ORAL ARGUMENT NOT YET SCHEDULED

No. 14-5182

In the United States Court of Appeals for the District of Columbia Circuit

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, APPELLANT

v.

FEDERAL TRADE COMMISSION, APPELLEE

On Appeal from the United States District Court
for the District of Columbia, No. 1:13-CV-01974 (BAH)

TABLE OF CONTENTS

TABLE OF AUTHORITIES *

CASES PAGE

Wg1Td (e)4(s)1(v)4(3d 929 ()n-2(I)-3Td (4 Tw [(T)-8(el)-2(eco(')-53(s)-er)27(G (ca(d)-2

REGULATIONS

GLOSSARY

Act	Hart-Scott-Rodino Act
Antitrust agencies	The Federal Trade Commission and the Antitrust Division of the Department of Justice
APA	Administrative Procedure Act
Commission	Federal Trade Commission
DOJ	The Department of Justice Antitrust Division
FTC	Federal Trade Commission
HSR Act	Hart-Scott-Rodino Act
HSR Rules	FTC Rules Implementing the HSR Act
NPR	Notice of Proposed Rulemaking

1. Whether the Hart-Scott-Rodino Act gives the FTC discretion to define what it means to "acquire" an "asset" in the form of exclusive rights to a pharmaceutical patent without having to extend the same definition for every other type of patent; and

2. Whether the FTC supplied a reasoned justification for adopting a definition for exclusive rights to a pharmaceutical patent rather than patents in all other industries.

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Appellant.

transfers all rights under a pharmaceutical patent exclusively to Company Y, except that X retains the limited right to continue manufacturing products under the patent for Y's exclusive benefit. Such asset transfers can raise all of the same economic concerns that underlie the reporting requirement for transfers of all patent rights. The Commission responded by adopting the rule at issue here, which makes such transactions reportable by adopting new definitions of the key statutory terms "acquire" and "asset" as they relate to exclusive rights to pharmaceutical patents. Because the Commission saw no indication that similar arrangements are used in other fields, it did not address non-pharmaceutical patents.

Appellant Pharmaceutical Research and Manufacturers of America (PhRMA) does not appear to challenge the substantive merits of the new rule. In particular, PhRMA nowhere explains why these asset transfers should be exempt from the reporting requirements despite their potential competitive significance. Instead, PhRMA argues that, in adopting the new rule, the FTC was required to subject *all other* companies throughout the economy to the same treatment, even though such transfers rarely (if ever) arise in other industries and no analogous regulatory problems have arisen there. Nothing in this statutory scheme requires that anomalous result, and the Commission acted reasonably in constraining its new rule to the scope of the identified problem.

A. Statutory and Regulatory Background

1. The Premerger Notification Program

The Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act) requires persons intending to "acquire, directly or indirectly, any … assets of any other person" at or above a threshold value to provide notice of the transaction to the FTC and the Department of Justice and wait a designated period before consummating it. 15 U.S.C. § 18a(a). The Act enables the antitrust enforcement agencies to evaluate the competitive implications of large acquisitions before they occur and to seek to enjoin a transaction if either agency foresees a substantially likely harm to competition. *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; *Mattox v. FTC*, 752 F.2d 116, 119-20 (5th Cir. 1985).

Congress expressly authorized the FTC to "define the terms used" in the HSR Act, 15 U.S.C. § 18a(d)(2)(A), and to "prescribe … rules as may be necessary and appropriate to carry out the purposes" of the Act, 15 U.S.C. § 18a(d)(2)(C). The Commission has issued rules implementing the Act, which are codified at 16 C.F.R. Parts 801 through 803. It periodically amends these rules to improve the program's effectiveness in order to better assess anticompetitive transactions before they happen.

the question can be more complex. The PNO has long advised the public that the transfer of exclusive rights to a patent is a reportable asset acquisition because such a transaction is substantively the same as an outright sale and carries the same potential anticompetitive effects. JA 6-7, 75.[1]

The PNO has traditionally analyzed such exclusive patent licenses by asking whether the license transferred all of the rights granted by the patent. The right to "make, use, and sell" the products covered by the patent. *See* 35 U.S.C. § 271(a) (defining patent infringement). Thus, an exclusive license to manufacture a product, develop it for all potential uses, and sell it without restriction would constitute the acquisition of an asset under the HSR Act. JA 6-7, 75. Although not codified, the "make, use and sell" approach is well-established and widely known by practitioners. JA 7, 75; *see* ABA Section of Antitrust Law, PREMERGER NOTIFICATION PRACTICE MANUAL 38 (4th ed. 2007).[2]

---

[1] *See also* U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 5.7 (1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,13Tw 14d in

Transfers of exclusive rights to a patent by license are commonly used in the pharmaceutical industry, which has been filing HSR notifications and seeking guidance from the PNO involving such transactions since the early 1980s. JA 75, at n.7. In the five years before this rulemaking, *all* of the 66 HSR filings received by the PNO involving exclusive patent licenses were for pharmaceutical patents. JA 77. Moreover, almost all of the requests to the PNO for guidance about the reportability of exclusive patent licenses have concerned transactions in the pharmaceutical industry. JA 7, 77.

In recent years, patent licensing practices in the pharmaceutical industry have evolved from straightforward grants of the exclusive right to "make, use and sell" products under a patent to arrangements in which the pharmaceutical company acquires almost all, but not quite all, of the exclusive rights under a patent. For example, the patent holder may retain the limited right to manufacture products under the patent, but only for the licensee's benefit. JA 7, 75. Such an arrangement may be beneficial to both parties because the licensor has manufacturing expertise or owns a production facility that has already obtained the requisite approval from the Food and Drug Administration. JA 7. Yet the arrangement nevertheless may effect a transfer of all *commercially significant* 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 traditional “make, use, and sell” approach, the licensor’s retention of these limited manufacturing rights made the transaction non-reportable.

the Commission proposed, "even if the patent holder retains limited manufacturing rights" or co-rights. *Id*. The agency explained that the proposed definitions "should greatly simplify the question of whether an asset acquisition is occurring" in a pharmaceutical patent transaction, while "providing [the FTC and DOJ] with a better opportunity to review the transfers of exclusive rights to a patent in the pharmaceutical industry for competitive concerns." JA 8.

The Commission received three public comments. PhRMA opposed the proposed rule, while two other commenters supported it. PhRMA also met with each of the Commissioners and FTC staff to discuss the proposed rule. JA 65-70. In November 2013, after reviewing the comments, the Commission unanimously adopted the Rule as proposed, and the DOJ concurred. JA 74-82.

The Commission explained that "[i]n recent years … it has become more common for pharmaceutical companies to transfer most but not all of the rights" under a patent. JA 75. As a result, the traditional "make, use, and sell" test "is no longer adequate in evaluating the reportability of exclusive licenses in the pharmaceutical industry." *Id*. The new rule, the Commission explained, would "capture[] 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 the patent." JA 76.

The Final 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); JA 82. As proposed in the notice, the term "commercially significant rights" means "the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)." 16 C.F.R. § 801.1(o); JA 81. Commercially significant rights are transferred, the Rule makes clear, "even if the patent holder retains limited manufacturing rights" or "co-rights."[3] The Rule provides various examples of the application of these concepts. JA 82.

[3] The term "limited manufacturing rights" 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)." 16 C.F.R. § 801.1(p); JA 81. The term "co-rights" is defined to mean "shared rights retained by the patent holder to assist the recipient of the exclusive

The Commission explained that, for two core reasons, it adopted definitions of "acquire" and "asset" only for pharmaceutical patents. First, based on HSR filings made and questions posed to the PNO, the pharmaceutical industry is the only one in which the Commission has identified a need to clarify the reportability of transactions involving transfers of exclusive patent licenses. JA 77. The PNO "has not processed filings" involving exclusive patent licenses "in any other industry in the past five years," *id*., and the pharmaceutical industry is "the only industry to the PNO's knowledge in which exclusive patent licenses are prevalent," JA 77-78; *see also* JA 75 (such deals becoming "more common"). Second, the Commission explained that its experience with such transactions in the pharmaceutical industry "allow[ed] it to develop a rule that is tailored to exclusive patent licenses in the pharmaceutical industry, defining the relevant scope of the transfer of part of a patent by reference to the therapeutic area or specific indication within a th

C. The District Court Proceeding

pharmaceutical industry. JA 339-40, 342-44. The court found that, in distinguishing between pharmaceutical and non-pharmaceutical exclusive patent licenses, the FTC had properly relied on its expertise "informed by years of administering the premerger notification program." JA 346. The court similarly rejected PhRMA's argument that the FTC was required to produce "physical records of everything that has contributed to its expertise over time." JA 347. The PNO's informal interpretations are publicly available and searchable on the FTC's website, and the Notice of Proposed Rulemaking apprised commenters that the FTC was relying on this database to support the proposed rule. Thus, PhRMA had an opportunity to respond, and it did in fact respond by using information in this database to craft its comments. JA 352-54.

SUMMARY OF ARGUMENT

Congress broadly authorized the Commission to "define the terms used" in the HSR Act and to "prescribe … rules … necessary and appropriate to carry out the purposes" of the Act. 15 U.S.C. § 18a(d)(2)(A), (C). Exercising that authority here, the Commission defined when a transfer of exclusive rights to a pharmaceutical patent constitutes the "acquisition" of an "asset" under the Act. PhRMA does not dispute the substance of the Commission's definition of those two terms. Instead, PhRMA complains that the Rule is too narrow. It argues that,

with respect to parties of transactions that *meet* those thresholds.

The Commission’s statutory construction is also entirely reasonable under *Chevron* Step 2. When writing regulations, agencies “need not deal in one fell swoop with the entire breadth of a novel development; instead, ‘reform may take place one step at a time, addressing itself to the phase of the problem which seems most acute to the [regulatory] mind.’ ” *Nat’l Ass’n of Broadcasters*, 740 F.2d 1190, 1207 (D.C.Cir.1984) (quoting *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955)). PhRMA identifies no reason why an incremental approach is unreasonable here. And PhRMA is likewise wrong to argue (for the first time on appeal) that the Commission has previously “disclaimed” authority to issue notification rules that apply to specific industries. To the contrary, the Commission has in fact previously defined terms in the Act on an industry-specific basis.

2. PhRMA’s various APA claims are without merit. As the Commission explained, it limited the Rule as it did because, in its experience administering the HSR notification program, the kinds of exclusive patent licenses covered by the Rule appear frequently in the pharmaceuty e

policy distinctions, but that argument collides with a solid wall of contrary precedent.

There is also no merit to PhRMA's argument that the Commission inadequately disclosed the basis for its exemption of licensing from HSR filings. The FTC highlighted the PNO guidance on the reportability of exclusive licenses. The FTC highlighted the PNO's database of informal guidance in the Notice of Proposed Rulemaking, and that database is both publicly available and easily searchable. Indeed, PhRMA itself used this database in formulating its comments on the Rule. As to the HSR filings, PhRMA does not challenge the district court's finding that the FTC could not lawfully disclose such confidential submissions, and PhRMA also does not explain how its lack of access to them could have prejudiced it.

Finally, contrary to PhRMA's argument, the Commission responded adequately to the report of PhRMA's expert declarant. In particular, the Commission reasonably found that the licensing agreements he cited from other industries were mere distribution agreements and, as such, were entirely unlike the kinds of exclusive patent licenses at issue here.

3. Even if there were some basis for a remand, vacatur of the Rule would be unwarranted. If, as PhRMA argues, the Commission somehow acted improperly in limiting its Rule to the pharmaceutical context, the most obvious solution on

remand would be to extend that Rule to other contexts, not to rescind it in the one context—exclusive pharmaceutical patent licenses—where it is most needed. The pharmaceutical industry would thus almost certainly end up on remand being subject to the same filing requirements as today. And vacatur would be not only pointless in that respect, but also, in the interim, affirmatively harmful to the core objective of the HSR Act: ensuring that large transactions of this type are reviewed for potentially anticompetitive consequences.

PhRMA's favor, PhRMA's members would face exactly the same filing obligations they complain about here.

It is thus uncertain that PhRMA has pleaded an injury in fact that is "likely" to be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal quotation marks omitted); *see also Amer. Chem. Council v. Dep't of Transp*., 468 F.3d 810, 818-21 (D.C. Cir. 2006) (holding that petitioners failed to establish standing to challenge narrowness of agency's rule because the court was "left to wonder," among other things, "how setting aside the [agency's] Final Rule would likely remedy any alleged injury").[4] But even if PhRMA could identify some basis for Article III standing, it has no valid basis on the merits for challenging the Commission's decision to confine the Rule to the lone industry context where it is demonstrably needed.

[4] If this Court were to vacate the Rule outright, as PhRMA requests, PhRMA's members would not face the relevant filing obligations until the Commission adopted a new rule. But that vacatur request is untenable, *see* Section III, *infra*, and thus cannot satisfy the redressability requirement. In the event of a remand, the Commission would far more likely broaden the reporting rule than eliminate it altogether. Vacatur would thus be inappropriate because it would accomplish nothing beyond a brief suspension of the Rule's operations in the one industry where it is actually needed, thereby imposing "disruptive consequences" in the form of "an interim change that [would] itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d, 146, 150-51 (D.C. Cir. 1993).

question about *who* must report such a transaction. Whether a given transaction constitutes an "asset" "acquisition" that gives rise to potential antitrust concerns can vary from one economic context to another. Here, the FTC reasonably determined that certain transfers of exclusive pharmaceutical patent rights are functionally equivalent to, and have the same potential antitrust effects as, an outright sale of a patent, and thus are properly viewed as asset acquisitions under the Act. That determination, moreover, is binding on all "persons" that might engage in such transactions, not just some. PhRMA wrongly suggests otherwise, *e.g.*, Br. 13-14, 19, but only because it jumps straight to the "no person" language without examining, much less challenging, the FTC's underlying definitions of "asset" and "acquisition."

In short, nothing in the Act remotely—let alone "unambiguously," *Vill. of Barrington*, 636 F.3d at 661—speaks to whether the antecedent terms "acquire" and "asset" may be defined with respect to transactions that arise only in particular industries. Instead, Congress left that question to the Commission—both2 -2.(te)4(a)12(d0.004

Second, PhRMA's argument would fail even if it were meaningful to focus on the term "no person" in isolation from the defined terms "asset" and "acquisition." Congress authorized the Commission to "exempt, from the requirements of this section, classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws." 15 U.S.C. § 18a(d)(2)(B). This language shows that Congress wished to grant the Commission discretion to apply the reporting requirements flexibly, as will best serve the purposes of the antitrust laws while minimizing unnecessary burdens on commerce. As the district court held, that authority directly supports the FTC's authority to adopt rules that apply narrowly because it "make[s] plain that the reporting requirements were intended to be a scalpel, rather than a blunt sword." JA 323.

There is no merit to PhRMA's contrary interpretation of the same provision. PhRMA argues that section 18a(d)(2)(B) authorizes the agency to allow exemptions from generally applicable reporting duties, but does not authorize selective imposition of such duties. Br. 21. Of course, the power to exempt and power to impose are simply two sides of the same coin, as the district court recognized. JA 323. Thus, any regime that forbade selective impositions of rules but permitted selective exemptions would be inadministrable and, indeed,

conceptually intractable. But even if that were not the case, PhRMA's argument rests on the assumption that "no person" is the controllTt]ontaintractable

PhRMA also errs in arguing for the first time on appeal that the Commission's authority to prescribe rules as "necessary and appropriate" pertains only to the contents of the notification to be filed with the antitrust agencies. Br. 28. Even if PhRMA could raise newly minted arguments now, the claim fails because it confuses two independent grants of authority. Section 18a(d)(1), on which PhRMA relies, directs the FTC to prescribe that HSR filings "be in such form and contain such documentary material and information relevant to a transaction as is necessary and appropriate to enable the [antitrust agencies] to determine whether such acquisitions may, if consummated, violate the antitrust laws," 15 U.S.C. § 18a(d)(1). But section 18a(d)(2)(C) Šthe provision relevant here Šauthorizes the FTC 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) (emphasis added). The first provision does not limit the authority conveyed by the second, and PhRMA's reading would render the latter provision redundant.[5]

[5] PhRMA cites *NRDC v. EPA*, 749 F.3d 1055 (D.C. Cir. 2014), to challenge the FTC's execution of its "necessary and appropriate" authority. Br. 28-29. That

Having fundamentally misread this statutory scheme, PhRMA relies in vain on inapposite APA cases involving entirely dissimilar statutory schemes. *See generally United States v. Ali*, 718 F.3d 929, 938 (D.C. Cir. 2013) (noting the "fundamental canon of statutory construction that the words of a statute must be read in their context"). For example, *Whitman v. American Trucking Ass'n, Inc.*, 531 U.S 457, 468 (2001), is irrelevant here because it involved an agency regulation that, unlike this one, was "unambiguously" at odds with the text of the statute. And *NRDC v. EPA*, 489 F.3d 1250, 1259 (D.C. Cir. 2007), likewise concerned an agency-defined term that directly contradicted an applicable statutory definition. PhRMA's other "no person" cases—*Eagle Broad. Grp., Ltd. v. FCC*, 563 F.3d 543 (D.C. Cir. 2009), and *Emory v. United Air Lines, Inc.*, 720 F.3d 915 (D.C. Cir. 2013)—involved entirely different statutory language and did not even address the question whether, or how, the "no person" language in those schemes affected the agency's rulemaking authority.

B. The Legislative History Of The HSR Act Does Not Resolve The Statutory Silence.

Without support in the statutory text, PhRMA turns next to the legislative history of the HSR Act and focuses on the interplay between the House and Senate

---

the absence of such clear expressions of congressional intent, courts defer broadly to agency decision to regulate "as necessary and appropriate." *Associated Gas Distrib. v. FERC*, 824 F.2d 981, 1001 (D.C. Cir. 1987).

bills. That legislative history does not support PhRMA's position at all, let alone so clearly and directly as to overcome normal principles of *Chevron* deference. *See Texas Oil & Gas Ass'n*, 161 F.3d at 938 (holding that "[t]he legislative history also falls short of expressing a clear congressional intent to prevent differentiated treatment").

The Senate bill for what became the HSR Act would have authorized the FTC to require premerger notification from "any person or persons, or any class or category thereof," "[n]otwithstanding any other provision of law or the applicability of section (a) of this section"—the section that prescribes size thresholds triggering the premerger notification requirement. Hart-Scott Antitrust Act of 1976, S. 1284, 94th Cong. § 7A(b)(2)(A)-(B) (May 6, 1976). That language did not ultimately appear in the bill as enacted. According to PhRMA, that omission proves that Congress must have intended to bar the FTC from tailoring its statutory definitions to transactions that arise only in particular industries.

It shows no such thing. As the Act's sponsors indicated and the "notwithstanding" clause confirms, the Senate provision would have allowed the Commission to require particular categories of persons to report transactions *falling below the Act's minimum thresholds*. Senator Hart explained that the Senate bill provision addressed "transactions between persons not meeting the

minimum size criteria." 122 Cong. Rec. 29,342 (Sept. 8, 1976); *see also* 122 Cong. Rec. 30,877 (Sept. 16, 1976) ("[t]he Senate bill permitted the FTC, with participation of the Department of Justice, to promulgate rules subjecting 'small' mergers . . . to the notification and waiting requirements"). Thus, when Rep. Hutchinson[6] stated that "[t]he grant of discretion to enforcement agencies to enlarge the coverage of the

PhRMA nonetheless contends that the accompanying floor statements suggest congressional disfavor for *any* industry-specific notification rules. Not so. PhRMA cites Sen. Hart's statement that the Senate provision would permit the antitrust agencies "to require premerger notifications from particular companies or industries or from any class or category of persons." But that snippet ignores Sen. Hart's prefatory explanation that this provision specifically related to "transactions between persons not meeting the minimum size criteria." 122 Cong. Rec. 29,342. As the district court correctly determined, "[t]his 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." JA 331.

C. The FTC's Construction of the HSR Act Is Reasonable.

Because Congress has not "directly addressed the precise question at issue," the Commission's interpretation must be upheld if it "is based on a permissible

---

corporation shall"). For that reason, in addition to those discussed in Section I.A above, there is no basis for PhRMA's claim that the House somehow used that language to repudiate what PhRMA calls the Senate bill's "industry-specific focus." *See* Br. 30, 33. PhRMA also mischaracterizes Rep. Rodino's statement that "the House prevailed in 90 percent of the areas …." *See* Br. 31. It is clear from the context that Rep. Rodino was talking about the *parens patriae* provisions

construction of the statute."

Rather than grappling with such issues, PhRMA's *Chevron* Step 2 argument boils down to a rehash of its Step 1 claim. It asserts, for example, that deference is warranted only "when Congress has delegated to the agency the power it claims." Br. 35. Again, however, Congress *has* delegated to the Commission the authority to define terms in the Act. *See United States v. Mead Corp.*, 533 U.S. 218, 229 (2001) ("We have recognized a very good indicator of delegation meriting *Chevron* treatment in express congressional authorizations to engage in the process of rulemaking or adjudication that produces regulations or rulings for which deference is claimed."). If PhRMA means to argue that Congress must have *affirmatively* authorized industry-specific notification rules, that argument would turn *Chevron* on its head. The point of *Chevron* is that congressional *silence* authorizes the agency to fill the legislative gap Š D Q G W K D W reasonable interpretation of an ambiguous statute merits deference. 467 U.S. at 843; *see NACS v. Bd. of Governors of Fed. Reserve Sys.*, 746 F.3d 474, 488 (D.C. Cir. 2014) ("the question then is how [the statutory provision] limits the Board's

---

(upholding EPA regulation treating apartment buildings differently from manufactured home communities for purposes of determining whether submetering constituted a sale of water, effectively exempting apartment buildings from certain water safety requirements; although EPA had deemed the water distribution system to be safe in apartment houses, it could not categorically say the same for manufactured home communities, which would be exempted on a case-by-case basis).

discretion to define the statutory term … not whether that section affirmatively grants the Board authority to allow [the substance of the rule]").[9]

Finally, PhRMA argues for the first time on appeal that

criteria are satisfied and that the agency is appropriately cautious about granting exemptions for particular industries. The Commission nowhere disclaimed the authority to define statutory terms for a particular industry. Indeed, at the time it made those statements, the Commission simultaneously issued the above industry-specific definitions

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." JA 75. In the five years prior to the rulemaking, for example, the PNO received filings for 66 transactions involving exclusive patent licenses, all of which were for pharmaceutical patents. JA 77. Similarly, the pharmaceutical industry is where the need for clarification has arisen. Requests for guidance from the PNO on the treatment of exclusive patent licensing transactions have come overwhelmingly from practitioners in matters involving the pharmaceutical industry. JA 78.[10]

By contrast, "the Commission has not found a need for a rule applicable to other industries" because they have not given rise to similar transactions or been the subject of inquiries to the PNO. JA 77. The Commission recognized that exclusive patent licenses of the type covered by this rule might be used in other industries Šand it pledged to monitor the market and take action if necessary. But it found no evidence that such licensing arrangements are common outside of the pharmaceutical industry today. Notably, no third-party commenters, such as

[10] Although PhRMA purported to identify similar licensing agreements from other industries, the Commission properly determined that those agreements were, in fact, not comparable; instead, they were simple distribution agreements. *See* Section II.C, *infra*.

The specificity of the Commission's approach is a strength, not a shortcoming. The Commission is appropriately cautious about intruding in areas of the economy where it has lacked an opportunity to assess the need for, and impact of, its proposed regulatory actions. This Court, too, has encouraged agencies to exercise such regulatory caution. As it has explained, 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 (internal quotation marks omitted); *see* p. 31, *supra*. "Nothing in [the statute] or in the Administrative Procedure Act, or in any judicial decision, forces an agency to refrain from solving one problem while it ponders what to do about others." *Personal Watercraft Indus. Ass'n*, 48 F.3d at 546; *accord City of Las Vegas*, 891 F.2d at 935 ("agencies have great discretion to treat a problem partially"). Those principles are dispositive here.

PhRMA next argues that the Commission inadequately explained its supposed "depart[ure]" from a "longstanding view[]" that HSR rules should apply across all industries. *See* Br. 41-42 (emphasis and quotation marks omitted). That argument is without merit. While HSR rules and practices have typically applied to all industries, the Commission has sometimes tailored specific rules to particular

industries, *see* p. 33, *supra*, and here the Commission explained at length its reasons for acting incrementally in this case. Thus, even if the FTC could be said to have modified some discernible policy,

licenses that convey all rights. PhRMA has never identified any basis for questioning that finding—not before the Commission, not in the district court, and not here on appeal. Any challenge to that finding, or to the reportability of exclusive licenses more generally, is thus waived.[12]

B. The Commission Properly Relied On Its Experience.

The Commission's experience in assessing exclusive patent licenses informed its decision to address such licenses in the pharmaceutical industry. PhRMA claims that the Commission may not legitimately rely on its experience in formulating regulatory policy. Br. 44-45. That argument runs headlong into numerous decisions of this Court. It is black letter law that, where a rule is the product of an agency's "long experience administering the existing … rules," the agency's "perceptions based on its experience" provides sufficient support under the arbitrary and capricious standard to sustain the rule change as a rational decision. *Nat'l Tour Brokers Ass'n v. ICC*, 671 F.2d 528, 533 (D.C. Cir. 1982).

[12] Contrary to PhRMA's contention, there is no FTC policy that transactions are reportable only if the agency determines that, at some level of specificity, they are "likely to be anticompetitive." Br. 42. The statute requires reporting any time a person "acquires an asset" above a certain size. If it does, Congress provided that the transaction triggers sufficient competitive concern to require a filing, subject only to the FTC's discretionary exemption authority. That filing requirement applies whether particular transactions are likely to cause competitive harm or would prove difficult to unwind.

Put another way, an agency may

First, PNO’s

Finally, there is no merit to PhRMA's complaint that the FTC "did not say how many—if any—[of the 66 filings] were the 'exclusive patent licensing arrangements that transfer all of the rights to commercially use a patent or part of a

are entirely unlike "the kinds of agreements that are the subject of the Rule." JA 77. That determination was reasonable.

The Rule applies to patent licenses that transfer all significant rights to commercially use a patent to the exclusion of all other potential users, even the licensor. Such licenses "are functionally equivalent to patent transfers and are thus properly viewed as asset acquisitions under the Act." JA 78. As the Commission emphasized, however, "[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." JA 76, at n.10 (emphasis added).[14] The Commission further explained that the licensing agreements from other industries cited by Dr. Varner are in fact mere "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." JA 77.

The two non-pharmaceutical licensing agreements that PhRMA cites in its brief illustrate the Commission's point. *See* Br. 56. The Donlar-FMC agreement

[14] Such distribution agreements are not commonly considered transactions in which one party "acquires" the "assets" of another. *See generally* 8 Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶ 1600 (3d ed. 2010) (discussing distribution restraints).

is a "Market Development and Distributorship Agreement" specifying that the relationship between the parties "shall be that of a seller and buyer," and granting to the licensee "and its customers" a non-exclusive license "to practice" the patented technology.[15] The Medi-Ject-BIG license is 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.[16]

Those agreements starkly contrast with exclusive patent licenses in the pharmaceutical industry that grant the licensee all commercially significant rights, which extend well beyond mere distribution and bar the licensor from playing any continued role in product development. As Dr. Varner's own declaration reveals, such licenses encompass the rights granted in, for example, (1) an "Agreement . . . For the Licensing and Development of Glufosfamide," granting an "exclusive license . . . under and using the Licensed Patents and Licensed Know-How . . . to develop, make, have made, use, supply, offer for sale, sell, import, export and otherwise distribute [the] Licensed Product";[17] and (2) a "Licensing Agreement"

---

[15] JA 39 (Varner Dec. at n.34, citing ex. 10.6 of http://sec.gov/Archives/edgar/data/1047175/0000950124-97-005153.txt).

[16] JA 41 (Varner Dec. at n.39, citing 10.4 of http://www.sec.gov/Archives/edgar/data/1016169/0001045969-00-000229.txt).

[17] JA 43 (Varner Dec. n.50, citing Ex. 10.2 of http://www.sec.gov/Archives/edgar/data/1183765/000119312504059933/dex106.h

granting "an exclusive (even as to NexMed) . . . license, under the NexMed Patent Rights and NexMed Know-How to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, offer for sale, sell, have sold and otherwise commercialize" the licensed products.[18] Unlike the other agreements discussed above, these licenses transferred all significant rights to decide if and when to commercialize a patent and how to market and price the product covered by the license.

The Commission thus did not "disregard" Dr. Varner's study, as PhRMA wrongly charges. The Commission examined those materials, found them unpersuasive, and explained its reasons for doing so. As the district court noted, the Commission "simply arrived at a different conclusion," and did so reasonably. JA 357. The Commission "made clear enough the limitations of the study," and there is "no cause to disturb its ultimate judgment that the study was unpersuasive evidence." *Chamber of Comm.*, 412 F.3d at 143 (internal quotation marks omitted).

---

tm).

[18] JA 45 (Varner Dec. at n.63, citing Ex. 99.1 of http://www.sec.gov/Archives/edgar/data/1017491/000114420405028876/v025708_ex99-1.htm).

III. VACATUR

retained rights. The question here is thus *not* whether the FTC can require pharmaceutical companies to notify the agency of such licenses. The only question is whether the Commission must extend that approach to *other* segments of the economy and whether it has adequately explained its decision not to do so. However the Court decides that issue, the pharmaceutical industry, where nearly all such licenses arise, would almost certainly end up on remand being subject to the same HSR filing requirements as it is today.

It would be pointless to vacate those requirements as to the pharmaceutical industry only to have them promptly reapplied. *See Allied-Signal*, 988 F.2d at 150-51 (vacatur analysis turns in part on concerns about "the disruptive consequences of an interim change that may itself be changed"). And doing so would risk anticompetitive harm in the interim. The HSR Act ensures that antitrust enforcement agencies can review potentially anticompetitive transactions before they occur. It would make little sense to expose the public to such harm merely because the existing rule is insufficiently broad.

CONCLUSION

This Court should affirm the judgment of the district court.

Respectfully submitted,

Of Counsel: JONATHAN E. N

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. 32 (a)(7)(B), in that it contains 11,301 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and D.C. Circuit Rule 32(a)(1), and complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

s/ Michele Arington
MICHELE ARINGTON

CERTIFICATE OF SERVICE

I hereby certify that on December 10, 2014, I served the foregoing Brief for the Federal Trade Commission on counsel for record by electronic service through the Court's CM-ECF system.

In addition, pursuant to D.C. Circuit Rule 31(b) and this Court's Administrative Order Regarding Electronic Case Filing, I will cause to be mailed to the Court eight paper copies of this brief within two business days of this filing.

s/ Michele Arington