UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. FEDERAL TRADE COMMISSION, Defendant.	Civil Case No. 13-1974 (BAH) Judge Beryl A. Howell

MEMORANDUM OPINION

The plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association which "represents the country's leading biopharmaceutical researchers and biotechnology companies," *see* Compl. ¶¶ 9–10, ECF No. 1, seeks to set aside a Final Rule issued by the Federal Trade Commission ("FTC") that requires the pharmaceutical industry to report certain transfers of exclusive patent rights under Section 7A of the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"), 15 U.S.C. § 18a; Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705 (Nov. 15, 2013) ("Final Rule"); Jt. App. ("JA") at 7–15, ECF No. 19.[1] PhRMA challenges the Final Rule as violative of the Administrative Procedures Act ("APA"), 5 U.S.C. § 706, because the FTC: (1) lacked statutory authority to issue an industry-specific rule rather than a rule of general application; (2) failed to establish a rational basis for such an industry-specific rule; and (3) failed to comply with legally required procedures. *See* Compl. ¶¶ 89–106. Pending before the Court are the parties' cross motions for summary judgment. *See* Pl.'s Mot. Summ. J. ("Pl.'s Mot."), ECF No. 13; Def.'s

[1] In compliance with Local Civil Rule 7(n), the FTC filed a certified list of the contents of the Administrative Record in this case, s*ee* ECF No. 14, and also filed a Joint Appendix, which appears to contain the entirety of the AR. Relevant citations are made to the Joint Appendix.

Mot. Summ. J. ("Def.'s Mot."), ECF No. 15. For the reasons explained below, PhRMA's motion is denied and the FTC's motion is granted.[2]

I. BACKGROUND

The Final Rule states, and PhRMA does not dispute, that "the granting of an exclusive right to commercially use a patent or part of a patent is a potentially reportable asset acquisition under the [HSR] Act." 78 Fed. Reg. at 68,706; JA at 8. The gravamen of PhRMA's complaint is that the Final Rule imposes "fundamental changes to the HSR Act pre-merger notification requirements that would, for the first time in the Act's 37-year history, single out and burden one industry alone with additional notification requirements for patent license transactions previously not regarded by the antitrust agencies as potentially anticompetitive enough to warrant any pre-closing review whatsoever." Pl.'s Mem. Pts & Authorities Supp. Mot. Summ. J. ("Pl.'s Mem.") at 5, ECF No. 13. According to PhRMA, this "selective coverage," *id*., exceeds the FTC's statutory authority "*to relieve* certain classes of persons or transactions" from notification requirements and "[i]nstead, the Rule *imposes new burdens* selectively on a targeted class of persons (*i.e.*, those in the pharmaceutical industry only) in connection with patent license transactions suddenly now regarded by the agency as likely anticompetitive," *id*. at 17 (emphasis in original). Specifically, the Final Rule addresses two types of transfers of exclusive patent rights that the FTC observed occurred frequently, if not exclusively, in the pharmaceutical industry, prompting the agency to limit application of the Rule to this industry: (1) the transfer of exclusive rights under a patent to use and sell, with retention by the licensor of the right to manufacture ("retained manufacturing rights"); and (2) the transfer of exclusive rights under a

[2] The parties have requested oral argument on the pending motion, Compl. at 25; Pl.'s Mot. at 1; Def.'s Mot. at 1, but given the sufficiency of the parties' written submissions, this request is denied. *See* D.D.C. Local Rule 7(f) (allowance of oral hearing is "within the discretion of the court").

patent to make, use, and sell, with retention by the licensor of co-rights, in whole or part ("retained co-rights"). 78 Fed. Reg. at 68,707–08; JA at 9–10.

PhRMA contends that the "selective coverage" of the Final Rule exceeds the FTC's authority under the plain terms of the HSR Act and, furthermore, even if the statute were found to be ambiguous, the agency's "interpretation of its authority is completely at odds with congressional intent," Pl.'s Reply Supp. Mot. Summ. J. & Opp'n FTC's Cross-Mot. Summ. J. ("Pl.'s Reply") at 1, ECF No. 17, such that the Final Rule "is entitled to no deference, and [] should be vacated," *id*. at 18. The FTC disputes PhRMA's view that the meaning of the HSR Act is plain, positing instead that the statute is silent regarding whether "Congress intended to prohibit the Commission from issuing industry-specific coverage rules." Def.'s Mem. Pts. & Authorities Supp. Mot. Summ. J. & Opp'n Pl.'s Mot. Summ. J. ("Def.'s Mem.") at 11, ECF No. 15. The FTC further contends that the Final Rule is an appropriate exercise of its authority to define terms used in the Act "as necessary and appropriate to carry out the purposes of" the statute. *Id*. at 14.

To aid in resolution of this dispute over statutory interpretation, the Court begins with an overview of the HSR Act, before turning to a discussion of the challenged rule and procedural history of the instant case.

A. Statutory and Regulatory Framework

Enacted in 1976, the HSR Act was intended to assist enforcement agencies in determining whether an anticipated merger or acquisition was likely to violate federal antitrust laws. *See* S. REP. No. 94-803, at 1 (1976); H. R. REP. NO. 94-1373, at 5 (1976), *reprinted in* 1976 U.S.C.C.A.N. 2637, 1976 WL 13988; *Mattox v. FTC*, 752 F.2d 116, 119–20 (5th Cir.

1985) (finding that the HSR Act "was designed to allow review of mergers before they were completed" to determine, pre-consummation, whether such mergers violated antitrust laws). To this end, Section 7A of the HSR Act, codified in 15 U.S.C. § 18a, requires the transferring parties to report to the FTC and the Assistant Attorney General at the U.S. Department of Justice any anticipated transfers of assets when the transferred asset and/or the transferring parties meet certain minimum size requirements specified in the Act.[3] The Act "reflects a congressional judgment that divestiture and other post-acquisition remedies were difficult, expensive and sometimes futile," and that safeguards were therefore necessary to evaluate anticipated mergers before they occurred. *Mattox*, 752 F.2d at 119.

Section 7A of the HSR Act provides that, when planned acquisitions meet statutorily defined minimum size requirements, "[e]xcept as exempted pursuant to subsection (c) of this section, no person shall acquire, directly or indirectly, any voting securities or assets of any other person, unless both persons . . . file notification pursuant to rules under subsection (d)(1) of this section and the waiting period described in subsection (b)(1) of this section has expired." *See* 15 U.S.C. § 18a(a); *see also* An Act to Improve and Facilitate the Expeditious and Effective Enforcement of the Antitrust Laws, And For Other Purposes, Pub. L. No. 94-435 tit. II, § 7A(a) (1976).[4] Subsection (c) of the Act exempts altogether certain classes of transactions from the

[3] The HSR Act amended the Clayton Antitrust Act of 1914, s*ee* An Act to Improve and Facilitate the Expeditious and Effective Enforcement of the Antitrust Laws, And For Other Purposes, Pub. L. No. 94-435 tit. II, § 7A(a) (1976), and is codified in the U.S. Code as follows: Title I in 15 U.S.C. §§ 1311–14 and 18 U.S.C. § 1505; Title II, which is at issue in the instant litigation, in 15 U.S.C. § 18a; and Title III in 15 U.S.C. § 15c–15h. *See* Pub. L. No. 94-435; *Mattox*, 752 F.2d at 119.

[4] The minimum size requirements for an acquisition to trigger notification requirements under the HSR Act specify that parties must report transactions where:

> [A]s a result of such acquisition, the acquiring person would hold an aggregate total amount of the voting securities and assets of the acquired person--

reporting requirement in subsection (a). 15 U.S.C. § 18a(c). In addition to eleven categories of statutorily defined exempt transactions, subsection (c) also authorizes the FTC to exempt from premerger notification "such other acquisitions, transfers, or transactions" that otherwise meet the minimum size requirements. *See id.* § 18a(c)(12).

The FTC's broad exemption authority is also repeated in subsection (d), which provides for the exercise of rulemaking and exemption authorities at issue in the instant suit. Specifically, subsection (d)(1) authorizes the FTC to promulgate rules to implement the Act, stating that the FTC "shall require that the notification required under subsection (a) of this section be in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Federal Trade Commission and the Assistant Attorney General to determine whether such acquisition may, if consummated, violate the antitrust laws[.]" 15 U.S.C. § 18a(d)(1). Subsection (d)(2) grants the FTC authority to "define the terms used in this section" and "prescribe such other rules as may be necessary and

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> (A) in excess of $200,000,000 (as adjusted and published for each fiscal year beginning after September 30, 2004, in the same manner as provided in section 19(a)(5) of this title to reflect the percentage change in the gross national product for such fiscal year compared to the gross national product for the year ending September 30, 2003); or
> (B)(i) in excess of $50,000,000 (as so adjusted and published) but not in excess of $200,000,000 (as so adjusted and published); and
> (ii)(I) any voting securities or assets of a person engaged in manufacturing which has annual net sales or total assets of $10,000,000 (as so adjusted and published) or more are being acquired by any person which has total assets or annual net sales of $100,000,000 (as so adjusted and published) or more;
> (II) any voting securities or assets of a person not engaged in manufacturing which has total assets of $10,000,000 (as so adjusted and published) or more are being acquired by any person which has total assets or annual net sales of $100,000,000 (as so adjusted and published) or more; or
> (III) any voting securities or assets of a person with annual net sales or total assets of $100,000,000 (as so adjusted and published) or more are being acquired by any person with total assets or annual net sales of $10,000,000 (as so adjusted and published) or more.

15 U.S.C. § 18a(a)(1), (2)(A)–(B). The minimum size requirements have been updated since the passage of the HSR Act, *compare id.*, *with* Pub. L. No. 94-435 tit. II, § 7A(a)(2), pursuant to the FTC's authority to make annual updates that "reflect the percentage change in the gross national product," *see* District of Columbia Appropriations—FY 2001, Pub. L. No. 106-553, 114 Stat. 2762 (2000), but such changes are immaterial to the resolution of the instant motion.

appropriate to carry out the purposes of this section." *Id.* § 18a(d)(2)(A), (C). Finally, subsection (d)(2)(B) authorizes the FTC to "exempt, from the requirements of this section, classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws[.]" *Id.* § 18a(d)(2)(B).[5] Pursuant to the rulemaking authority granted by subsection 18a(d), the FTC has promulgated rules codified in 16 C.F.R. §§ 801–03. The Final Rule challenged in this action amended the regulation at 16 C.F.R. § 801.2.

In sum, three provision in the HSR Act, subsections (a), (c), and (d), expressly authorize the FTC to exempt certain "classes of persons, acquisitions, transfers, or transactions" from the requisite reporting, even if the transfer of assets meets the minimum size requirements under subsection (a).

B. Challenged FTC Rule

In order to clarify the meaning of an acquiring or acquired person, used in section (a) of the HSR Act, 15 U.S.C. § 18a(a), the Final Rule adds a new paragraph (g) to 16 C.F.R. § 801.2, which sets out the criteria for transfers that are reportable under the HSR Act. 78 Fed. Reg. at 68,712–13; JA at 14–15. This new paragraph (g) clarifies that the "[t]ransfers of patent rights within NAICS Industry Group 3254[6] [*i.e.*, the pharmaceutical industry] . . . constitutes an asset acquisition . . . if and only if all commercially significant rights to a patent . . . for any

[5] The language of subsections (c) and (d) has remained largely unchanged in the nearly four decades since the HSR Act was passed in 1976. *Compare* 15 U.S.C. § 18a(c)(1)–(12), (d), *with* Pub. L. No. 94-435 tit. II, § 7A(c) and (d).

[6] The NAICS (North American Industry Classification System) is a code system developed for the benefit of businesses and Federal statistical agencies under the auspices of the White House Office of Management and Budget that numerically classifies industries based on the activities they engage in. *See* INTRODUCTION TO NAICS, http://www.census.gov/eos/www/naics/ (last revised Feb. 27, 2014). The Final Rule specifies that the industries comprising NAICS Industry Group 3254 are: medical and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing, and biological product (except diagnostic) manufacturing. 78 Fed. Reg. at 68,705.

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 . . . or co-rights . . . ." 78 Fed. Reg. at 68,713; JA at 15. The Final Rule also adds and defines three new terms: "[a]ll commercially significant rights,"[7] "[l]imited manufacturing rights,"[8] and "co-rights"[9] to 16 C.F.R. § 801.1, which contains HSR Act definitions, 78 Fed. Reg. at 68,712–13; JA at 14–15. The rulemaking process underlying the adoption of the Final Rule is described below.

1. Notice of Proposed Rulemaking

On August 20, 2012, the FTC issued a Notice of Proposed Rulemaking ("NPRM") to clarify when "the transfer of exclusive rights to a patent in the pharmaceutical industry [for a specific therapeutic area]. . . constitute[s] a potentially reportable asset acquisition." Premerger Notification; Reporting and Waiting Period Requirements, 77 Fed. Reg. 50,057, 50,058 (Aug. 20, 2012); JA at 2. The NPRM proposed a new paragraph to 16 C.F.R. § 801.2 stating that the transfer of patent rights covering products for which the manufacture and sale would generate

[7] The term "all commercially significant rights," as used in the Final Rule's new paragraph describing "all commercially significant rights" subject to reporting, is defined in the Final Rule 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 (or specific indication within a therapeutic area)." 77 Fed. Reg. at 50,061; JA at 5.

[8] The term "limited manufacturing rights," as used in the Final Rule's new paragraph describing "all commercially significant rights" subject to reporting, is defined to "mean[] 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)." *Id.*

[9] The term "co-rights," as used in the Final Rule's new paragraph describing "all commercially significant rights" subject to reporting, is defined to mean "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." *Id.*

revenues in the pharmaceutical industry, are reportable acquisitions when "[a]ll commercially significant rights" are transferred even if the patent holder retains "limited manufacturing rights" or "co-rights," as defined in the new proposed definitions at 16 C.F.R. § 801.1 (p) and (q), respectively. 77 Fed. Reg. at 50,061; JA at 5. Since the discussion in the NPRM about the proposed rule is repeated and supplemented in the Final Rule, the Court summarizes the background and rationale for the new definitions and new paragraph comprising the challenged rule in the discussion of the Final Rule.

The FTC received three comments in response to the NPRM, two in support and one in opposition. JA at 16–21 (Comment 1 from Antonio Burrell, private citizen) (Oct. 25, 2012) (supporting the rule); *id.* at 22–68 (Comment 2 from PhRMA ("PhRMA Comment")) (Oct. 25, 2012) (opposing the rule); and *id.* at 69 (Comment 3 from Clyde Dinkins, private citizen) (Aug. 13, 2012) (supporting the rule as "long overdue"). In support of its critical comment, PhRMA submitted the declaration of economic consultant Thomas R. Varner ("Varner Decl."), who was retained by PhRMA. *See generally* Varner Decl., JA at 38–68. After the close of the comment period on October 25, 2012, 78 Fed. Reg. at 68,706; JA at 8, PhRMA met with Commissioners on the FTC on four different occasions to discuss the proposed rule. *See* JA at 71 (Summary of Communications: Apr. 18, 2013 meeting between PhRMA and FTC Chairwoman Edith Ramirez and FTC staff); JA at 70 (Summary of Communications: Apr. 3, 2013 meeting between PhRMA and FTC Commissioner Joshua D. Wright and his advisers); JA at 75 (Summary of Communications: Mar. 13, 2013 meeting between PhRMA and FTC Commissioner Julie Brill and her attorney advisors and staff); JA at 77 (Summary of Communications: Feb. 26, 2013 meeting between PhRMA and FTC Commissioner Maureen K. Ohlhausen and her attorney

advisors). Over the course of these meetings, PhRMA submitted "additional information about [the] projected costs" of the proposed rule, *see* JA at 72–74 (Letter dated June 7, 2013, from plaintiff's counsel to an FTC Commissioner), reiterated the objections discussed in its comment to the proposed rule, and raised three additional objections: (1) the rule conflicted with international antitrust principles of nondiscrimination, *id.* at 70, 71, 77; (2) pharmaceutical transactions subject to the proposed rule would be easy to unwind, *id.* at 70, 75; and (3) the proposed rule would set a bad precedent, *id.* at 77.

2. The Final Rule

Notwithstanding the critical views expressed by PhRMA in response to the NPRM and in meetings with FTC Commissioners, the Final Rule was promulgated without any changes from the proposed version on November 15, 2013, and became effective on December 16, 2013. 78 Fed. Reg. at 68,705; JA at 7; *see also* 78 Fed. Reg. at 68,706; JA at 8 (stating that "[a]fter carefully considering the comments," the FTC decided to "adopt[] the rule as proposed"). The Final Rule rested on the FTC's authority under 15 U.S.C. 18(a)(d) "to require that premerger notification be in such form and contain such information and documentary material as may be necessary and appropriate," and "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 the section. 78 Fed. Reg. at 68,705–06; JA at 7–8 (citing 15 U.S.C. § 18a(d)(1), (2)). The rule "is limited to the pharmaceutical industry," but makes clear that "to the extent [] other industries engage in similar exclusive licensing transactions, such transactions remain potentially reportable events under the Act," and that the FTC continued "to assess the appropriateness of a rule for other industries." 78 Fed. Reg. at 68,706; JA at 8

A brief review of the practice of transferring exclusive patent rights, as described in the Final Rule (and the NPRM), is helpful in understanding the context for the FTC's action.

a) *Transfer of Exclusive Patent Rights*

As noted, while the HSR Act sets out statutory minimum threshold size requirements for reportable acquisitions, 15 U.S.C. § 18a(a), the Act also authorizes the FTC to define critical terms in order to target those transactions triggering the reporting requirement, *id.* § 18a(d)(2)(A). A patent is considered an asset by the FTC, the transfer of which may be reportable. 78 Fed. Reg. at 68,706 & n.4; JA at 8 & n.4 (citing *SCM Corp. v Xerox Corp*., 645 F.2d 1195, 1210 (2d Cir. 1981), for proposition that "[s]ince a patent is a form of property . . . and thus an asset, there seems little reason to exempt patent acquisitions from scrutiny under" the HSR Act). Transactions may, however, involve the transfer of certain exclusive patent rights without transferring the patent in its entirety, which requires a more searching analysis of the nature of the rights being transferred. *See id.* According to the FTC, the transfer of the "right to commercially use [a] patent, or a part of [a] patent, to the exclusion of all others . . . is substantively the same as buying the patent or part of the patent outright" and is "a potentially reportable asset acquisition under the Act." *Id.* "For years" the Premerger Notification Office ("PNO"), the division of the FTC that administers the premerger notification program, Def.'s Mem. at 3, would evaluate whether the transfer of rights to a patent was potentially reportable by analyzing whether the exclusive rights to "make, use, and sell" under a patent were being transferred, *see* 78 Fed. Reg. at 68,706; JA at 8 ("[T]he PNO had only to verify that the transfer involved the exclusive right to use a patent or part of a patent to develop a product, manufacture the product, and sell that product without restriction"); *see also* Def.'s Mem. at 4. The FTC

explained that "[a]lthough never codified, the 'make, use and sell' approach became well-known throughout the HSR bar and is reflected in the numerous letters and emails from practitioners in the PNO's informal interpretation database on its Web site," 78 Fed. Reg. at 68,706 & n.8; JA at 8 & n.8 (including in a footnote a link to the online location of the informal interpretation database).

The Final Rule discussed two categories of patent rights transfers that, according to the FTC, appeared predominantly, if not exclusively, in the pharmaceutical industry. 78 Fed. Reg. at 68,707–08; JA at 9–10. The first category of transactions occurs when the licensor sells exclusive rights to use and sell a patent to a licensee, but retains for itself manufacturing rights. *Id*. The FTC noted that "in the pharmaceutical industry, the right to manufacture is less important than the right to commercialize," such that transferring use and sale rights to a patent and retaining "the right to manufacture solely for the licensee . . . has the same effect as a transfer to the licensee of all patent rights" under the "make, use, and sell" approach. 78 Fed. Reg. at 68,708; JA at 10. The second category of transactions occurs when the licensor retains co-rights, which are "shared rights to assist the licensee in developing and commercializing the patented product and includes rights to co-develop, co-promote, co-market, and co-commercialize," even though the licensor has already granted the licensee "an exclusive license to 'make, use, and sell' under a patent." 78 Fed. Reg. at 68,707; JA at 9. Under such agreements, the licensor does not retain the right "to commercially use the patent or part of the patent" and, consequently, even under the "make, use, and sell" approach, such transaction is potentially reportable under "the PNO staff's established position." *Id.* These two categories of patent rights transfers, where the licensor retains only manufacturing rights or co-rights, are the

subject of the FTC's Final Rule.

b) *Need for Proposed Rule*

According to the FTC, transfers of exclusive patent rights covered by the Final Rule "carr[y] the same potential anticompetitive effects" as buying a patent outright. 78 Fed. Reg. at 68,706; JA at 8; *see also* 78 Fed. Reg. at 68,709; JA at 11 (transfers of patent rights subject to the Final Rule "are functionally equivalent to patent transfers and are thus properly viewed as asset acquisitions under the Act"); 78 Fed. Reg. at 68,711; JA at 13 ("Like patent sales, exclusive patent licenses prevalent in the pharmaceutical industry are asset acquisitions that may produce anticompetitive effects."). Further, in the FTC's view, "[a]llowing such transactions to go unreported would deprive the Commission of an opportunity, consistent with the purpose of the Act, to review these significant asset acquisitions that, like other reportable asset acquisitions, are potentially anticompetitive." 78 Fed. Reg. at 68,709; JA at 11. Consequently, the Final Rule adopts the "all commercially significant rights" concept to determine whether the exclusive rights to a patent are an "asset" subject to reporting under the Act, as proposed in the NPRM. 78 Fed. Reg. at 68,707; JA at 9; *see also* 77 Fed. Reg. at 50,059; JA at 3. The FTC pointed out that the test for "'all commercially significant rights'" adopted in the rule "captures more completely what the 'make, use, and sell' approach was a proxy for, namely whether the license has transferred the exclusive right to commercially use a patent or a part of a patent." 78 Fed. Reg. at 68,707; JA at 9. The FTC stated that "the amended reporting requirements are necessary to effectuate the purposes of the HSR Act," which "is intended to allow the Agencies to review significant transactions to determine, prior to consummation of a transaction, if it is anticompetitive." 78 Fed. Reg. at 68,711; JA at 13. The FTC clarified that the rule only codified

"the PNO's long-standing position that the retention of co-rights does not render a license to the patent or part of the patent as non-exclusive," and explained that "a reportable asset transfer may occur even if the licensor retains the limited right to manufacture under the patent or part of a patent for the licensee." 78 Fed. Reg. 68,707; JA at 9; *see also id.* ("[W]ith the exception of the treatment of the right to manufacture exclusively for the licensee, the rule treats the reportability of exclusive licensing arrangements, including those where the licensor retains co-rights, in the same way that the PNO has for decades.").

c) *Justification for Limiting Rule to the Pharmaceutical Industry*

The FTC limited the Final Rule to the pharmaceutical industry based upon the following four findings: First, "exclusive patent licensing agreements that transfer all of the rights to commercially use a patent or part of a patent almost solely occur in the pharmaceutical industry." 78 Fed. Reg. at 68,708; JA at 10; *see also id.* ("[T]he PNO typically does not see exclusive transfers of rights to a patent or part of a patent outside the pharmaceutical context, and this is likely a result of the incentives that characterize the industry.").

Second, the use of this transfer mechanism in the pharmaceutical industry is growing. 78 Fed. Reg. at 68,706; JA at 8 ("In recent years . . . 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 [this] approach is no longer adequate in evaluating the reportability of exclusive licenses in the pharmaceutical industry for HSR purposes."); *see also* 78 Fed. Reg. at 68,707; JA at 9 ("[D]ue to the evolution of pharmaceutical patent licenses, the 'make, use, and sell' approach is no longer adequate to evaluate the HSR reportability of exclusive patent licenses in the pharmaceutical industry.").

Third, according to the FTC, transfers of exclusive patent rights in the pharmaceutical industry operate differently as compared to other industries. 78 Fed. Reg. at 68,708; JA at 10. As explained in the Final Rule, a licensor typically grants exclusive patent rights to a licensee in exchange for the requisite resources and funding to complete the FDA approval process, whereas in other industries, the sale of a patent comes "at a much later stage in development, and the patent owner can simply sell the patent for its proven value." *Id.*[10] Further, outside the pharmaceutical industry, licensors are typically incentivized to "engag[e] as many licensees as possible," rather than to grant exclusive licenses, as in the pharmaceutical industry. *Id.* The FTC explained that it reached this conclusion "[b]ased on HSR filings and requests for advice on the reportability of transactions," *id.*, noting that the FTC found that "[p]ractitioners who represent clients in the pharmaceutical industry have often sought guidance from the PNO about" the acquisitions covered by the Final Rule, 78 Fed. Reg. at 68,706; JA at 8. Consequently, the Final Rule was limited to 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; JA at 10. The Final Rule elaborated that, since 2008,

> the PNO received filings for 66 transactions involving exclusive patent licenses, and all were for pharmaceutical patents. The PNO has not found other industries that rely on these types of arrangements. Although it is possible for other industries to engage in the kind of exclusive licensing that typifies the pharmaceutical industry, the PNO has not processed filings related to these kinds of exclusive licenses in any other industry in the past five years. In addition, requests for guidance on the treatment of exclusive patent licensing transactions have generally been limited to the pharmaceutical industry. *Accordingly, the*

[10] The FTC provided an explanatory scenario that "[t]he PNO quite frequently sees": an innovator discovers and obtains a patent for a compound but lacks the resources to bring it to market, and subsequently enters into an exclusive licensing agreement with a typically larger pharmaceutical company that will usher the drug through the FDA approval process and subsequent marketing and promotion. 78 Fed. Reg. at 68,708; JA at 10. While the licensee reaps the lion's share of any profits, the innovator-licensor receives a smaller share of profits "through royalties or other revenue sharing arrangements." *Id.*

Commission has not found a need for a rule applicable to other industries.

Id. (emphasis added). The Final Rule reiterated the points made in the NPRM that the rule would "address the evolving structure of exclusive patent licenses in the pharmaceutical industry, [and] provide[] the Agencies with a more effective means of reviewing exclusive patent licenses meeting the statutory requirements under the Act." 78 Fed. Reg. at 68,707; JA at 9.

Finally, the FTC limited the new rule to one industry because it "need not take an all-or-nothing approach . . . [but] may proceed incrementally" in promulgating regulations and "may limit rules to those areas where [it has] observed a problem to be addressed." 78 Fed. Reg. at 68,709–10; JA at 11–12. The FTC believed it was "not required to resolve a problem that may occur more broadly 'in one fell regulatory swoop'" but will, instead, "continue to assess the appropriateness of a rule for other industries." 78 Fed. Reg 68,710; JA at 12.

d) *Consideration and Rejection of PhRMA's Objections*

Throughout the Final Rule, the FTC addressed the objections PhRMA raised in its comment to the NPRM. *See generally* 78 Fed. Reg. at 68,705–13; JA at 7–15. Specifically, PhRMA criticized the proposed rule for three significant perceived shortcomings, none of which were determined by the FTC to warrant modification or rejection of the rule as proposed in the NPRM.

i. *Objection to Treatment of Retained Co-Rights*

First, PhRMA objected to the PNO's uniform treatment of the retention of co-rights as "unclear and/or inconsistent," because it failed to "differentiate between the kinds, magnitude, or scope of co-rights being retained," as required under the HSR Act. 78 Fed. Reg. at 68,707; JA at 9. PhRMA reasoned that such a "blanket rule . . . mak[ing] the nature, extent, and other terms of

co-rights retained by a licensor irrelevant to the transaction's HSR reportability is at a minimum overbroad." PhRMA Comment at 12; JA at 33. The FTC gave two reasons for rejecting the objection. First, the FTC explained that the new approach reflected in the Final Rule treated co-rights consistently with the prior "make, use and sell" approach, "as illustrated by numerous informal interpretations" available on the FTC's public informal interpretations database. 78 Fed. Reg. at 68,707; JA at 9. Second, the asset transfer determination "does not hinge" on the scope of the co-right retained, "but on whether the exclusive patent license allows only the licensee to commercially use the patent[.]" *Id.*

ii. *Objection to Limitation to Pharmaceutical Industry*

Second, PhRMA vigorously objected to limiting the Final Rule to the pharmaceutical industry on five separate grounds, ranging from the use by other industries of similar patent rights transfers and extending to challenging the fundamental authority of the agency to issue such a rule. Each of these grounds were addressed in the Final Rule. First, in PhRMA's view, "there are agreements in other industries that involve the retention of manufacturing rights," which undermines the agency's rationale for restricting the Final Rule to the pharmaceutical industry. 78 Fed. Reg. at 68,708; JA at 10. In support of this objection, PhRMA cited examples identified in the Varner Declaration of license agreements in which a party retains manufacturing rights occurring outside of the pharmaceutical industry. *See* PhRMA Comment at 9 & n.36; JA at 30 & n.36; Varner Decl. at 12–14; JA at 49–51. These agreements include "licensors licens[ing patent rights] on an exclusive basis . . . and retain[ing] manufacturing rights" in the chemical, electronic component, and medical device industries. Varner Decl. at 12–14; JA at 49–51; *see, e.g.*, Varner Decl. at 13; JA at 50 ("Electronic Components: Licensor Sanken

Electric Co., Ltd., entered into a Distribution Agreement with Allegro MicroSystems, Inc. in which Sanken licensed on an exclusive basis semiconductor technologies and retained the manufacturing rights."); Varner Decl. at 14; JA at 51 ("Medical Device Industry: Licensor Unique Mobility, Inc. entered into a License Agreement and a Supply Agreement with Invacare Corporation in which Unique Mobility licensed patented motor technology for wheelchairs on an exclusive basis and retained the manufacturing rights."). The FTC declined to expand the rule across industries for two reasons. First, although acknowledging the examples of agreements of purportedly similar rights transfers in other industries, the FTC viewed such arrangements as distinct from the patent rights transfers covered in the Final Rule. Specifically, the FTC explained that the proffered examples "are exclusive distribution agreements, which convey to the licensee only the exclusive right to distribute the patented product . . . [and] the licensor retains not just the right to manufacture but all commercially significant rights to the patent," by contrast to the type of transaction the FTC sought to regulate by promulgation of this rule. 78 Fed. Reg. at 68,708; JA at 10 (citing and distinguishing the Varner Declaration). Second, the FTC noted that, other than these distribution agreements, PhRMA "has not identified any other industry in which exclusive patent licenses, as opposed to exclusive distribution agreements, are common." 78 Fed. Reg. at 68,709; JA at 11.

Second, PhRMA contested the premise expressed in the NPRM restricting the Final Rule to the pharmaceutical industry on the basis that manufacturing is less important in the pharmaceutical industry than the right to commercialize. 78 Fed. Reg. at 68,708; JA at 10. Again, relying on the Varner Declaration, PhRMA's Comment pointed out that "the right to manufacture in pharmaceuticals can be important," in part because pharmaceutical products may

have patents based on, *inter alia*, manufacturing technologies. *See* Varner Decl. at 15; JA at 52. As support, the declaration listed a number of agreements in the pharmaceutical industry that grant manufacturing, process, or production patents. *Id.* at 15–16; JA at 52–53; *see, e.g.*, Varner Decl. at 16; JA at 53 ("Merck & Co, Inc. entered into an Asset Transfer and License Agreement with Guilford Pharmaceuticals Inc. in which "Process Patents" are specified"); *id.* ("Amgen Inc. entered into a License and Commercialization Agreement with InterMune Pharmaceuticals, Inc. in which 'Manufacturing Patents' are specified"). In response, the FTC stated that the referenced discussion in the NPRM was not "a general assessment of the value of manufacturing," but only sought to "provide a possible explanation as to why the PNO sees exclusive patent licenses in the pharmaceutical industry structured the way they are structured, namely more and more frequently without the transfer of manufacturing rights." 78 Fed. Reg. at 68,708; JA at 10.

Third, PhRMA objected to the Final Rule's restriction to the pharmaceutical industry based on the industry's unique "regulatory hurdles," "incentives[,] and market structure," since these characteristics may be found in other industries. *Id.* The Final Rule acknowledged PhRMA's identification of other industries that encounter the same "regulatory hurdles" and, further, that have similar "royalty rates" reflecting that "the incentives to maximize future profits are no different." *Id.*; *see also* Varner Decl. at 9–11; JA at 46–48. Nevertheless, the FTC explained that "[t]he rule is limited to the pharmaceutical industry not because of the uniqueness of the incentives in that industry but because it is the only industry to the PNO's knowledge in which exclusive patent licenses are prevalent." 78 Fed. Reg. at 68,708–09; JA at 10–11; *see also* 78 Fed. Reg. at 68,709; JA at 11 ("[T]he exclusive patent licenses frequently seen in the pharmaceutical industry have not been seen by the PNO in other industries."). The FTC clarified

that its discussion of incentives and market structure was not a justification for restricting the rule, but was raised to "help explain" why transferring patent rights in the pharmaceutical industry "takes the form of an exclusive license instead of an outright sale." 78 Fed. Reg. at 68,709; JA at 11.

Fourth, PhRMA objected on the same grounds raised in this lawsuit, that the FTC does not have the authority to "expand[] the Act's requirements with respect to only a single industry." *Id*. In PhRMA's view, the plain language and legislative history of the HSR Act reflect Congress's intent for uniform application of the FTC's regulations, and, consequently, the FTC has never before promulgated an HSR rule that "increases the [HSR] Act's requirements for only a single industry, nor has it even tried to do so until now." PhRMA Comment at 3; JA at 24; *see also* PhRMA Comment at 4–5; JA at 25–26 (reasoning that Congress "nowhere granted the FTC authority to increase the HSR Act's reporting burden for only a single industry"). By contrast to other statutory schemes, where Congress has explicitly imposed additional filing requirements on the pharmaceutical industry, Congress has not done so under the HSR Act. PhRMA Comment at 4–5; JA at 25–26. The FTC disagreed with this statutory interpretation for two reasons. First, the FTC stated its view that the Final Rule was not an expansion of the FTC's statutory authority, nor an expansion of the HSR Act's coverage, but a rulemaking to determine which types of transactions already covered by the HSR Act constitute asset transfers requiring notification. 78 Fed. Reg. at 68,709; JA at 11. Second, the FTC stated that "Section 18(a)(d)(2)(B), which grants the Commission [exemption] authority . . . does not limit the broad and discretionary rulemaking authority granted in Sections 18a(d)(2)(A) and (C)." *Id.* It further reasoned that "[t]he authority to exempt specific industries or transactions from the Act's filing

requirements is not inconsistent with the authority to implement these requirements on an industry-specific basis prior to consummation of these agreements." *Id.*

Finally, PhRMA objected that applying the rule selectively on an industry-specific basis was "arbitrary and capricious" for failure to provide sufficient evidentiary support. PhRMA Comment at 8; JA at 29. As support for this objection, PhRMA stated that the FTC does not provide "facts and analysis" or objective evidence in support of the rule but "offers up only its own [agency] 'expertise,'" which is insufficient. *Id.* Furthermore, since the licensing transactions subject to the rule "are not limited to the pharmaceutical industry" and are found in other industries, which have the same incentives for retaining co-rights and manufacturing rights as the pharmaceutical industry, the industry-specific rule is not well-reasoned. PhRMA Comment at 9–10; JA at 30–31. The FTC disagreed, providing three reasons justifying its adoption of the rule as proposed. First, the FTC explained that the rule applied to the pharmaceutical industry "because the PNO has not received filings over the past five years for exclusive patent licensing arrangements in other industries and requests for guidance on the treatment of exclusive patent licensing arrangements have nearly always come from practitioners in the pharmaceutical industry." 78 Fed. Reg. at 68,709; JA at 11. The FTC added that its experience allows it "to tailor the rule to the pharmaceutical industry." *Id.* Second, the FTC stated that its experience "indicated a need for a rule for the pharmaceutical industry" but that "at this time, the [FTC] has not yet determined that a specific rule is necessary with respect to other industries." *Id.* The FTC stated that to the extent they occur, such transfers of exclusive rights may still be reportable "under the Act and existing HSR rules." *Id.* Third, the FTC stated that it "may limit rules to those areas where they have observed a problem to be addressed," *id.*, and

that the FTC "need not take an all-or-nothing approach" but may "proceed incrementally," 78 Fed. Reg. at 68,710; JA at 12.

iii. *Objections As To Cost*

As a third category of objections to the Final Rule, PhRMA raised concern over the costs of the proposed rule. Specifically, PhRMA's objected to the premerger notification requirement because the filing cost would have a negative impact on small businesses, 78 Fed. Reg. at 68,711; JA at 13, by "increas[ing] by at least 50% the number of HSR filings required annually by members of the pharmaceutical industry" resulting in "substantial" costs "with small businesses bearing a significant brunt of" these costs. PhRMA Comment at 13; JA at 34. The FTC rejected this predicted impact on small businesses for three reasons. First, the FTC stated that a transaction "must be valued at more than $50 million (as adjusted)" to fall under the HSR Act, which "typically [would] not catch most transactions involving small entities." 78 Fed. Reg. at 68,710; JA at 12. Second, the FTC reasoned that because the HSR Act requires a party to the transaction to have at least $10 million in sales, the "size of person test also ensures that the Act does not regularly reach small entities." *Id.* Third, the FTC stated that any small business having to file such notification "would in most instances be filing under the Act as the acquired person in the context of an asset transaction and would therefore be submitting less information" resulting in less of a burden on small entities. *Id.* Regarding the concerns that such increased filing costs "could chill pharmaceutical transactions," the FTC responded that such filing costs are relatively small compared to "the profits at stake in the multi-million dollar transactions reportable under the Act," and thus, would not be a deterrent. *Id.* Moreover, the FTC pointed out that the parties would likely "conduct a patent valuation as part of their due

diligence notwithstanding HSR" and that therefore the transferring parties would already be incurring these costs regardless of the promulgation of the Final Rule. *Id.*

Additionally, related to the concern over cost, the FTC analyzed the cost estimates of filing requirements and filing fees submitted by PhRMA in its original comment and supplemental documentation. JA at 72–74 (Letter dated June 7, 2013, from plaintiff's counsel to an FTC Commissioner); 78 Fed. Reg. at 68,711–12; JA at 13–14; *see also* PhRMA Comment at 13–14; JA at 34–35. The FTC concluded that PhRMA's estimates were higher than those of the FTC's, and consequently adjusted its burden increase estimate "out of an abundance of caution and in light of the comments." 78 Fed. Reg. at 68,712; JA at 14; *see also id.* (responding to PhRMA comment's concern regarding the costs of responding to additional information requests).

e) *PhRMA's Complaint*

Less than a week before the effective date of the Final Rule, PhRMA filed the instant action challenging the FTC's promulgation of the Final Rule. *See generally* Compl. PhRMA alleges in three claims under the APA that the issuance of the Final Rule was: (1) "in excess of [the FTC's] statutory jurisdiction, authority, or limitations" under the HSR Act, 5 U.S.C. § 706(2)(C); Compl. ¶¶ 89–93 (Count I); (2) "arbitrary, capricious, and an abuse of discretion," 5 U.S.C. § 706(2)(A); Compl. ¶¶ 94–100 (Count II); and (3) "without observance of procedure required by law," 5 U.S.C. § 706(2)(D); Compl. ¶¶ 101–06 (Count III). Count Four of PhRMA's complaint seeks a declaratory judgment "clarifying the legal relations of the parties." Compl. ¶¶ 107–09 (Count IV). In addition, PhRMA seeks vacatur of the Rule, attorneys' fees, and a permanent injunction preventing the FTC and its officers from "enforcing, applying, or

implementing" the Final Rule. Compl. at 26.

The parties' cross-motions for summary judgment are now pending before this Court. *See* Pl.'s Mem.; Def.'s Mem.

II. STANDARD OF REVIEW

A. Summary Judgment Standard

Pursuant to Federal Rule of Civil Procedure 56, summary judgment may be granted when the Court finds, based upon the pleadings, depositions, and affidavits and other factual materials in the record, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a), (c); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "A genuine issue of material fact exists if the evidence, 'viewed in a light most favorable to the nonmoving party,' could support a reasonable jury's verdict for the non-moving party." *Muwekma Ohlone Tribe v. Salazar*, 708 F.3d 209, 215 (D.C. Cir. 2013) (quoting *McCready v. Nicholson*, 465 F.3d 1, 7 (D.C. Cir. 2006)).

When, as here, "a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal. The 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (citing *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); and *Univ. Med. Ctr. of S. Nevada v. Shalala*, 173 F.3d 438, 440 n. 3 (D.C. Cir. 1999)). Accordingly, this Court need not and ought not engage in lengthy fact finding, since "[g]enerally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions." *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996); *see also Sierra Club v. Mainella*, 459 F. Supp. 2d

76, 90 (D.D.C. 2006) ("Under the APA . . . the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.") (quotation marks and citation omitted)); *accord McDonough v. Mabus*, 907 F. Supp. 2d 33, 42 (D.D.C. 2012); *Wilson v. McHugh*, 842 F. Supp. 2d 310, 315 (D.D.C. 2012). Judicial review is limited to the administrative record. 5 U.S.C. § 706(2) ("[T]he Court shall review the whole record or those parts of it cited by a party . . . ."); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) (in applying the arbitrary and capricious standard under the APA, "[t]he focal point for judicial review should be the administrative record already in existence . . . ." (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973))).

B. *Chevron* Framework

The D.C. Circuit has applied the familiar two-step process set out in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.* (*Chevron*), 467 U.S. 837, 842 (1984), for judicial review determining whether an agency has acted "in excess of statutory jurisdiction, authority or limitations, or short of statutory right" under the APA. *See Am. Fed'n of Gov't Emps., AFL-CIO, Local 3669 v. Shinseki*, 709 F.3d 29, 32–33 (D.C. Cir. 2013). The court must begin at *Chevron* Step One by "ask[ing] whether Congress has directly addressed the precise question at issue." *Mayo Found. for Med. Educ. & Research v. United States*, 131 S. Ct. 704, 706 (2011) (internal citations omitted). "'If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *City of Arlington, Tex. v. FCC*, 133 S. Ct. 1863, 1868 (2013) (quoting *Chevron*, 467 U.S. at 842–43). A statute that is unambiguous "means that there is 'no gap for the agency to fill' and thus 'no room for agency discretion.'" *United States v. Home Concrete & Supply, LLC*, 132 S. Ct.

1836, 1843 (2012) (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982–83 (2005)). To discern whether Congress has addressed the precise question, the court applies the "traditional tools of statutory construction." *Id.* at 1844 (quoting *Chevron*, 467 U.S. at 843 n.9). These tools include evaluation of the plain statutory text at issue, the purpose and structure of the statute as a whole, while giving effect, if possible, to every clause and word of a statute, and—where appropriate—the drafting history. *See Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014) (quoting *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001)); *see also Duncan v. Walker*, 533 U.S. 167, 174 (2001); *Bell Atl. Tel. Co. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997).

If the statute is silent or ambiguous with respect to the specific issue under consideration, however, the analysis shifts to *Chevron* Step Two, where "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *City of Arlington, Tex.*, 133 S. Ct. at 1868. The job of the courts is not to engage in "their own interstitial lawmaking" and "mak[e] public policy by prescribing the meaning of ambiguous statutory commands." *Id.* at 1873. Rather, the "archetypal *Chevron* questions, about how best to construe an ambiguous term in light of competing policy interests" belongs to the "agencies that administer the statutes." *Id.* When Congress has delegated to the agency authority to make rules carrying the force of law, and the challenged agency interpretation was promulgated in the exercise of that authority, then the agency's rule is entitled to deference "as long as it is a permissible construction of the statute, even if it differs from how the court would have interpreted the statute in the absence of an agency regulation." *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 826 (2013); *see also Nat'l Cable & Telecomms. Ass'n*, 545 U.S. at 980 ("If

a statute is ambiguous, and if the implementing agency's construction is reasonable, *Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation.").

Even when Congress has not provided the agency an express delegation of authority or responsibility "'to implement a particular provision or fill a particular gap, [ ] it can still be apparent from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law, even one about which Congress did not actually have an intent as to a particular result.'" *Home Concrete & Supply, LLC,* 132 S. Ct. at 1843–44 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001)). Agencies are owed deference under *Chevron* even where their interpretation of an ambiguous statutory provision "could be said to delineate the scope of the agency's jurisdiction." *Verizon v. FCC*, 740 F.3d 623, 635 (D.C. Cir. 2014) (noting that "the Supreme Court has recently made [this] clear"); *see also City of Arlington, Tex.*, 133 S. Ct. at 1870 (holding that "there is *no difference*, insofar as the validity of agency action is concerned, between an agency's exceeding the scope of its authority (its 'jurisdiction') and its exceeding authorized application of authority that it unquestionably has" (emphasis in original)).

C. Administrative Procedure Act

Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction,

authority, or limitations, or short of statutory right," *id.* § 706(2)(C), or "without observance of procedure required by law," *id.* § 706(2)(D).

In evaluating agency actions under the "arbitrary and capricious" standard, courts must consider "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oregon Natural Res. Council,* 490 U.S. 360, 378 (1989) (citation and internal quotation marks omitted); *Citizens to Preserve Overton Park v. Volpe,* 401 U.S. 402, 416 (1971); *Blue Ridge Envtl. Def. League v. Nuclear Regulatory Comm'n*, 716 F.3d 183, 195 (D.C. Cir. 2013). The scope of review under this standard "is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.* (*State Farm*), 463 U.S. 29, 30 (1983); *see also Verizon*, 740 F.3d at 644 (citing *Nat'l Tel. Coop. Ass'n v. FCC,* 563 F.3d 536, 541 (D.C. Cir. 2009)); *Agape Church, Inc. v. FCC*, 738 F.3d 397, 408 (D.C. Cir. 2013) (citing *Cablevision Sys. Corp. v. FCC,* 597 F.3d 1306, 1311 (D.C. Cir. 2010)).

"[T]he arbitrary and capricious standard is 'highly deferential' and 'presumes agency action to be valid[.]'" *Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.,* 724 F.3d 243, 245 (D.C. Cir. 2013) (quoting *Am. Wildlands v. Kempthorne,* 530 F.3d 991, 997 (D.C. Cir. 2008)); *Envtl. Def. Fund, Inc. v. Costle,* 657 F.2d 275, 283 (D.C. Cir. 1981). If an agency, however, "failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action." *Cnty. of Los Angeles v. Shalala,* 192 F.3d 1005, 1021 (D.C. Cir. 1999). At the very least, the agency must have reviewed relevant data and articulated a satisfactory explanation establishing a "rational connection between the facts found and the choice made." *State Farm,* 463 U.S. at 43 (internal quotation marks omitted); *see also*

Pub. Citizen, Inc. v. FAA, 988 F.2d 186, 197 (D.C. Cir. 1993) ("The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result.").

"[A]n agency acts arbitrarily or capriciously if it 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Am. Wildlands*, 530 F.3d at 997–98 (quoting *State Farm*, 463 U.S. at 43). While the agency's explanation cannot "run[ ] counter to the evidence," *State Farm*, 463 U.S. at 43, courts should "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," *Bowman Transp., Inc. v. Arkansas–Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). Furthermore, when an agency has acted in an area in which it has "special expertise," the court must be particularly deferential to the agency's determinations. *Sara Lee Corp. v. Am. Bakers Ass'n Ret. Plan*, 512 F. Supp. 2d 32, 37 (D.D.C. 2007) (quoting *Bldg. & Constr. Trades Dep't, AFL–CIO v. Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988)). "Deferring as appropriate to the agency's expertise and looking only for 'a rational connection between the facts found and the choice made,'" *Am. Trucking Ass'ns, Inc.*, 724 F.3d at 249 (quoting *State Farm*, 463 U.S. at 43), "we remain ever mindful that in performing 'a searching and careful inquiry into the facts, we do not look at the [agency's] decision as would a scientist, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.'" *Id.* (quoting *Nat'l Envtl. Dev. Ass'ns Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012)).

III. DISCUSSION

In challenging the Final Rule regulating the transfer of certain exclusive patent rights in the pharmaceutical industry, PhRMA contends that the limited application of the Rule to the pharmaceutical industry exceeds the FTC's grant of statutory authority under the HSR Act, Compl. ¶¶ 89–93 (Count I), in violation of 5 U.S.C. § 706(2)(C), and was arbitrary and capricious, Compl. ¶¶ 94–100 (Count II), in violation of 5 U.S.C. § 706(2)(A). *See* Pl.'s Mem. at 1–2. PhRMA further argues that the Rule should be set aside because the FTC failed to include in the rulemaking record the factual basis for its decision contrary to the procedure required by law, Compl. ¶¶ 101–06 (Count III), in violation of 5 U.S.C. § 706(2)(D), by failing to include in the rulemaking record the factual basis for its decision. *See* Pl.'s Mem. at 29–30. The FTC cross-moves for summary judgment, contending: (1) the FTC is entitled to *Chevron* deference in its interpretation of the HSR Act's grant of authority to promulgate industry-specific rules, Def.'s Mem. at 9–15; and (2) the FTC provided a reasoned basis for its promulgation of the Rule that was supported by sufficient facts referenced in publicly available information, Def.'s Mem. at 15–28. For the reasons set out below, the Court agrees with the FTC.

A. FTC is Entitled to Deference on Scope of Statutory Authority

PhRMA contends that the FTC has exceeded its grant of authority under the HSR Act by promulgating a rule that applies only to the pharmaceutical industry because Congress has directly spoken on the issue and expressed its intent to have the premerger notification requirements apply uniformly across all industries. Pl.'s Mem. at 16–22. Thus, PhRMA asserts that the Court's analysis may stop at *Chevron* Step One because "Congress has directly addressed the precise question at issue." *Mayo Found. for Med. Educ. & Research*, 131 S. Ct. at

706 (internal citations omitted). PhRMA supports this argument with four points: (1) the FTC's power to exempt certain industries from premerger notification requirements under section 18a(d)(2)(B) does not grant the FTC authority to expand selectively the scope of the pre-merger reporting requirements on a piecemeal basis, Pl.'s Mem. at 16–17; (2) the legislative history of the HSR Act "confirms that Congress did not intend to give the FTC authority to extend the Act's coverage on such selective terms," *id*. at 17–18; (3) industry-specific notification requirements, such as those promulgated in the Final Rule, contravene the purpose of the HSR Act, *id.* at 18–19; and (4) the FTC's rulemaking authority, including the discretion to define the terms in the HSR Act under subsection (d)(2)(A), and prescribe other "necessary and appropriate" rules to carry out the purpose of the HSR Act under subsection (d)(2)(C), do not otherwise grant the FTC the authority to issue an industry-specific rule, *id.* at 19–22. The FTC disputes that Congress has directly addressed the issue in the HSR Act and instead contends, under *Chevron* Step Two, that the agency's interpretation of the statute is entitled to deference. *See* Def.'s Mem. at 11–14.

The Court first addresses the parties' arguments under *Chevron* Step One and concurs with the FTC that the statute does not expressly address whether the HSR Act premerger notification requirements may be applied selectively to a particular industry. Next, the Court examines the parties' arguments under *Chevron* Step Two, finding that the FTC's interpretation is entitled to deference.

1. HSR Act Does Not Directly Address Industry-Specific Rules

Subsection (a) of the HSR Act states that "[e]xcept as exempted pursuant to subsection (c) of this section, *no person* shall acquire, directly or indirectly, any . . . assets of any other

person, unless both persons file notification . . . ." 15 U.S.C. § 18a(a) (emphasis added). PhRMA seizes upon the "broad, unqualified" "no person" words to conclude that the HSR Act was intended to apply with equal force across all industries, subject only to the exceptions under subsection (c). Pl.'s Mem. at 16; Pl.'s Reply at 4–5. PhRMA's narrow focus on these two words is too thin a reed to rest its conclusion given the broader language granting the FTC rulemaking and exemption authority.

To determine the plain meaning of a statute, the court must look not only to "the particular statutory language at issue," but also to "the language and design of the statute as a whole." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) (citations omitted); *see also United States v. Ali*, 718 F.3d 929, 938 (D.C. Cir. 2013) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000), for the proposition that "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme"). The court assumes "that the legislative purpose is expressed by the ordinary meaning of the words used." *Sec. Indus. Ass'n v. Bd. of Governors*, 468 U.S. 137, 149 (1984) (internal quotation and citations omitted). Here, the inclusion of the "no person" words does not manifest Congress's express intent to have the statute apply uniformly because Congress also enumerated multiple broad exemptions, including a catch-all exemption in subsection (c)(12), which the FTC is authorized to apply. Under subsection (c), certain "classes of transactions" are expressly exempt from the HSR Act, including any "acquisitions of goods or realty transferred in the ordinary course of business," "acquisitions of bonds, mortgages, deeds of trust, or other obligations which are not voting securities," "transfers to or from a Federal agency or a State or political subdivision," and certain "acquisitions, solely

for the purpose of investment, by any bank, banking association, trust company, investment company, or insurance company." 15 U.S.C. § 18a(c)(1), (2), (4), (11). These exemptions militate against finding that Congress intended uniform application of the reporting requirements for three reasons. First, these statutory exemptions distinguish between industries. For example, exemption (c)(11) exempts the banking industry from certain transactions that other industries must report. This is an explicit recognition by Congress that crafting industry-specific rules may be necessary to achieve the goals of the HSR Act. Second, while some exemptions are circumscribed, Congress also included broad exemptions, such as transfers "in the ordinary course of business." *id*. § 18a(c)(1). Congress granted authority to the FTC to define the transactions constituting transfers "in the ordinary course of business" and thereby limit the otherwise potentially boundless scope of this exemption. *See id.* § 18a(d)(2)(A) (granting FTC definitional authority). Third, the FTC was granted authority to exempt from the reporting requirement "classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws." *See* 15 U.S.C. § 18a(d)(2)(B); *see also id.* § 18a(c)(12) (exempting from reporting requirements "such other acquisitions, transfers, or transactions, as may be exempted under subsection (d)(2)(B) of this section"). While the FTC is not permitted to exempt a specific "person" from the reporting requirements, Section 18a(c)(12) and (d)(2)(B) authorize the FTC to exempt general "classes" of persons or transactions. This plain language is sufficiently broad to cover or exempt entire industries or certain classes of transactions within industries. The broad scope of the exemptions provided in the HSR Act significantly undermines PhRMA's argument that the "no person" words reflect a Congressional intent for uniform application of the reporting requirements, with only limited exemptions. To the

contrary, the nature of the statutory exemptions, combined with the express grants of authority to the FTC to extend those exemptions even more broadly, make plain that the reporting requirements were intended to be a scalpel, rather than a blunt sword, to target precisely those transactions actually posing an antitrust threat.

PhRMA acknowledges that subsection (d)(2)(B) grants the FTC exemption authority, but contends that this authority is "narrowly drawn, authorizing the agency *to relieve* certain classes of persons or transactions" but not "to *impose*[] *new burdens* selectively on a targeted class of persons (*i.e.*, those in the pharmaceutical industry only)." Pl.'s Mem. at 17 (emphasis in original). In other words, PhRMA's view is that the FTC has authority to exercise forbearance, but not to subject selected industries to regulation. This argument rests on two inter-related premises: first, that the FTC's definitional and rulemaking authority, under 15 U.S.C. § 18a (d)(1), (d)(2)(A), and (d)(2)(C), which it exercised in promulgating the Final Rule, may only be exercised to promulgate rules of *general* applicability; and, second, that the FTC may only use its exemption authority, under 15 U.S.C. § 18a (c)(12) and (d)(2)(B), narrowly to relieve from, not subject to, reporting requirements a class of persons or transactions. Pl.'s Mem. at 16–17, 19. PhRMA's interpretation of the manner in which the FTC may exercise its definitional, rulemaking, and exemption authority under the HSR Act is not implausible, but that is simply not enough. In order "to prevail under *Chevron* step one, the [plaintiff] must do more than offer a reasonable or, even the best, interpretation; it must show that the statute *unambiguously* forecloses the [agency]'s interpretation." *See Vill. of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 661 (D.C. Cir. 2011) (citing *Chevron*, 467 U.S. at 843 n.11). With regards to the first premise, the FTC's rulemaking and definitional authority are not expressly limited by the

requirement that the FTC promulgate only general rules and not industry-specific rules. For example, subsection (d)(1) authorizes the FTC to require reporting "in such form" with "such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable" a determination "whether such acquisition may, if consummated, violate the antitrust laws." 15 U.S.C. § 18a(d)(1). Rather than directing all documentation for every covered acquisition to be the same, this provision authorized the enforcement agencies to focus on "necessary and appropriate" documentation for a specific "proposed acquisition." Likewise, the FTC's definitional authority is not restricted to bar selective application of regulations, but rather gives the agency a blank slate to "define the terms used in this section." 15 U.S.C. § 18a (d)(2)(A). Finally, the rulemaking authority granted to the FTC is broadly awarded to "prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section." 15 U.S.C. § 18a (d)(2)(C). Nothing in this text restricts the FTC to generating only general rules rather than industry specific rules. In short, the FTC's issuance of an industry-specific rule is not foreclosed by the use of the words "no person" in the general prohibition, as PhRMA contends, when contextual examination of this provision reveals such varied and open-ended exemptions also authorized by Congress.

The D.C. Circuit's decision in *Environmental Defense Fund, Inc. v. EPA*, 82 F.3d 451, 465 *amended sub nom. Envtl. Def. Fund v. EPA*, 92 F.3d 1209 (D.C. Cir. 1996), is illustrative of this point, although not cited or discussed in the briefing on the pending cross-motions for summary judgment. The plaintiff in that case made the same unsuccessful statutory interpretation argument asserted by PhRMA here: namely, that a statute written with the operative prohibition covering "[n]o department, agency or instrumentality" indicates Congress's

intent that the regulations issued pursuant to that statute must apply uniformly. *Id.* At issue in *Environmental Defense Fund* was a statutory provision providing that "[n]o department, agency, or instrumentality of the Federal Government shall engage in . . . any activity" that does not "conform" to an EPA implementation plan, which language, according to the plaintiff in that case, "shows that the Congress intended the general conformity requirement to apply to every activity of the federal government." *Id.* The Circuit disagreed. It found that such language was not "so rigid" that it must apply to all federal government activity, finding that, despite the sweeping language, "nothing in the statute [] preclude[d]" the EPA from categorically exempting certain federal government activities that produced *de minimis* emissions from conforming to the EPA's implementation plan. *Id.* at 466–67. Rather, the Circuit remarked that "it seems eminently reasonable for the EPA to interpret this provision to refer to 'any activity' that is likely to interfere with the attainment goals" in the statute rather than any activity undertaken by the federal government. *Id.* In other words, the D.C. Circuit rejected the argument that the "no department, agency, or instrumentality" language at issue there, similarly to the "no person" language highlighted by PhRMA here, necessarily entails broad, uniform application, as PhRMA contends. Furthermore, in that case, unlike the instant case, the EPA was not expressly granted the authority to exempt any "department, agency, or instrumentality" from the provisions of the statute, yet the Court still found the agency authorized to grant exemptions from the purportedly "broad prohibition" without contravening the statute's terms. *Id.* at 465–67; *see also id.* at 456 n.7. Here, not only does the FTC have exemption authority, the "no person" language is further qualified by exemptions that Congress enumerated.

The conclusion that PhRMA's interpretation that the HSR Act requires uniform application of reporting requirement to all "persons" is further undermined by a structural review of the statute. The nature of the FTC's rulemaking authority makes plain Congress's intent for the FTC to promulgate rules "necessary and appropriate to carry out the purposes of this section." 15 U.S.C. § 18a(d)(2)(C). Indeed, as another Judge on this Court found in *American Petroleum Institute v. SEC*, 953 F. Supp. 2d 5, 20–23 (D.D.C. 2013), promulgating a rule of general applicability may contravene Congress's express intent that the FTC promulgate "necessary and appropriate" rules. In *American Petroleum*, the Securities and Exchange Commission ("SEC")'s rulemaking was ruled arbitrary and capricious when the SEC promulgated a rule of general applicability providing for no exemptions. *Id.* at 20, 23. The SEC justified its general rule by stating that adopting exemptions "would be inconsistent with the structure and language" of the statutory text and "would undermine Congress' intent," which the SEC did not wish to "frustrate." *Id.* at 21. Notably, the statute in that case contained language similar to the HSR Act, granting the SEC discretion to "exempt in whole or in part any issuer or class of issuers . . . upon such terms and conditions . . . as it deems necessary or appropriate" if "not inconsistent with the public interest." *Id.* The Court held that exercising this discretionary exemption authority may "in some circumstances, be *required* by the Commission's competing statutory obligations," such as a separate provision stating that the SEC "'shall not adopt any . . . rule or regulation which would impose a burden on competition not *necessary or appropriate* in furtherance of the purposes of this chapter." *Id.* (citing 15 U.S.C. § 78w(a)(2)) (emphasis added). Similarly, here the FTC may be compelled by the terms of the HSR Act to issue a rule that is not generally applicable when the FTC determines that it is not necessary or appropriate to

regulate similar transactions in other industries. This structural review of the Act lends further support to the FTC's interpretation that the agency's authority is not limited to issuing only generally applicable rules, as PhRMA contends, but rather that the statute requires otherwise in some circumstances.

With regards to PhRMA's second premise—that the FTC's exemption authority under 15 U.S.C. § 18a(c) and (d)(2)(B)—allows for enforcement forbearance but not selective application of certain regulations, is of limited relevance since this is not the source of the authority relied upon by the FTC to promulgate the Final Rule. In any event, the word "exempt," which is defined as "to free or release from a duty or liability to which others are held," *see* BLACK'S LAW DICTIONARY 653 (9th ed. 2009), does not, standing alone, indicate that the number of entities subject to "a duty or liability" must outnumber those entities "free[d] or release[d]" from a duty. In other words, broad applicability of an exemption does not run afoul of the plain meaning of the word "exempt."

Nor is there any indication in the statute that Congress intended to foreclose the FTC's effective grant of such broad exemptions. The only limit on the FTC's authority to exempt "classes of persons" or transactions are that they "are not likely to violate the antitrust laws." 15 U.S.C. § 18a(d)(2)(B). The D.C. Circuit has held that similar statutory language granting exemption authority confers "very broad discretion" on the agency. *See Nat'l Small Shipments Traffic Conference, Inc. v. Civil Aeronautics Bd.*, 618 F.2d 819, 827 (D.C. Cir. 1980) (interpreting plain meaning of agency's authority to "exempt 'any person or class of persons' from 'the requirements of this title or any provision thereof' . . . if it finds that the exemption is consistent with the public interest."). Indeed, even when an agency is not expressly granted

exemption authority in the statute, the D.C. Circuit has held that "[c]ategorical exemptions from the clear commands of a regulatory statute," though disfavored, are permissible. *Ala. Power Co. v. Costle*, 636 F.2d 323, 358–60 (D.C. Cir. 1979) (outlining situations where agency could promulgate broad, categorical exemptions from statute even if "not explicitly provided in the statute," such as for the sake of administrative necessity or infeasibility, or if activity has *de minimis* effect (citing *Morton v. Ruiz*, 415 U.S. 199 (1973); *Nat'l Res. Def. Council, Inc. v. Train*, 510 F.2d 692 (1974)); and *District of Columbia v. Orleans*, 406 F.2d 957, 959 (1968))).

Given the FTC's broad exemption authority, the agency could have achieved the same purpose reflected in the Final Rule by issuing a generally applicable rule that exempted all industries other than the pharmaceutical industry on the basis that similar transactions in other industries do not pose an antitrust threat. Under PhRMA's reasoning, formulation of the rule in this manner would have comported with the FTC's statutory authority. Requiring the FTC to promulgate rules according to this formulation, however, would have the same effect as an industry-specific regulation and would "elevate form completely over substance." *See Simmons v. ICC*, 697 F.2d 326, 332–34 (D.C. Cir. 1982) (finding that, in order to grant a partial exemption, agency was not required to "first have to grant a total exemption and then revoke that exemption in part" in "a two-step process" of rulemaking). The more faithful reading of the HSR Act is that the FTC's authority to promulgate industry-specific rules is not foreclosed by the "no person" language. Indeed, as the D.C. Circuit held after evaluating the scope of another agency's exemption authority, even if Congress "did not expect that the [agency] would use its exemption authority in a particular fashion[, this] does not indicate that Congress did not

authorize the [agency] to act in this manner" based on the plain language of the statute. *Nat'l Small Shipments Traffic Conference, Inc.*, 618 F.2d at 828.

Consequently, the plain language of the statutory text does not mandate that the FTC only promulgate rules of general applicability and does not foreclose the FTC's issuance of an industry-specific rule. Given that Congress has not directly addressed the FTC's authority in this respect based on the plain text and structure of the HSR Act, the Court turns to legislative history, which PhRMA insists supports its view that the FTC exceeded the agency's statutory authority.

2. The Legislative History Confirms That Congress Has Not Directly Addressed the Issue

PhRMA points to two changes made in the precursor bills to the HSR Act to support its contention that Congress expressly intended for uniform application of the premerger notification requirements. *See* Pl.'s Mem. at 17–18; Pl.'s Reply at 5–8. The Court disagrees with PhRMA's interpretation of the legislative history and instead concludes that the record of changes to bill language prior to enactment does not resolve the ambiguity in the statutory language, or otherwise suggest that Congress intended to bar the FTC from promulgating industry-specific rules.

First, PhRMA points out that the Senate's version of the HSR Act, Senate Bill No. 1284, included a provision, at section 7A(B)(2), which would have permitted the FTC to "*impose reporting burdens* on certain 'classes or categories' of persons," but the "House deliberately removed that provision." Pl.'s Mem. at 17–18 (emphasis in original). According to PhRMA, this change "clear[ly]" reflects Congress's intent "to impose pre-merger notification requirements for like transactions only uniformly and even-handedly, not by selectively

burdening some with reporting obligations while leaving others unaffected." *Id*. at 18. In further support of this claim, PhRMA points to a statement by Senator Hart describing the removed provision as one that "require[d] pre-merger notifications from particular companies or industries or from any class or category of persons," *id.* at 17 (quoting 122 CONG. REC. 29,342 (1976)), and a statement from Representative Rodino explaining that the provision was omitted because "the coverage of this bill should be decided by Congress—not the FTC and the Justice Department," *id.* at 18 (quoting 122 CONG. REC. 30,877 (1976)).

Contrary to PhRMA's reading of the legislative history, the deletion of the Senate provision cited by PhRMA does not reveal Congress's intent to foreclose the FTC's promulgation of industry-specific rules. *See* Hart-Scott Antitrust Improvements Act of 1976, S. 1284, 94th Cong. § 7A(b)(2)(A)–(B) (1976). This deleted provision would have granted the FTC the authority to require premerger notifications for *any* class of person or transaction, "[n]otwithstanding any other provision of law or the applicability of subsection (a) of this section," which prescribes threshold size requirements to trigger the premerger reporting requirements. *Id.* § 7A(b)(2). In other words, the removed Senate provision would have granted the FTC discretion to compel parties to report any transaction, no matter how small. By removing this provision, the House version made clear that the FTC could not compel reporting of transactions falling below the size thresholds described in subsection (a). Nevertheless, as Senator Hart explained, "[d]eletion of this provision is not intended to affect the authority of the Federal Trade Commission to require such notification under existing provisions . . . ." 122 CONG. REC. 29,342 (1976) (statement of Sen. Hart). This clarifies that the FTC's authority to impose rules, create definitions, and exempt industries from the requirements of the section was

left intact for all transactions that *meet* the minimum size requirements.

Further, PhRMA's invocation of Representative Rodino's statement that "the coverage of this bill should be decided by Congress—not the FTC and the Justice Department," 122 CONG. REC. 30,877 (1976), is unpersuasive. The fuller context of his remarks makes clear that Representative Rodino's concern was to bar the FTC from reaching out to regulate small transactions, consistent with the clarifying statement of Senator Hart. Specifically, Representative Rodino was concerned that the removed Senate provision "permitted the FTC . . . to promulgate rules subjecting 'small' mergers—involving companies with less than $100 million and $10 million in sales or assets—to the notification and waiting requirements provided by this bill." *Id.*[11] His remark that Congress should set the scope of the bill referred to Congress's responsibility to determine the applicability of the HSR Act based on the *size* of the transaction, rather than to detract from the FTC's authority to require notification for transactions that meet the size requirements set out in subsection (a). The statements of Senator Hart and Representative Rodino, and the removal of the Senate bill's provision on which PhRMA relies, do not speak directly to Congress's intent that the FTC promulgate rules that require premerger notification uniformly for any transaction that meets or exceeds subsection (a)'s minimum size requirements. The legislative history only demonstrates that Congress did not wish to burden small companies, or parties engaging in small transactions, with the HSR Act's reporting requirements.

Notably, after removing the disputed Senate provision from the bill, the House added

[11] In the hearing explaining the House's revisions to the Senate's version of the HSR Act, Rep. Rodino stated that "[i]t may in future years appear that additional coverage is desirable; for example, in industries that are 'highly concentrated' . . . or with respect to a large firm that makes a series of acquisitions of firms *below this bill's $10 million size limits*." 122 CONG. REC. 30,877 (1976) (emphasis added).

subsection (d)(2)(B), granting the FTC authority to "exempt classes of corporations and acquisitions, transfers, or transactions which are not likely to violate Section 7 of this Act from the requirements of this section." H.R. REP. NO. 94-1373, at 3 (1976) (reprinting the amendments to the Clayton Act in H.R. 14580). This grant of broad exemption authority is a clear indication of Congress's support for the FTC to determine categories of transactions and persons exempt from the HSR Act and, also, undermines PhRMA's claim that Congress intended uniform application of the HSR Act's reporting requirements. Clearly, if the House's intent were to prohibit "piecemeal coverage" authorization "for transactions above *and* below the thresholds," as PhRMA contends, *see* Pl.'s Reply at 6, the House would not have added this provision explicitly permitting the FTC to exempt certain industries or transactions from subsection (a)'s reporting requirements. Contrary to PhRMA's view, a more comprehensive review of the legislative history shows that Congress contemplated a stark difference in the FTC's authority with respect to small transactions falling below subsection (a)'s minimum size thresholds, and those transactions meeting the requirements and subject to premerger reporting.

Second, PhRMA points to the Senate's removal of another provision from the version of the Senate bill, S. 1284, that passed the Senate, as evidence of Congress's "unwavering view that the FTC was not authorized to target specific companies or industries for pre-merger coverage." Pl.'s Reply at 7–8. Specifically, an early version of the Senate bill gave the FTC authority "to promulgate rules of general or special applicability as may be necessary or proper to the administration of this section," S. 1284, 94th Cong. § 7A(b)(4)(A) (1976), but this provision was subsequently removed by its proponent because, as he explained, "it appeared to give the FTC rulemaking authority 'so broad and general as to undermine an otherwise carefully structured

statutory scheme.'" Pl.'s Reply at 8 (citing 122 CONG. REC. 15,812 (1976) (statement of Sen. Hruska)). PhRMA selectively quotes from Senator Hruska's statements on the matter. In full, the Senator explained that the provision was removed because "[t]hese authorities *are either appropriately dealt with in other sections*, or are so broad and general as to threaten to undermine an otherwise carefully structured statutory scheme." 122 CONG. REC. 15,812 (1976) (emphasis added). The statement provides no further elaboration. This explanation is not conclusive proof of "Congress's unwavering view" that the FTC was not permitted "to fashion rules of 'special applicability'" as PhRMA contends. Pl.'s Reply at 8. At best, the statement is ambiguous as to whether Congress intended to foreclose the FTC's promulgation of industry-specific rules. Moreover, the perfunctory statement of one Senator explaining the deletion of a phrase in a draft version of a bill prior to the issuance of a new version of the bill ultimately considered by the Senate does not indicate the "'unambiguously expressed intent of Congress.'" *City of Arlington, Tex.*, 133 S. Ct. at 1868 (quoting *Chevron*, 467 U.S. at 842–43); *see also N. Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 526 (1982) ("[T]he statements of one legislator made during debate may not be controlling (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 311 (1979))).

Consequently, PhRMA has not demonstrated that Congress has clearly spoken on the FTC's ability to promulgate industry-specific rules based on the legislative history.

3. The Purpose of the HSR Act Is Not Uniform Application, But Prophylactic Prevention of Anticompetitive Mergers

PhRMA contends that the FTC is required to "exercise its rulemaking authority only in a manner 'consistent with the purposes'" of 15 U.S.C. § 18a, and that the Final Rule is inconsistent with "the HSR Act's grant to the FTC of authority exercisable *only* uniformly and even-handedly

as to all similarly situated 'persons' or 'classes of persons.'" Pl.'s Mem. at 18–19. The only statutory language relied on by PhRMA for this proposition are the "no person" words in subsection (a), stating that "[e]xcept as exempted . . . no person" meeting the size requirements under subsection (a) shall engage in a transaction without satisfying the notification requirements. 15 U.S.C. § 18a(a); *see also* Pl.'s Reply at 9 ("The statute's explicit command [states] that FTC rulemaking for coverage of over-threshold transactions excuse 'no person' not otherwise exempted . . . ."). PhRMA's reliance on the "no person" words in subsection (a) to divine Congress's purpose does not support its argument because, as noted, other statutory provisions granting both express exemptions and authority to the FTC to devise additional appropriate exemptions demonstrate that Congress did not anticipate uniform application of the HSR Act. *See* 15 U.S.C. § 18a(a), (c)(12), (d)(2)(B).

Indeed, the purpose of the HSR Act was not to ensure uniformity in the promulgation of rules under the premerger notification requirements. To the contrary, the express statement of purpose by the Senate and the House upon passage of the HSR Act was to combat illegal acquisitions that violate antitrust laws. The Senate Report accompanying the Senate's bill stated that the purpose of the HSR Act "is to support and invigorate effective and expeditious enforcement of the antitrust laws, to improve and modernize antitrust investigation and enforcement mechanisms, to facilitate the restoration and maintenance of competition in the marketplace, and to prevent and eliminate monopoly and oligopoly power in the economy." S. REP. NO. 94-803, at 1 (1976). The House report accompanying the House Bill, Antitrust Premerger Notification Act, H.R. 14580, 94th Cong. (1976), stated that the purpose of the Act is to "giv[e] the government antitrust agencies a fair and reasonable opportunity to detect and

investigate large mergers of questionable legality before they are consummated." H. R. REP. No. 94-1373, at 5 (1976), *reprinted in* 1976 U.S.C.C.A.N. 2637, 1976 WL 13988; *see also* H.R. 14580, 94th Cong. (1976).[12] The House Report described the history and need for the premerger notification provisions, stating that "the chief virtue of this bill is that its provisions will help to eliminate endless post-merger proceedings . . . and replace them with far more expeditious and effective premerger proceedings." H. R. REP. No. 94-1373, at 10 (1976). The Report further states that the premerger notifications "will help prevent the consummation of so-called 'midnight' mergers, which are designed to deny the government any opportunity to secure preliminary injunctions. It will ease burdens on the courts by forestalling interminable post-consummation divestiture trials, [a]nd it will advance the legitimate interests of the business community in planning and predictability." *Id.* at 11.

Notably, nowhere do the Senate or House reports specify that the purpose of the HSR Act is to ensure uniformity in the application of the premerger notification requirements. PhRMA has not presented any evidence, other than the "no person" words, to support its contention that the purpose of section 15 U.S.C. § 18a is to ensure application "*only* uniformly and even-handedly," Pl.'s Mem. at 19 (emphasis in original), particularly given the exemptions that qualify subsection (a), including the FTC's authority to exempt "classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws." 15 U.S.C. §

[12] Two additional House reports were drafted to accompany two alternate versions of the HSR Act, H.R. 8532, 94th Cong. (1975); H.R. 13489, 94th Cong. (1976), that were simultaneously considered with the third version, H.R. 14580, 94th Cong. (1976), which was ultimately enacted. *See* Pub. L. No. 94-435. The purpose of the HSR Act enumerated in all three House Reports consistently support the conclusion that the purpose of the HSR Act was to strengthen law enforcement tools. *See* H.R. REP. NO. 94-499(I), at 3 (1975) (purpose of the HSR Act is "to prevent antitrust violators from being unjustly enriched, and to deter future antitrust violations"); H.R. REP. NO. 94-1343, at 1–3 (1976) (purpose of HSR Act is to "provide the Justice Department's Antitrust Division with all the basic investigative tools necessary for effective and expeditious investigations into possible civil violations of the federal antitrust laws").

18a(d)(2)(B). As noted, the statutory language alone, and the "no person" words in particular, are unpersuasive indications that Congress directly addressed the issue. *See Envtl. Def. Fund, Inc.*, 82 F.3d at 465. Consequently, PhRMA cannot sustain its claim that the purpose of the HSR Act directly prohibits the FTC's promulgation of an industry-specific rule.

After review of the plain language, legislative history, and purpose of the HSR Act, the Court concludes that Congress has not directly addressed the issue of whether the FTC may issue industry-specific reporting requirements under the HSR Act. *See Duncan,* 533 U.S. at 174. Consequently, the Court will proceed to *Chevron* Step Two to determine "whether the agency's answer is based on a permissible construction of the statute." *City of Arlington, Tex.*, 133 S. Ct. at 1868.

4. Under Chevron *Step Two, FTC's Construction of the Statute is Permissible*

Mindful of the Supreme Court's recent admonition that agencies are entitled to *Chevron* deference even if they are interpreting an ambiguous statutory provision that governs the scope of the agency's own authority, *see id.*, 133 S. Ct. at 1870; *Verizon*, 740 F.3d at 635, the Court turns to the FTC's interpretation of the statute. The FTC is authorized to "define the terms used" in the Act and to "prescribe such other rules as may be necessary and appropriate to carry out the purposes" of the Act, which the FTC construes as enabling it to promulgate an industry-specific rule. *See* 15 U.S.C. § 18a(d)(2)(A), (C); *see also* 78 Fed. Reg. at 68,706; JA at 8. In the Final Rule, the FTC interpreted its grant of authority under the HSR Act as providing the FTC "broad authority to issue rules to facilitate the review of large transactions," reasoning that "[n]othing in the HSR Act prevents the Commission from issuing such rules on an industry-specific basis." 78 Fed. Reg. at 68,709; JA at 11. With respect to its exemption power, the FTC contends that this

"does not limit the broad and discretionary rulemaking authority granted in Sections 18a(d)(2)(A) and (C)," and that this authority "is not inconsistent with the authority to implement these requirements on an industry-specific basis[.]" *Id*. The FTC also explained that the Final Rule was not "expanding the HSR requirements to parties or transactions not covered by the Act," but "simply clarifying the types of transactions that constitute asset transfers for which the Act requires prior notification." *Id*.

Such a rationale is a permissible construction of the authorities granted to the FTC under the HSR Act. Although it may not be the best construction, or the construction this Court would adopt, such alternative interpretations are immaterial to the Court's inquiry because an agency's rule is entitled to deference "as long as it is a permissible construction of the statute, even if it differs from how the court would have interpreted the statute in the absence of an agency regulation." *Sebelius*, 133 S. Ct. at 826; *see also Nat'l Cable & Telecomms. Ass'n*, 545 U.S. at 980 ("If a statute is ambiguous, and if the implementing agency's construction is reasonable, *Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation." (citation omitted)).

PhRMA responds that the FTC's interpretation of the HSR Act is unreasonable for three reasons. First, PhRMA reiterates that Congress's clear intent was uniform application of reporting requirements. Pl.'s Reply at 10–11. As discussed in Parts III.A.1–3, *supra*, it is not clear from the plain language, legislative history, or purpose of the Act that Congress's intent was to apply reporting requirements uniformly. Instead, the inclusion of subsection (d)(2)(B), granting the FTC authority to exempt classes of persons and transactions "not likely to violate

the antitrust laws" strongly indicates that Congress envisioned reporting requirements tailored to transactions that actually posed an antitrust threat, which, as the FTC points out, is not a restriction of its rulemaking authority under subsections (d)(2)(A) and (C).

Second, PhRMA contends that the FTC has failed to point to any ambiguous statutory text from which it could derive its implicit Congressional delegation of power. PhRMA relies on *Railway Labor Executives' Association v. National Mediation Board*, 29 F.3d 655, 664 n.5, *amended*, 38 F.3d 1224 (D.C. Cir. 1994), for the contention that "statutory silence on the extent of [an] agency's power is 'no ambiguity.'" Pl.'s Reply at 12. That case is distinguishable, however, because the Court found "that Congress left no ambiguity" in the statute because the agency action at issue directly contravened the text of the applicable statute. *Id.* at 664. No statutory text directly forecloses the FTC's authority to apply an industry-specific rule. Moreover, in this argument, PhRMA misinterprets the deference owed to the FTC's interpretation under *Chevron*. PhRMA suggests that "the prerequisite to *Chevron* deference is some indication that Congress *chose* to delegate a particular power," and that the FTC has failed to show "that Congress contemplated delegating the decision to discriminate against a particular industry through increased coverage burdens." Pl.'s Reply at 10 (emphasis in original). This is simply not the FTC's burden. As noted, once the Court has determined that Congress has not directly addressed the issue, the agency is entitled to *Chevron* deference of its interpretation of the scope of its authority. *City of Arlington, Tex.*, 133 S. Ct. at 1870–71. Where, as here, the statute is silent on the issue, the agency's interpretation of its authority is due deference.

Third, PhRMA criticizes the FTC's interpretation for failure to articulate a reasonable basis that these patent license transactions "now suddenly pose an antitrust threat, let alone that

they pose such a threat in the pharmaceutical industry but not in any other." Pl.'s Reply at 16. PhRMA adds that the FTC's caveat in its Final Rule that similar transactions occurring in other industries "remain potentially reportable events under the Act" "cast[s] doubt on the Rule's 'necessity.'" *Id.* (quoting 78 Fed. Reg. at 68,706; JA at 8).[13] To the extent PhRMA is arguing that the FTC has exceeded its statutory grant of authority because it did not explain the necessity of the promulgated rule, this argument overlaps with the challenge to the Final Rule for being arbitrary and capricious, and will be addressed more fully in the next part of this Memorandum Opinion. Briefly, the FTC stated in its Final Rule that the patent rights transfers covered by the Final Rule "are functionally equivalent to patent transfers and are thus properly viewed as asset acquisitions under the Act," and "[a]llowing such transactions to go unreported would deprive the Commission of an opportunity, consistent with the purpose of the Act, to review these significant asset acquisitions that, like other reportable asset acquisitions, are potentially anticompetitive." 78 Fed. Reg. at 68,709; JA at 11. The FTC further explained that the rule was necessarily limited to the pharmaceutical industry because "[w]hile the PNO's experience . . . has indicated a need for a rule for the pharmaceutical industry, at this time the Commission has not yet determined that a specific rule is necessary with respect to other industries." *Id.* Such explanation is sufficient to show both a need for the "all commercially significant rights" concept and the limitation of the rule to the pharmaceutical industry. *See Nat'l Ass'n of Broadcasters v. FCC*, 740 F.2d 1190, 1210 (D.C. Cir. 1984) (finding that the Circuit has "recognized the

[13] PhRMA also argues that the FTC may not exercise its rulemaking authority to promulgate the industry-specific Rule because, according to PhRMA, in a "blatant abuse of its delegated authority to define terms *in the Act*," the FTC has included three new terms—"all commercially significant rights," "limited manufacturing rights" and "co-rights"—in the "definitions" section of its regulations that "*do not* appear in the Act." Pl.'s Mem. at 20 (emphasis in original). As the FTC correctly explains, these terms are used to define the terms "asset" and "acquisition" which do appear in the HSR Act, and the Commission "may of course use and define additional terms and concepts that do not themselves appear in the Act." Def.'s Mem. at 13–14. PhRMA does not dispute this explanation, *see generally* Pl.'s Reply, and no further discussion is merited here.

reasonableness of [an agency's] decision to engage in incremental rulemaking and to defer resolution of issues raised in a rulemaking" given that "an agency would be paralyzed if all the necessary answers had to be in before any action at all could be taken").

Accordingly, because Congress has not directly spoken on the issue and the FTC has set forth a permissible construction of its authority to issue industry-specific rules under the HSR Act, under *Chevron*, the FTC's promulgation of the Final Rule does not exceed its statutory jurisdiction under 5 U.S.C. § 706(2)(C) and, consequently, is entitled to deference.

B. FTC's Rulemaking Was Not Arbitrary, Capricious, or an Abuse of Discretion

PhRMA contends that the rulemaking was arbitrary and capricious for three reasons. First, according to PhRMA, the Final Rule was not the product of reasoned decisionmaking because it did not establish "a rational connection between the facts found and the choice made" to explain, both, why the exclusive patent rights targeted by the Final Rule are potentially anticompetitive, and to justify the selective targeting of the pharmaceutical industry. Pl.'s Mem. at 28. Second, the FTC's "vague and unembellished references to agency 'experience'" is not the sort of reasoned analysis required by the APA to justify the FTC's conclusion that exclusive patent license transfers in the pharmaceutical industry, and no other industry, poses a potential anticompetitive threat. Pl.'s Mem. at 23–24; *id.* at 28–29. Finally, the FTC's explanation ran "counter to the evidence before the agency," and failed to respond to "substantial problems raised by commenters," including the problems identified in the Varner Declaration attached to PhRMA's comment to the NPRM. Pl.'s Mem. at 24–27. The Court addresses each of these arguments in turn.

1. FTC Articulated a Rational Basis for Promulgating the Final Rule

The FTC explained in its NPRM the impetus behind adopting the "all commercially significant rights" concept in its Final Rule. The FTC stated that the transfer of patent rights was considered a reportable asset under the HSR Act, but that the widely-adopted, uncodified "make, use, and sell" approach was "no longer adequate in evaluating the reportability of exclusive licenses in the pharmaceutical industry for HSR purposes." 78 Fed. Reg. at 68,706; JA at 8. The FTC explained that adopting and applying the "all commercially significant rights" concept for the transfer of patent rights better "address[es] the evolving structure of exclusive patent licenses in the pharmaceutical industry, providing the [FTC] with a more effective means of reviewing exclusive patent licenses meeting the statutory requirements under the Act." 78 Fed. Reg. at 68,707; JA at 9. The FTC explained that the "'all commercially significant rights' test in the rule captures more completely what the 'make, use, and sell' approach was a proxy for, namely whether the license has transferred the exclusive right to commercially use a patent or a part of a patent." *Id*. In other words, according to the FTC, the all commercially significant rights test is a more accurate measure of whether the transfer of patent rights resembles the transfer of a patent in the pharmaceutical industry, in order to determine whether the parties have transferred an "asset" that is potentially reportable under the HSR Act.

The FTC articulated the reasons for limiting the Rule to the pharmaceutical industry, stating that the agency "has found that exclusive patent licensing agreements that transfer all of the rights to commercially use a patent or part of a patent almost solely occur in the pharmaceutical industry," 78 Fed. Reg. at 68,708; JA at 10, and that these transfers have "become more common for pharmaceutical companies." 78 Fed. Reg. at 68,706; JA at 8. The

FTC further stated that it "typically does not see exclusive transfers of rights to a patent or part of a patent outside the pharmaceutical context, and this is likely a result of the incentives that characterize the industry." 78 Fed. Reg. at 68,708; JA at 10. The FTC based this determination "on HSR filings and requests for advice on the reportability of transactions," *id.*, adding that "[p]ractitioners who represent clients in the pharmaceutical industry have often sought guidance from the PNO about" the acquisitions covered by the Final Rule, 78 Fed. Reg. at 68,706; JA at 8. According to the FTC, in the five years prior to promulgation of the Final Rule, the FTC "received filings for 66 transactions involving exclusive patent licenses, and all were for pharmaceutical patents." 78 Fed. Reg. at 68,708; JA at 10. By contrast, "[t]he PNO has not found other industries that rely on these types of arrangements . . . . [and] has not processed filings related to these kinds of exclusive licenses in any other industry in the past five years." *Id*. Consequently, the FTC "has not found a need for a rule applicable to other industries." *Id.*; *see also* 78 Fed. Reg. at 68,709; JA at 11 (stating that "[w]hile the PNO's experience . . . has indicated a need for a rule for the pharmaceutical industry, at this time the Commission has not yet determined that a specific rule is necessary with respect to other industries"). This analysis provides cogent reasoning for the agency's decision to promulgate the Final Rule and to restrict the rule to the pharmaceutical industry.

The FTC further justified limiting the rule by stating that, generally, agencies "need not take an all-or-nothing approach . . . [but] may proceed incrementally" when rulemaking, 78 Fed. Reg. at 68,710; JA at 12, and "may limit rules to those areas where they have observed a problem to be addressed," 78 Fed. Reg. at 68,709; JA at 11. The FTC nevertheless noted that "[i]f the PNO finds that such arrangements occur in other industries, [it] can then assess the

appropriateness of a similar rule for those other industries." *Id.* The D.C. Circuit recently affirmed an agency's decision to promulgate rules using such a "step-by-step approach." In *WildEarth Guardians v. U.S. EPA*, No. 13-1212, 2014 WL 1887372 (D.C. Cir. May 13, 2014), the plaintiff challenged the Environmental Protection Agency ("EPA")'s denial of its petition for rulemaking to regulate coal mines under the Clean Air Act, where the EPA stated that due to "limited resources and ongoing budget uncertainties," the EPA would not "commit to conducting the process to determine whether coal mines should be" regulated as requested, *id.* at *1 (quoting Notice of Final Action on Petition From Earthjustice To List Coal Mines as a Source Category and To Regulate Air Emissions From Coal Mines, 78 Fed. Reg. 26,739 (May 8, 2013)), and was instead "taking a common-sense, step-by-step approach intended to obtain the most significant greenhouse-gas-emissions reductions through using the most cost-effective measures first," *id.* at *3, and may address the issue in a future rulemaking, *id.* at *1. The D.C. Circuit held that the EPA's decision not to initiate rulemaking on this basis "was within the scope of its statutory authority, consistent with the record, and supported by reasoned decisionmaking," because the agency had "good reasons for prioritizing its regulatory agenda," which it explained and supported on the record. *Id.* at *6.

In the instant case, the FTC has similarly supported its incremental approach with a sensible reason—the agency's lack of experience with patent rights transfers outside the pharmaceutical industry. The FTC need only provide a rational basis for its decision, *see Am. Trucking Ass'ns, Inc.*, 724 F.3d at 249 (quoting *State Farm*, 463 U.S. at 43) (finding that reviewing courts "exercis[e] our narrowly defined duty [under the arbitrary and capricious standard] of holding agencies to certain minimal standards of rationality.'"); *State Farm*, 463

U.S. at 43 (holding that agencies need only establish a "rational connection between the facts found and the choice made,"); *Pub. Citizen, Inc.*, 988 F.2d at 197 (holding that agency must "adequately explain its result"), and it has done so, explaining the need for the rule, the need to limit the rule to the pharmaceutical industry, for which the FTC has determined regulation is "necessary and appropriate," and further supported the rule on the basis of the FTC's discretion to address problems incrementally.

2. FTC's Reliance on Its Expertise As Basis for Promulgating Rule is Not Improper

The FTC supported its promulgation of the Final Rule citing the following three factual sources: (1) the agency's expertise, informed by years of administering the HSR Act, 78 Fed. Reg. at 68,708–09; JA at 10; (2) 66 HSR filings related to patent rights transfers occurring in the pharmaceutical industry, with no comparable filings in other industries, 78 Fed. Reg. at 68,708; JA at 10; and (3) informal requests for interpretation from practitioners in the pharmaceutical industry that are available in the PNO's searchable, online database, 78 Fed. Reg. at 68,706; JA at 8. PhRMA contends that the FTC's analysis cannot be rational where the agency relies on its own experience, arguing that the FTC must produce physical records that have informed the agency's expertise, such as the informal requests for interpretation and any records of phone calls the PNO received related to patent rights transfers. *See* Pl.'s Reply at 22. In addition, PhRMA asserts that the FTC should have undertaken an independent investigation to elicit facts in support of its rule. Pl.'s Mem. at 24. While PhRMA's suggestion about an independent investigation may be a good—and even a preferable—factual basis for promulgation of a rule, this does not necessarily mean that the FTC's three sources are insufficient.

First, agencies may rely on their experience in administering statutes and promulgating

regulations so long as the agency identifies this and there is "an adequate opportunity to respond." *See Nat'l Classification Comm. v. United States*, 779 F.2d 687, 695 (D.C. Cir. 1985) ("It is beyond dispute that an agency may provide the factual predicate for a finding by taking 'official notice' of matters of common knowledge . . . and of matters known to the agency through its cumulative experience and consequent expertise" if there was "adequate opportunity to respond" (citations omitted)); *Nat'l Tour Brokers Ass'n v. ICC*, 671 F.2d 528, 533 (D.C. Cir. 1982) (finding that agency's rule was "not an unreasoned decision" because it "was based on the [agency's] long experience administering the existing licensing rules and its consequential dissatisfaction with those procedures"); *Thomas v. Lujan*, 791 F. Supp. 321, 322–23 (D.D.C. 1992), *aff'd*, No. 92-5240, 1993 WL 32329 (D.C. Cir. Jan. 29, 1993) ("[T]he Court finds that the agency's own expertise, as well as the data presented to the agency during the course of the rulemaking, justify the storage regulation.") (internal citation omitted); *Black Citizens for a Fair Media v. FCC*, 719 F.2d 407, 422 (D.C. Cir. 1983) (finding that proposed rulemaking justifying rule change based on agency's experience was not arbitrary and capricious); *see also Nat'l Ass'n of Pharm. Mfrs. v. Dep't of Health & Human Servs.*, 586 F. Supp. 740, 756 (S.D.N.Y. 1984) (finding that inclusion of "raw documents reflecting the [agency's] day-to-day enforcement and compliance activities" in inspection reports was unnecessary for effective judicial review where the comments were open to public inspection and Freedom of Information Act requests and the agency "carefully reviewed the comments received and explained [the] basis for adopting the final version of the regulations").

PhRMA relies on *Coburn v. McHugh*, 679 F.3d 924, 926 (D.C. Cir. 2012), and *Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 77

(D.C. Cir. 2006), for the proposition that an agency's invocation of its own expertise or experience is owed no deference when founded upon "unsupported assertions." Pl.'s Mem. at 23–24. *Tripoli*, which the *Coburn* opinion cites for this proposition, is distinguishable from the instant case. In *Tripoli*, the agency designated a material as "deflagrating"[14] without articulating the standard used by the agency "for determining when a particular material deflagrates." *Id.* at 83–84. The Court found that the agency's definition of a deflagration reaction as "much faster" than the reaction of burning material was insufficient because "[t]he agency never defined the threshold for 'much faster,'" and was thus not entitled to judicial deference because the agency's judgment was not reasoned. 437 F.3d at 79, 83. By contrast, in the instant case, the FTC's expertise is not being invoked to justify reaching a decision that is otherwise objectively or scientifically determinable. Rather, the FTC has relied on its expertise to justify promulgating a rule that is "necessary and appropriate." The determination of whether a rule is "necessary and appropriate" in the FTC's view necessarily relies on the agency's expertise, informed by years of administering the premerger notification program, which differs from *Tripoli*, where the determination at issue was the agency's definition of a chemical reaction.[15]

[14] Deflagration is a rapid, sharp combustion, which term the Bureau of Alcohol, Tobacco, Firearms and Explosives uses to classify explosives under the Organized Crime Control Act. *Tripoli Rocketry Ass'n Inc.*, 437 F.3d at 332–33.

[15] PhRMA relies on three additional cases to support its contention that the FTC's experience is an insufficient basis to support its Final Rule under the APA. *See* Pl.'s Mem. at 23–29. All three cases are distinguishable. PhRMA cites *Am. Mining Cong. v. EPA*, 907 F.2d 1179, 1189 (D.C. Cir. 1990), but that case is inapposite because there, as in *Tripoli*, the agency supplied a summary statement to support a determination—whether "discarded" materials constituted "solid wastes"—that was best supported through reasoned technical or scientific evidence. *Id.* at 1188–89. PhRMA also cites for support *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177 (D.C. Cir. 2009), which is distinguishable because the Court there determined that the agency had only made a general determination that any rule, no matter the substance, was necessary to provide clarity in a previously unregulated area, but did not provide reasoning to support the agency's decision to adopt the specific rule at issue. *Id.* Here, as previously discussed, the FTC has articulated the need for promulgation of the Final Rule. Third, *Morall v. DEA*, 412 F.3d 165, 167 (D.C. Cir. 2005), is distinguishable because in that case the Court found that the agency's lapse of "reasonable and fair decisionmaking" stemmed from the agency's "stunningly one-sided" rationale, which "completely ignore[d]" and "fail[ed] to acknowledge" contrary evidence. By contrast here, as discussed *infra*, Part III.B.3, the

Nor is the FTC required to produce physical records of everything that has contributed to its expertise over time, as PhRMA contends. Indeed, the Supreme Court has said as much in *NLRB v. Seven-Up Bottling Co. of Miami*, 344 U.S. 344, 349 (1953). At issue in that case was an employer's challenge of a decision by the National Labor Relations Board ("NLRB") to award back pay to eleven discriminatorily discharged employees based on their earnings per quarter, rather than calculating their back pay based on the "entire period during which an employee was denied reemployment in violation of the Act." *Id.* at 346–48. The employer argued that the NLRB ordered quarterly payments based on a formulation it had adopted in a prior adjudication, but that "no evidence in *this* record supports this back pay order; . . . and the reasons [the NLRB] assigned for adopting [the formulation] do not rest on data which [it] has derived in the course of the proceedings before" the NLRB in that case. *Id.* at 348–49 (emphasis added). The Supreme Court found that the agency could rely on its cumulative experience (as it did in the earlier adjudication and the adjudication at issue in the suit) and was "not confined to the record of a particular proceeding." *Id.* at 349. The Court found that, "[a]s is true of many comparable judgments by those who are steeped in the actual workings of these specialized matters, the Board's conclusions may 'express an intuition of experience which outruns analysis . . . .'" *Id.* at 348 (citing *Chicago, Burlington & Quincy R. Co. v. Babcock*, 204 U.S. 585, 598 (1907)). The Court noted that "[i]t is not for us to . . . require the Board to make a quantitative appraisal of the relevant factors, assuming the unlikely, that such an appraisal is feasible," *id.*, recognizing that "'[c]umulative experience' begets understanding and insight by which judgments not objectively demonstrable are validated or qualified or invalidated," *id.* at 348–49. As the Supreme Court

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FTC cited to, discussed, and adopted a reasoned basis rejecting the contrary evidence raised in PhRMA's objections to the NPRM.

made clear in that case, often agency experience is not quantifiable. Agency decisions are not made by "a particular judge-like individual or group of individuals," but often stem from "[p]iecemeal decisions . . . [made] over time, across the desks of numerous members of agency staff" that "gradually accumulate." PETER L. STRAUSS, ADMINISTRATIVE JUSTICE IN THE UNITED STATES 231 (2d ed. 2002). In some cases, as the Supreme Court recognized, it is "unlikely[] that such an appraisal [of agency experience] is feasible," *Seven-Up Bottling Co. of Miami*, 344 U.S. at 348, because quantifying an agency's "many unnamed and tangled impressions," *id.*, is difficult when multiple agency staff members, over the course of years, "bring to bear whatever they learn" and "[m]uch that has been relied upon [to make a decision] will not have been collected," STRAUSS, *supra*, at 231. Consequently, "[t]o speak of a 'record' in this context . . . is highly artificial." *Id.* In the instant case, for example, PhRMA asserts that the FTC's decision is arbitrary and capricious because it has not supported its experience with documentation, suggesting that the FTC must provide, *inter alia*, a record of "the 'thousands' of calls the PNO staff fields every year, what topics were discussed, with whom, and for what purpose," so that PhRMA may test the basis for the FTC's expertise. Pl's Reply at 22. Placing such a requirement on the FTC would be unwieldy, particularly where there is no indication that the FTC transcribes or records the many calls it receives at all, much less that it does so in the manner the FTC desires.

Moreover, the agency is not required, as PhRMA asserts, to undergo an independent investigation in search of evidence to support its rationale for the Final Rule. The D.C. Circuit addressed this issue in *National Tour Brokers Association*, 671 F.2d at 533. In that case, the plaintiff challenged as arbitrary and capricious the ICC's decision to change tour broker

licensing procedures on the basis that "the administrative record [was] devoid of evidence supporting the decision to alter existing procedures" because the ICC did not undertake a study of the tour broker industry that would have elicited all the relevant factors. *Id.* The Circuit concluded that although the record was "devoid" of a systematic study, the decision was not "unreasoned" but was "based on the Commission's long experience administering the existing licensing rules." *Id.* The Circuit concluded that where the agency had "fully explained its perception that existing rules . . . are without substantial value" and do not contribute to achieving the goals of the relevant statute, such "explanation of its experience provide[d] sufficient support under the arbitrary and capricious standard to sustain the rule change as a rational decision," and therefore the agency was not required to further supplement its finding with additional investigatory evidence. *Id.* The Circuit found that the agency's experience was "made part of the record and susceptible to judicial review" by virtue of the agency's explanation, and was therefore sufficiently reasoned. *Id.* While PhRMA's frustration with the nature of the record support for the FTC's Final Rule is palpable, there are practical limitations on the extent to which any agency's experience may be compiled on paper. In this context, the FTC may rely on its own experience without providing documentation or statistics showing "the nature, extent, or other particulars" of their experience or "how, under what circumstances, and under the tutelage of which individuals that alleged 'experience' may have been derived." Pl.'s Reply at 23.[16]

Second, with respect to the 66 HSR filings the FTC cited in support of its Final Rule, it is likely that the FTC could not have provided PhRMA or the general public these documents to

[16] Although the FTC permissibly relied on its experience, as discussed below, the FTC did not rest solely on its own experience but further supported the Final Rule with additional information: HSR filings and requests for information.

facilitate comment on the NPRM because HSR filings are confidential. Under the HSR Act, "[a]ny information or documentary material filed . . . pursuant to this section shall be exempt from disclosure . . . and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding." 15 U.S.C. § 18a(h). Although this little-analyzed provision contains an "exception" for "any administrative or judicial action or proceeding," no court has broached the question of whether HSR filings may be disclosed when the HSR filing itself is not the subject of an "administrative or judicial action or proceeding," but is tangentially related to a separate proceeding. Indeed, few courts have interpreted this provision of the HSR Act at all. The two cardinal cases discussing § 18a(h), issued by the Fifth and Second Circuits, have interpreted this provision in the context of disclosing HSR filings to state law enforcement officials, and both Circuits concluded that the FTC shall not disclose the information, even on a "confidential" basis. *See Mattox*, 752 F.2d at 122; *Lieberman v. FTC*, 771 F.2d 32, 38 (2d Cir. 1985). The Fifth Circuit in *Mattox* examined the "skimpy" legislative history behind this provision, and concluded that Congress "was concern[ed] over the disclosure of materials . . . [and] may have been worried that such disclosures would be a disincentive to prompt and complete compliance with the premerger notification procedures by potential merger partners." *Mattox*, 752 F.2d at 122–23. The Second Circuit similarly concluded in *Lieberman* that "Congress wanted premerger information kept confidential." 771 F.2d at 38. The *Mattox* and *Lieberman* courts' analyses suggest that the FTC may not disclose the HSR filings for public comment where they are merely referenced in a rulemaking.

Even if disclosure is not prohibited by the HSR Act itself, as the FTC has noted in an

agency adjudication, given the confidential information contained in HSR filings, other provisions of law may prevent the FTC from making HSR filings publicly available. *See In the Matter of Gen. Motors Corp.*, 103 F.T.C. 58, at *3 (1984). In this agency adjudication, the FTC denied a petition by Chrysler Corporation to release documents that had informed the FTC's decision to accept a consent agreement permitting a joint venture by General Motors Corporation ("GM") and Toyota Corporation. *Id.* at *1. Chrysler argued that the FTC improperly redacted or withheld key documents from public commenters during the comment period preceding the FTC's approval of the GM-Toyota joint venture, even though the "judicial or administrative proceeding" exception under § 18a(h) applied, and the FTC was permitted to disclose the underlying filings for public comment. *Id.* at *1–2. The FTC found that although a public comment period on a proposed consent agreement "constitutes an administrative action or proceeding," *id.* at *6, the FTC "has historically refrained from making public in consent order proceedings any trade secrets or confidential commercial or financial information obtained from any person," *id.* at *5, because the HSR Act's exception does not override "other legal bars to disclosure," such as "in discovery rules (FED. R. CIV. P. 26(c)(7)), statutes (*e.g.*, Sections 6(f) and 21(d)(1)(B) of the FTC Act and 18 U.S.C. 1905); the Freedom of Information Act, 5 U.S.C. 552(b)(4); and the common law (Restatement of Torts Section 759)," *id.* at *3.

In the instant case, although the parties have not addressed whether the 66 HSR filings the FTC relied on could have been disclosed for public comment given § 18a(h)'s exemption from disclosure, it is apparent that, in light of the sensitive trade information contained in HSR filings, and given longstanding FTC practice keeping similar information confidential, the FTC likely is unable to share these filings with PhRMA. Notably, PhRMA does not contest that the

66 HSR filings reporting exclusive patent rights transfers in the pharmaceutical industry comprise the sum total of all such filings, not does PhRMA contend that the FTC has manipulated or misread such information. *See generally* Pl.'s Mem. As noted, although PhRMA would ideally wish to access these records to provide more robust comments on the FTC's proposed rule, the FTC is limited in the amount of information it may provide for the public's review.

Third, with respect to the requests for interpretation submitted to the PNO, 78 Fed. Reg. at 68,708; JA at 10, PhRMA contends that the agency should have provided these requests for public comment, arguing that it is otherwise unable to test the FTC's determinations based on these requests. Pl.'s. Reply at 19. The informal interpretations the PNO produces in response to requests for interpretation from practitioners are publicly available and searchable on the FTC's website. Def.'s Mem. at 27; 77 Fed. Reg. at 50,059; JA at 3. Indeed, PhRMA cited to an informal interpretation in its comment to the NPRM. *See* PhRMA Comment at 11 & n.48; JA at 32 & n.48 (citing to a PNO Informal Staff Opinion and including a link to the FTC database in footnote 48). As the D.C. Circuit has noted, "[i]n some instances, 'publicly available' information . . . may be so obviously relevant that requiring it be specifically noticed and included in the rulemaking record would advance none of the goals of the APA, such as improving the quality of the information used by the agency, ensuring fairness to affected parties, or enhancing the quality of judicial review." *Chamber of Commerce of U.S. v. SEC*, 443 F.3d 890, 906 (D.C. Cir. 2006) (internal citations omitted). Moreover, "the public availability of such information might fall into an implied exception to the general requirement that extra-record data critical to support a legislative rule be subject to public comment." *Id*. (citation

omitted); *see also U.S. Lines, Inc. v. Fed. Mar. Comm'n*, 584 F.2d 519, 533–35 (D.C. Cir. 1978) (collecting cases) (holding that an agency may "rely on data in its files, or on public information, in reaching its decision . . . [so long as it] specif[ies] what is involved in sufficient detail to allow for meaningful adversarial comment and judicial review."). An agency "may rely on publicly available information so long as it is referenced, thereby enabling 'meaningful adversarial comment and judicial review;' such material need not be directly introduced into the record. A footnote is enough." *See Wis. Power & Light Co. v. FERC*, 363 F.3d 453, 462–63 (D.C. Cir. 2004) (citing *U.S. Lines, Inc.*, 584 F.2d at 534–35 & 534 n.44).

PhRMA cites *Chamber of Commerce of U.S. v. SEC*, 443 F.3d at 906, for the proposition that reliance on publicly available documents not in the rulemaking record results in prejudice to the affected party. *See* Pl.'s Reply at 20. This case is distinguishable. In *Chamber of Commerce of U.S.*, the agency's Final Rule relied on an "extra-record summary of extra-record survey data" that the agency did not warn commenters it would review in the notice of proposed rulemaking, and the data was not of the sort "relied upon by the [agency] during the normal course of its official business." *Id.* at 895, 904–05. By contrast, in the instant case, commenters were apprised that the FTC was relying on the PNO's public informal interpretation database to support the NPRM. *See* 77 Fed. Reg. at 50,059; JA at 3. Thus, reliance on this evidence in the Final Rule came as no surprise to PhRMA, which cited to the database in its comment to the NPRM. *See* JA at 32. In the NPRM, the FTC stated that "[w]hile each situation in the database is factually unique, the questions 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." 77 Fed. Reg. at 50,059; AR at 3.[17] By so doing, the NPRM alerted commenters that the FTC relied on requests for interpretation to inform the proposed rule and PhRMA used the public database as a resource in its comment providing thorough, substantive comments critiquing the proposed rule. Consequently, although the FTC did not collect the requests for information and provide them for PhRMA's inspection, the agency permissibly relied on this information because it allowed PhRMA an opportunity "for meaningful adversarial comment." *See Wisconsin Power & Light Co.*, 363 F.3d at 462–63 (citing *U.S. Lines, Inc.*, 584 F.2d at 534–35 & 534 n.44).

Consequently, the Final Rule is not arbitrary and capricious because the FTC relied on its expertise, HSR filings, and publicly available data in support of its Final Rule.

3. Objections Raised During the Comment Period Were Addressed

PhRMA contends that the FTC "disregard[ed]" the record evidence and "fail[ed] to offer a meaningful response to" the Varner Declaration or the purported "substantial problem" raised in the declaration, namely, that similar transactions occur in other industries not similarly covered by the Final Rule. Pl.'s Mem. at 25–26. The Court disagrees. First, the FTC did consider the evidence in the record. The Final Rule mentions PhRMA's comment twenty-three times and engages in multi-paragraph discussions of each of the three separate objections raised in that comment as supported by the Varner Declaration. *See generally* 78 Fed. Reg. at 68,705; *see also supra* Part I.B.2.d; *cf. Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 441, 449 (D.C. Cir. 2012) (holding that agency action failed to address commenters' concerns

[17] The parties dispute whether the requests for information made available on the FTC's public database are complete. Pl.'s Reply at 21–22; Def.'s Reply at 8. The Court need not delve into a comparison of the search terms used and the documents retrieved by PhRMA and the FTC because, as noted, the agency's reliance on its expertise and the 66 HSR filings, which the FTC cannot produce for public inspection, provide sufficient support for the Final Rule.

where agency "grouped together related comments" and "address[ed] them in a conclusory manner" (internal quotation marks and citation omitted)). For example, the Final Rule noted the objection raised by PhRMA that the pharmaceutical incentives, market structure, and regulatory hurdles appearing in the pharmaceutical industry also appear in other industries, and gave a reasoned explanation as to why the FTC disagreed with such claim and would not alter its proposed rule on this basis. 78 Fed. Reg. at 68,708–09; JA at 10–11; *see also* 78 Fed. Reg. at 68,706; JA at 8 (adopting the Final Rule "as proposed"). The FTC stated that PhRMA's objection was distinguishable because the FTC was not justifying its decision on the basis of "the uniqueness of the incentives" in the pharmaceutical industry, but was only using this to "help explain" why transferring exclusive patent rights in the pharmaceutical industry "takes the form of an exclusive license instead of an outright sale." 78 Fed. Reg. at 68,708–09; JA at 10–11. The FTC also noted PhRMA's concern that the FTC was basing its restriction of the rule to the pharmaceutical industry on the assumption that manufacturing is less important than the right to commercialize in this industry, as compared to others. 78 Fed. Reg. at 68,708; JA at 10. The FTC reiterated in the Final Rule that the statement about manufacturing rights in the NPRM did not form the basis of its decision but was only described to "provide a possible explanation as to why the PNO sees exclusive patent licenses in the pharmaceutical industry structured the way they are structured, namely more and more frequently without the transfer of manufacturing rights." *Id.*

Second, with respect to the "substantial problem" raised by the Varner Declaration, the Final Rule recognized "that there are agreements in other industries that involve the retention of manufacturing rights," and, in fact, cited examples provided in the Varner Declaration. 78 Fed.

Reg. at 68,708 & n.19; JA at 10 & n.19 (citing Varner Decl. at 9–11). The FTC explained, however, its view that these "are exclusive distribution agreements, which convey to the licenses only the exclusive rights to distribute the patented product . . . [and] the licensor retains not just the right to manufacture but all commercially significant rights to the patent," which was not the type of transaction the FTC sought to regulate. 78 Fed. Reg. at 68,708 & n.16; JA at 10 & n.16 (citing Varner Decl. at 11–14); *see also* 78 Fed. Reg. at 68,709; JA at 11 (PhRMA's comment "has not identified any other industry in which exclusive patent licenses, as opposed to exclusive distribution agreements, are common"). The Final Rule acknowledged that "[a]lthough it is possible for other industries to engage in the kind of exclusive licensing that typifies the pharmaceutical industry, the PNO has not processed" or even seen such filings in other industries in the past five years. 78 Fed. Reg. at 68,708; JA at 10.

The FTC also justified promulgation of an industry-specific rule on separate grounds, that the FTC intended to "proceed incrementally" and to implement the rule where the FTC believed it was necessary. 78 Fed. Reg. at 68,709–10; JA at 11–12. The FTC explained that even if such transactions exist in other industries, the FTC has not encountered these and therefore the FTC "has not found a need for a rule applicable to other industries." 78 Fed. Reg. at 68,708; JA at 10. Given that the FTC's grant of authority under the HSR Act is to promulgate rules "as may be *necessary* and appropriate to carry out the purposes of this section," 15 U.S.C. § 18a(d)(2)(C) (emphasis added), applying such a rule across industries where there is no demonstrated need to do so might have rendered such rule vulnerable to a separate challenge that the FTC had exceeded its statutory authority on these grounds. *See, e.g.*, *Am. Petroleum Inst.*, 953 F. Supp. 2d at 20–23 (holding that agency's rule of general applicability across companies was "arbitrary and

capricious" for failing to provide for exemptions). Consequently, the FTC understandably decided to "limit [the Final Rule] to those areas where [the FTC has] observed a problem to be addressed." 78 Fed. Reg. at 68,709; JA at 11; *see also City of Las Vegas v. Lujan*, 891 F.2d 927, 935 (D.C. Cir. 1989) (explaining that "[s]ince agencies have great discretion to treat a problem partially, we [sh]ould not strike down [a regulation] if it [is] a first step toward a complete solution."); *Nat'l Ass'n of Broadcasters*, 740 F.2d at 1210–11; *Inv. Co. Inst. v. U.S. Commodity Futures Trading Comm'n*, 891 F. Supp. 2d 162, 187–88 (D.D.C. 2012), as amended (Jan. 2, 2013), *aff'd sub nom. Inv. Co. Inst. v. Commodity Futures Trading Comm'n*, 720 F.3d 370 (D.C. Cir. 2013) ("[I]n promulgating regulations, agencies may proceed incrementally . . . ."). This discussion, which summarized and distinguished the Varner Declaration, demonstrates that the FTC considered the points raised in the Varner Declaration and simply arrived at a different conclusion. This does not, as PhRMA asserts, demonstrate that the FTC "entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency." *Am. Wildlands*, 530 F.3d at 997–98 (quoting *State Farm*, 463 U.S. at 43).

An agency's duty to respond to "significant comments raised during the rulemaking . . . is not 'particularly demanding.'" *Ass'n of Private Sector Colls. & Univs.*, 681 F.3d at 441 (citing *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005)). Moreover, "the arbitrary and capricious standard is 'highly deferential' and 'presumes agency action to be valid.'" *Am. Trucking Ass'ns., Inc.*, 724 F.3d at 245 (quoting *Am. Wildlands*, 530 F.3d at 997–98); *Envtl. Def. Fund, Inc.*, 657 F.2d at 283. The Court must "look only for 'a rational connection between the facts found and the choice made.'" *Am. Trucking Ass'ns., Inc.*, 724 F.3d

at 245 (quoting *State Farm*, 463 U.S. at 43). In light of the FTC's explanation of its rule and its response to PhRMA's comments, the Court finds that the FTC has established such rational connection.

Accordingly, this Court concludes that the Final Rule promulgated by the FTC is not arbitrary and capricious.

C. FTC's Rulemaking Record Included Sufficient Factual Material In Support of Its Decision

Count III of PhRMA's complaint claims that the FTC did not observe the procedure required by law under 5 U.S.C. § 706(2)(D) because the FTC did not include the factual basis for its decision in the rulemaking record. *See* Compl. ¶¶ 101–06; Pl.'s Mem. at 29–30. PhRMA objects that the FTC violated the rulemaking process by failing to provide for public comment the specific records of the informal interpretation requests and any other information which the FTC relied on to inform its decision. *See* Pl.'s Mem. at 30. This argument essentially restates PhRMA's contention that the Final Rule is arbitrary and capricious for failing to provide record support informing its expertise. *See supra* Part III.B.2. The FTC stated in the Final Rule that the agency determined the rule was necessary based on informal requests for information and 66 HSR filings received from the pharmaceutical industry, and no other industry, with regards to exclusive patent rights transfers. 77 Fed. Reg. at 50,059; JA at 3; 78 Fed. Reg. at 68,708; JA at 10.

"The APA requires an agency to publish 'notice' of 'either the terms or substance of the proposed rule or a description of the subjects and issues involved,' in order to 'give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments.'" *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir.

2008) (citing 5 U.S.C. § 553(b)-(c)). Under the APA, the court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D). "Longstanding precedent instructs that "[n]otice is sufficient 'if it affords interested parties a reasonable opportunity to participate in the rulemaking process,' and if the parties have not been 'deprived of the opportunity to present relevant information by lack of notice that the issue was there.'" *Am. Radio Relay League, Inc.*, 524 F.3d at 237 (quoting *WJG Tel. Co., Inc. v. FCC*, 675 F.2d 386, 389 (D.C. Cir. 1982) (citations omitted)). The Court's inquiry focuses on whether "the interested parties could not reasonably have 'anticipated the final rulemaking from the draft [rule],'" and "whether the notice given affords 'exposure to diverse public comment,' 'fairness to affected parties,' and 'an opportunity to develop evidence in the record." *Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 116 F.3d 520, 530–31 (D.C. Cir. 1997) (internal citations omitted).

The Final Rule was adopted as proposed, and interested parties were apprised of the basis and rationale for the FTC's proposed rule in the NPRM and provided an opportunity to comment. As previously discussed, with respect to the 66 HSR filings the FTC relied upon, such information is confidential and likely could not have been made public. *See* 15 U.S.C. § 18a(h); *see also Mattox*, 752 F.2d at 122; *Lieberman*, 771 F.2d at 38; *In the Matter of Gen. Motors Corp.*, 103 F.T.C. at *3. The requests for interpretation were available on the PNO's public database recording informal requests for interpretation, and PhRMA accessed this database to support its comment to the proposed rule. *See* JA at 32; *see also Wis. Power & Light Co.*, 363 F.3d at 462–63 (citing *U.S. Lines, Inc.*, 584 F.2d at 534–35 & 534 n.44). Moreover, PhRMA representatives met with FTC Commissioners and staff members on four occasions after the

close of the comment period and were provided the opportunity to submit additional material for the FTC's consideration, providing them ample opportunity to comment on the proposed rule. See JA at 70–77. As a result, PhRMA was given "the opportunity to present relevant information" and "a reasonable opportunity to participate in the rulemaking process." *Am. Radio Relay League, Inc.*, 524 F.3d at 236 (quoting *WJG Tel. Co., Inc.*, 675 F.2d at 389 (citations and internal quotation marks omitted)). Consequently, the FTC's rulemaking process thus did not fail to observe the procedure required by law under 5 U.S.C. § 706(2)(D).

IV. CONCLUSION

For the aforementioned reasons, PhRMA's Motion for Summary Judgment is denied and the FTC's Motion for Summary Judgment is granted. An appropriate order accompanies this Memorandum Opinion.

Date: May 30, 2014

Digitally signed by Hon. Beryl A. Howell
DN: cn=Hon. Beryl A. Howell, o=District of Columbia, ou=U.S. District Court for the, email=Howell_Chambers@dcd.uscourts.gov, c=US
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BERYL A. HOWELL
United States District Judge