IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Plaintiff,

v.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

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

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not deal in one fell swoop with the entire breadth of a novel development; instead, 'reform may take place one step at a time, addressing itself to the phase of the problem which seems most acute to the [regulatory] mind.' " *Nat'l Ass'n of Broadcasters v. FCC*, 740 F.2d 1190, 1207 (D.C.Cir.1984) (quoting *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955)).

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

BACKGROUND

A. The Premerger Notification Program

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

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

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

The Act authorizes the Commission, with the concurrence of the DOJ, to prescribe rules implementing the premerger notification program, including to "define the terms used in" the

B.

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

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

In establishing reportability, the parties must determine whether the license conveys the exclusive rights to commercially use the patent or part of a patent. For years, the PNO analyzed these transactions by focusing on whether the license transferred the full panoply of rights recognized under patent law Š*i.e.*, the right to "make, use, and sell" under a patent. *See* 35 U.S.C. § 271(a). That is, the PNO's focus was on the transfer of the bundle of rights to use a patent to exclusively manufacture a product, develop the product for all potential uses, and sell that product without restriction. If the patent holder retained any of these rights, PNO staff viewed the transaction as not constituting a reportable "acquisition" of an "asset." 77 Fed. Reg. at 50,058-59; 78 Fed. Reg. at 68,706.

[7] *See also Eastman Kodak Co. v. Goodyear Tire & Rubber Co*., 114 F.3d 1547, 1552 (Fed. Cir. 1997) ("section 7 may prohibit an

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

The PNO also has often received questions about licenses in which the licensor retains certain "co-rights" to assist the licensee in maximizing its sales of the licensed product, such as the right to jointly co-develop, co-promote, co-market, and co-commercialize a product along with the licensee. *Id*.; 78 Fed. Reg. at 68,706. In such cases, all sales are typically booked by the licensee, but the licensor often benefits from sharing in a more robust royalty revenue stream

or other revenue sharing arrangement. Such retained co-rights, however, do not give the licensor the right to commercially use the patent or part of the patent. 78 Fed. Reg. at 68,707. The PNO has long advised that, if the license grants the rights to "make, use and sell" under the patent, the licensor's retention of such co-rights does not render the license non-exclusive, and the transaction is a reportable transfer of an "asset." *Id.*; 77 Fed. Reg. at 50,059.

C. The Commission's Rulemaking

1. The Notice and Comment Process

In August 2012, the Commission issued a Notice of Proposed Rulemaking ("NPR"), proposing to amend the HSR Rules to provide a framework for determining when the transfer of exclusive rights to a pharmaceutical patent is an acquisition under the HSR Act. The proposed rule adopted an "all commercially significant rights" test, which the Commission provisionally

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

2. The Final Rule

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

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

ARGUMENT

I. THE FTC REASONABLY INTERPRETED THE HSR ACT.

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

"When a litigant challenges the Commission's interpretation of a statute that it administers," the Court's review "is

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

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

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

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

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

In fact, the statute contains no support whatsoever for Plaintiff's argument. Contrary to Plaintiff's suggestion, there is no inconsistency between (1) requiring all parties in qualified transactions to file notification (unless exempted) and (2) allowing the Commission to implement the requirements of the Act on an industry-specific basis. Nothing in the text of the Act demonstrates that Congress intended to prohibit ement

decided by Congress Šnot the FTC and the Justice Department," *id*., he was talking about who gets to decide the size of the transactions that warrant mandatory pre-closing review. Nothing in this legislative history suggests that Congress intended to depriv

Particularly given this background principle of administrative law, Congress's silence in the

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

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

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

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

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

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

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

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

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

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

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

The Commission thoroughly explained its reasoning for issuing a rule that identifies when a transaction involving the transfer of exclusive rights to a patent or part of patent in the pharmaceutical industry constitutes an asset acquisition under the HSR Act. "In recent years," the Commission observed, "it has become more common for pharmaceutical companies to transfer most but not all of the rights to 'make, use and sell' under an exclusive license, such that the 'make, use and sell' approach is no longer adequate in evaluating the reportability of exclusive licenses in the pharmaceutical industry for HSR purposes." 78 Fed. Reg. at 68,706. For example, the Commission found, it has become increasingly common for a pharmaceutical

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

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

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

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

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

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

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

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

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

- A "Master Distributorship Agreement" granting the exclusive right "to purchase, inventory, promote, and resell" the licensor's product incorporating patented technology (Varner Decl. ¶ 23 n. 33, citing Ex. 10.14 of http://www.sec.gov/Archives

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

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

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

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

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

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

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

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

None of those agreements transfer all significant rights to commercially use a patent (or part of a patent) to the exclusion of

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

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

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

As already discussed, an agency "need not deal in one fell swoop with the entire breadth of a novel development; instead, reform may take place one step at a time, addressing itself to the phase of the problem which seems most acute to the [regulatory] mind." *Nat'l Ass'n of Broadcasters*, 740 F.2d at 1207 (D.C.Cir.1984) (internal quotation marks omitted). Here, the Commission reasonably decided to limit the Rule to exclusive patent licenses in the pharmaceutical industry because "this is where the need for clarification arises and where the Commission has experience with the relevant transactions." 78 Fed. Reg. at 68,708. The Commission further reasoned that cabining the Rule's scope in this manner allowed it to identify reportable transactions employing terminology that has precise meaning in the pharmaceutical industry but would be meaningless in other contexts. *Id*. Specifically, the Commission defined the relevant scope of the transfer of the exclusive rights to part

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

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

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

Lastly, Plaintiff argues that the Commission's Notice of Proposed Rulemaking did not adequately divulge the factual basis for the proposed rule, thereby depriving Plaintiff of a opportunity to meaningfully participate in the rulemaking. In particular, Plaintiff complains that it had no ability to test the Commission's statements concerning the PNO's experier6 Twt h

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

III. VACATUR WOULD BE UNWARRANTED EVEN IF PLAINTIFF'S

will be able to justify retaining its rule, the Court may remand without vacatur even where "the disruptive consequences of vacatur might not be great." *Fox Television Stations, Inc. v. FCC*,