the reporting of large asset acquisitions so that the antitrust agencies have an opportunity to review them. That statutory reporting requirement is based on size alone, without regard to whether particular transactions are likely to cause competitive harm or would prove particularly difficult to unwind. Here, the Commission reasonably concluded that the Rule is necessary to align these size-based reporting requirements with the economic realities of current licensing

practices in the pharmaceutical industry, so that large asset acquisitions with similar competitive effects will be treated similarly even if they differ in form. The Commission need show nothing more to justify this Rule.

In any event, Plaintiff is mistaken in drawing any inference from the extent of antitrust enforcement activity to date concerning exclusive patent licenses in the pharmaceutical industry. Commission investigations are nonpublic, so it would be inappropriate to draw inferences from whether there have been any publicly-disclosed investigations of exclusive patents license agreements of the type covered by this Rule. Plaintiff also claims that these types of transactions can be easily undone if challenged after consummation. Even if that claim were factually accurate, which it is not,[19] it would still be legally irrelevant because the statutory reporting requirements do not turn on the ease of unwinding particular transactions.

C. The Commission Provided Sufficient Notice of the Basis for its Rule.

Lastly, Plaintiff argues that the Commission's Notice of Proposed Rulemaking did not adequately divulge the factual basis for the proposed rule, thereby depriving Plaintiff of a opportunity to meaningfully participate in the rulemaking. In particular, Plaintiff complains that it had no ability to test the Commission's statements concerning the PNO's experience in

[19] In the pharmaceutical context, transfers of patent rights may occur while the compound is still in the developmental stage, with the licensee assuming the task of shepherding the compound through the FDA approval process. The licensee then is in a position to make critical decisions about how to conduct trials and develop data (or even whether to obtain FDA approval at all) that might not easily (or quickly) be altered in the event of a divestiture. *See* 77 Fed. Reg. at 50,059. Moreover, an anticompetitive acquisition can cause substantial interim harm even if the acquisition is later unwound by a subsequent divestiture. *See FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1085 (D.C. Cir. 1981) (preliminary injunctive relief under section 7 serves not only "to safeguard adequate eventual relief if the merger is ultimately found unlawful," but also "to check interim anticompetitive harm").

providing advice regarding the transfer of right to a patent through exclusive license. But the PNO's experience is by no means the black box that Plaintiff claims. As the Commission noted in the NPR (and the final Rule as well), The Commission maintains a database of the PNO's informal interpretations, containing the letters and emails from practitioners seeking advice from the PNO about the reportability of transactions. 77 Fed. Reg. at 50,059; 78 Fed. Reg. at 68,706 n. 8. This database is available on the Commission's public website and can be searched in various ways, including by date and keyword. *See* http://ftc.gov/bc/hsr/informal/index.shtm (cited at 78 Fed. Reg. at 68,706 n.8). And, indeed, Plaintiff availed itself of this website, as is evident from the fact that it cited material from the database in its comment to Commission. *See* PhRMA Comment p. 11 & n. 40 (citing Informal Interpretation No. 0806009, available at http://ftc.gov/bc/hsr/informal/opinions/0806009.htm).[20] Thus, Plaintiff cannot show any prejudice, "as [it] must to succeed on such a claim." *Investment Co. Inst. v. CFTC*, 720 F.3d at 381.

III. VACATUR WOULD BE UNWARRANTED EVEN IF PLAINTIFF'S SUBSTANTIVE CHALLENGES WERE MERITORIOUS.

Without even a nod to Circuit precedent, Plaintiff asserts that, if this Court agrees with any of its challenges on the merits, it must vacate the Rule. That is simply incorrect. Under longstanding D.C. Circuit case law, this Court may remand a rule to an agency for additional proceedings without vacating the rule during the interim. *E.g., Chamber of Commerce v. SEC*, 412 F.3d at 145; *Allied-Signal, Inc. v. United States Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51. (D.C.Cir.1993). Indeed, where there is a sufficiently high probability that the agency

[20] Ex. B to Plaintiff's Mot. At p. B-11.

will be able to justify retaining its rule, the Court may remand without vacatur even where "the disruptive consequences of vacatur might not be great." *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1049 (D.C. Cir. 2002); *see United States Telecom Ass'n v. FBI*, 276 F.3d 620, 627 (focusing upon first factor of *Allied-Signal* test).

Here, remand without vacatur would address Plaintiff's claims with the least potential for larger disruption because there is no real question that the Commission will be able to justify a rule addressing the reportability of such transactions in the pharmaceutical industry. Indeed, even if petitioners were correct that the Commission may not adopt industry-specific reporting requirements, the Commission would be entitled on remand to widen the scope of the Rule to encompass other industries (while preserving its effect on the pharmaceutical industry) rather than eliminating the Rule altogether. The Court should thus reject Plaintiff's request for vacatur in order to avoid "the disruptive consequences of an interim change that may itself be changed" on remand. *International Union, United Mine Workers of America v. Federal Mine Safety and Health Admin.*, 920 F.2d 960, 967 (D.C. Cir. 1990).

CONCLUSION

In sum, Plaintiffs have advanced no argument that would permit disturbing the Commission's decision to adopt a Rule that identifies when transfers of exclusive patent rights in the pharmaceutical industry constitute asset acquisitions under the HSR Act. Congress delegated to the Commission broad authority to prescribe such rules, and the Commission's interpretation of the Act to permit and industry-specific rule is entitled to *Chevron* deference. And the Commission provided ample explanation of its reasons and factual basis for the Rule, which is all the APA requires. Because Plaintiff's complaints about the Rule amount to "nothing more

than [a] policy disagreement" with the Commission, the Court "must reject it." *Investment Co. Inst. v. CFTC*, 720 F.3d at 380.

Respectfully Submitted,

JONATHAN E. NUECHTERLEIN
General Counsel
DC Bar No. 442470

JOHN F. DALY
Deputy General Counsel for Litigation
DC Bar No. 250217

JOEL MARCUS
Assistant General Counsel
DC Bar No. 428680

/s/ Michele Arington
MICHELE ARINGTON
Attorney
DC Bar No. 434082
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580
(202) 326-3157

Of Counsel:

J. Robert Kramer II
General Counsel

Nancy M. Olson
Deputy General Counsel-Civil
D.C. Bar No. 444801

U.S. Department of Justice
Antitrust Division
950 Pennsylvania Ave., NW
Washington, DC 20530

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