United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 24, 2015 Decided June 9, 2015

No. 14-5182

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
APPELLANT

v.

FEDERAL TRADE COMMISSION,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:13-cv-01974)

Evan A. Young argued the cause for appellant. With him on the briefs were *Aaron M. Streett*, *Shane Pennington*, *Wm. Bradford Reynolds*, *Joseph A. Ostoyich*, and *James F. Rill*.

Michele Arington, Assistant General Counsel, Federal Trade Commission, argued the cause for appellee. With her on the brief were *William J. Baer*, Assistant Attorney General, U.S. Department of Justice, *Kristen C. Limarzi*, Chief, Appellate Section, *Robert J. Wiggers*, Attorney, *Jonathan E. Nuechterlein*, General Counsel, Federal Trade Commission, *David C. Shonka*, Principal Deputy General Counsel, and *Joel Marcus*, Assistant General Counsel. *John F. Daly*, Attorney, Federal Trade Commission, appeared as trial counsel.

Before: GRIFFITH, *Circuit Judge*, MILLETT, *Circuit Judge*, and EDWARDS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* EDWARDS.

EDWARDS, *Senior Circuit Judge*: The Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "Act" or "HSR Act") was passed by Congress "[t]o improve and facilitate the expeditious and effective enforcement of the antitrust laws." Pub. L. No. 94-435, 90 Stat. 1383, 1383 (codified as amended at 15 U.S.C. § 18a). The Act added Section 7A to the Clayton Antitrust Act of 1914, 15 U.S.C. § 12 *et seq.*, to establish notification and waiting requirements for large acquisitions and mergers. The principal purpose of the Act is to facilitate Government identification of mergers and acquisitions likely to violate federal antitrust laws before the proposed deals are consummated. The Federal Trade Commission ("FTC" or "Commission"), with the concurrence of the Assistant Attorney General for the Antitrust Division, has extensive authority under the Act to define terms in the HSR Act and to promulgate regulations necessary to carry out the purposes of the Act.

In 2013, following notice and comment rulemaking, the FTC modified its reportable asset acquisition regulations to clarify that, even if patent holders retain limited manufacturing rights or co-rights, transfers of patent rights within the pharmaceutical industry constitute reportable asset acquisitions if all commercially significant rights are transferred (the "Rule"). Premerger Notification; Reporting and Waiting Period Requirements ("Notice of Final Rulemaking"), 78 Fed. Reg. 68,705, 68,706–07 (Nov. 15, 2013). Before the adoption of this Rule, the FTC had

considered a transfer of patent rights to be a reportable asset acquisition only if all rights to make, use, and sell the patent were passed to the acquiring person. The FTC's 2013 rulemaking action clarified that reportable asset requirements apply to transactions in the pharmaceutical industry in which the licensor transfers exclusive patent rights but retains limited manufacturing rights or co-rights to the patent. The FTC explained that the Rule focuses on the pharmaceutical industry because the agency had not found any other industry that relied on this type of patent transfer arrangement. The Commission made it clear, however, that if other industries adopted patent transfer practices of the sort found in the pharmaceutical industry, "such exclusive patent licenses remain potentially reportable." *Id.* at 68,709.

In 2013, Appellant, Pharmaceutical Research and Manufacturers of America ("PhRMA"), filed suit in District Court challenging the FTC's Rule. The District Court granted summary judgment for the FTC, *Pharm. Research & Mfrs. of Am. v. FTC*, 44 F. Supp. 3d 95 (D.D.C. 2014), and PhRMA now appeals. PhRMA's appeal to this court rests on several causes of action arising under Section 706 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. First, PhRMA contends that the Rule should be overturned under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), either because it is precluded by the plain meaning of the Act or because it is based on an impermissible interpretation of the Act. Second, PhRMA argues that the FTC's action in adopting the Rule was arbitrary and capricious and therefore the Rule should be vacated pursuant to the commands of *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Company* ("*State Farm*"), 463 U.S. 29 (1983), and its progeny. We find no merit in these claims.

It is noteworthy that PhRMA does not challenge the FTC's authority to regulate the pharmaceutical industry or the particular patent transfers at issue in the Rule. Indeed, PhRMA has made no argument in this appeal that the Rule would be inconsistent with the Act or violate the APA if it applied generally. As a result there is no claim before the court that the FTC erred in its determination that the patent transfers identified by the Rule are reportable asset acquisitions under the HSR Act. PhRMA merely challenges the form of the Rule in that it focuses on the pharmaceutical industry.

We affirm the judgment of the District Court because none of PhRMA's claims has merit. Nothing in the plain meaning, context, or legislative history of the Act unambiguously precludes the FTC from promulgating a rule, the substance of which is clearly within its delegated authority, merely because the rule focuses on a specific industry that is the sole source of the problem being addressed. Congress did not address the "precise question at issue" here, but it did "explicitly [leave] a gap [in the statute] for the agency to fill." *Chevron*, 467 U.S. at 843. Therefore, the only "question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* We answer that question in the affirmative. The Rule is obviously consistent with the purpose of the Act, which is to improve the enforcement capabilities of the FTC and the Department of Justice by facilitating their review of large acquisitions before they are consummated. And the FTC's explanation for its promulgation of the Rule is perfectly reasonable and supported by the record.

We also reject PhRMA's arguments that the FTC's adoption of the Rule was arbitrary and capricious. The

Commission reasonably explained and supported its position during the rulemaking process, and PhRMA was in no way prejudiced by any alleged lack of opportunity to comment on the proposed rule.

I. BACKGROUND

A. *The HSR Act*

As noted above, the Act fosters Government identification of mergers and acquisitions likely to violate federal antitrust laws before the proposed transactions are consummated. *Pharm. Research*, 44 F. Supp. 3d at 100 (citing S. REP. NO. 94-803, at 1 (1976); H.R. REP. NO. 94-1373, at 5 (1976); *Mattox v. FTC*, 752 F.2d 116, 119–20 (5th Cir. 1985)). The statute states in part that,

> [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 (or in the case of a tender offer, the acquiring person) 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 . . . .

15 U.S.C. § 18a(a). A merger or acquisition triggers the Act's requirements if one of the parties "is engaged in commerce or in any activity affecting commerce" and one of the threshold financial values defined in the Act is met. *Id.* § 18a(a)(1), (2). The HSR Act does not define "asset[]," "acquire," or "person." It does, however, list a number of exempt transactions, *id.* § 18a(c), none of which are relevant here.

The Commission's delegated authority under the Act is extensive. The Act provides in relevant part that:

> The Federal Trade Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of Title 5, consistent with the purposes of this section—
>
> > (1) 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; and
> >
> > (2) may—
> >
> > > (A) define the terms used in this section;
> > >
> > > (B) exempt, from the requirements of this section, classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws; and
> > >
> > > (C) prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section.

Id. § 18a(d).

The Act also provides enforcement mechanisms for the FTC and the Assistant Attorney General. The FTC or the Assistant Attorney General may apply to the United States

district courts to "order compliance" or "grant such other equitable relief as the court in its discretion determines necessary or appropriate." *Id.* § 18a(g)(2)(A), (C). It also provides for civil penalties of up to $10,000 for each day against "[a]ny person, or any officer, director, or partner thereof, who fails to comply with any provision of this section." *Id.* § 18a(g)(1).

B. *The Rule*

The FTC's disputed Rule is premised on certain undisputed assumptions: the Act covers asset acquisitions; a patent is an asset; therefore, the acquisition of a patent is potentially reportable under the Act. *See* Premerger Notification; Reporting and Waiting Period Requirements ("Notice of Proposed Rulemaking"), 77 Fed. Reg. 50,057, 50,058 (Aug. 20, 2012). Prior to the adoption of the Rule, the FTC had determined that a transfer of rights to a patent was a reportable asset acquisition only if all of the rights to "make, use, and sell" a patent or part of a patent were exclusively transferred to the licensee. This was because "[a]n exclusive license is substantively the same as buying the patent or part of the patent outright, and carries the same potential anticompetitive effects." Notice of Final Rulemaking, 78 Fed. Reg. at 68,706.

Transactions in the pharmaceutical industry caused the FTC to reconsider its position regarding when transfers of patents are reportable asset acquisitions. In the rulemaking leading to the new Rule, the FTC explained:

> 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 the "make, use and sell" approach is no

> longer adequate in evaluating the reportability of exclusive licenses in the pharmaceutical industry for HSR purposes. A licensor will often, for example, retain the right to manufacture under the patent, but under the agreement the licensor can only manufacture for the licensee. In such a case, under the [FTC's Premerger Notification Office's ("PNO's")] "make, use, and sell" approach, the retention of the right to manufacture would render the transaction non-reportable even though the licensor would not be manufacturing for its own commercial use, but exclusively for the licensee. . . . This rule addresses when an exclusive patent license to a pharmaceutical patent or part of a patent constitutes an asset transfer under the HSR Act.
>
> 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. § 801.2(g)(3) of the rule provides that the transfer of exclusive rights to a patent or a part of a patent in the pharmaceutical industry is a reportable asset transfer if it allows only the recipient to commercially use the patent as a whole, or a part of the patent in a particular therapeutic area or specific indication within a therapeutic area. The rule codifies 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. The rule also provides that such 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.

Id. at 68,706–07 (footnote omitted).

The Rule includes definitions of "all commercially significant rights," "limited manufacturing rights," and "co-rights" when such rights are transferred and/or retained in the context of an exclusive transfer of rights to a pharmaceutical patent. *Id.* at 68,712–13. The Rule also provides that a "transfer of patent rights [to a pharmaceutical patent] constitutes an asset acquisition" if "all commercially significant rights" are transferred even if the licensor retains "limited manufacturing rights" or "co-rights." *Id.* at 68,713. The Rule was adopted as proposed on November 15, 2013, and became effective on December 16, 2013. *Id.* at 68,705–06.

The FTC's determination that an exclusive transfer of rights to a patent or part of a patent, in a situation in which the licensor retains "limited manufacturing rights" or "co-rights," is a reportable asset acquisition under the HSR Act is not in dispute in this case. PhRMA merely challenges the Rule's focus on the pharmaceutical industry.

C. *The FTC's Rulemaking*

During the rulemaking proceedings, PhRMA opposed the FTC's Rule on the grounds that it "burdens . . . only a single industry to the exclusion of all others" and that it constitutes "discriminatory treatment of the pharmaceutical industry" because the Rule applies only to that industry. Comments of PhRMA on Notice of Proposed Rulemaking, *reprinted in* Joint Appendix ("JA") 12–13. In support of its position, PhRMA submitted the declaration of an economic consultant, Dr. Varner, which purported to refute the FTC's observation that the types of transactions at issue were limited to the pharmaceutical industry. Varner Declaration, *reprinted in* JA 28–47. Representatives of PhRMA also met with FTC

Commissioners to discuss the Rule. It does not appear that, in its written comments and in its meetings with the Commission, PhRMA ever disputed the FTC's determination that the exclusive license agreements that were covered by the Rule were asset acquisitions that were properly subject to the Act's reporting requirements.

The FTC responded in detail to each of PhRMA's objections. *See* 78 Fed. Reg. at 68,707–12; *see also Pharm. Research*, 44 F. Supp. 3d at 106–10 (describing in detail PhRMA's objections and the FTC's response to each of them). As relevant to the issues raised on appeal, the FTC elaborated on the reason why the Rule focused on the pharmaceutical industry:

> For the five-year period ending December 31, 2012, 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. . . . In addition, requests for guidance on the treatment of exclusive patent licensing transactions have generally been limited to the pharmaceutical industry. Accordingly, the Commission has not found a need for a rule applicable to other industries. Moreover, the Commission's experience with such transactions in the pharmaceutical industry allows 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 therapeutic area.

Notice of Final Rulemaking, 78 Fed. Reg. at 68,708. The FTC stated further that, "[b]ased on HSR filings and requests for advice on the reportability of transactions, the PNO 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." *Id.* The Commission made it clear, however, that to the extent that comparable agreements might exist in other industries, the "exclusive patent licenses [in those other industries would] remain potentially reportable." *Id.* at 68,709.

The FTC explained that the licensing agreements cited in the Varner Declaration were not the same as the transactions the FTC had seen in the pharmaceutical industry. On this point the agency said:

> The agreements cited by Comment 2 are not the kind of agreements that are the subject of the rule. They are exclusive distribution agreements, which convey to the licensee only the exclusive right to distribute the patented product. In exclusive distribution agreements, the licensor retains not just the right to manufacture but all commercially significant rights to the patent, such that no reportable asset acquisition takes place.

Id.

The FTC additionally addressed PhRMA's comment that the agency lacked statutory authority to promulgate the Rule. The FTC said that its action was justified by its authority to define terms and to prescribe rules "as may be necessary and appropriate to carry out the purposes of this section." *Id.* at 68,709. The FTC rejected PhRMA's "all-or-nothing approach," explaining that it had the discretion to "proceed incrementally" in promulgating rules that were designed to address known problems. *Id.* at 68,709–10 & n.30 (citing cases).

PhRMA filed suit in the District Court, arguing "that the limited application of the Rule to the pharmaceutical industry exceeds the FTC's grant of statutory authority under the HSR Act, in violation of 5 U.S.C. § 706(2)(C), and was arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A)." *Pharm. Research*, 44 F. Supp. 3d at 114 (citations omitted). The parties filed cross-motions for summary judgment. In a very thorough opinion, the District Court found no merit in PhRMA's claims and granted summary judgment in favor of the FTC.

II. ANALYSIS

A. *Standard of Review*

On appeal from a grant of summary judgment, our review is *de novo*. *See Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1118 (D.C. Cir. 2010). "In a case like the instant one, in which the District Court reviewed an agency action under the APA, we review the administrative action directly, according no particular deference to the judgment of the District Court." *Holland v. Nat'l Mining Ass'n*, 309 F.3d 808, 814 (D.C. Cir. 2002).

PhRMA claims that the FTC action violates Section 706(2)(C), which states that a court may "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). In addressing this claim, we apply the familiar *Chevron* framework. The first step is to determine whether Congress has directly addressed the "precise question at issue." *Chevron*, 467 U.S. at 842. If not, we then proceed to *Chevron* Step Two. Under this step, "[i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of

authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843–44.

As is often the case, our review here of the FTC's interpretation of its authority under *Chevron* Step Two overlaps with our arbitrary and capricious review under 5 U.S.C. § 706(2)(A). *See* EDWARDS, ELLIOTT, & LEVY, FEDERAL STANDARDS OF REVIEW 217–18 (2d ed. 2013) (discussing the interplay of *Chevron* Step Two and arbitrary and capricious review). Section 706(2)(A) provides that a court may "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." In this case, in light of the claims raised by PhRMA, arbitrary and capricious review requires us to consider whether the FTC action is supported by reasoned decisionmaking, *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998); whether the agency "relied on factors which Congress [did] not intend[] it to consider," *State Farm*, 463 U.S. at 43; and whether the Rule was promulgated in "observance of procedure required by law," 5 U.S.C. § 706(2)(D).

B. *The FTC's Rule Does Not Violate the Plain Terms of the Act (***Chevron** *Step One)*

It is axiomatic that, "[b]efore a court may invoke *Chevron* Step One, it must find that 'the intent of Congress is clear,' meaning that the statutory provision at issue is 'unambiguous[]' with respect to the question presented." EDWARDS, ELLIOTT, & LEVY, *supra*, at 174 (quoting *Chevron*, 467 U.S. at 842–43) (second alteration in original). We look to the "text, structure, purpose, and history" of the statute for

evidence of congressional intent on the precise question at issue. *See Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004). Here, the "precise question" before the court is whether the Act unambiguously precludes the FTC from promulgating a rule, the substance of which is clearly within its delegated authority, merely because the rule focuses on a specific industry that is the sole source of the problem being addressed. Given the relevant terms of the statute, the answer is no.

The Act provides that "[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 satisfy the prescribed waiting period]." 15 U.S.C. § 18a(a). "Person" is not defined. However,

- Subsection (d)(2)(A) authorizes the FTC to "define the terms used in this section";

- Subsection (d)(1) says 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"; and

- Subsection (d)(2)(C) authorizes the FTC to "prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section."

Id. § 18a(d). Taken together, these statutory provisions give the FTC, with the concurrence of the Assistant Attorney General, great discretion to define statutory terms and to promulgate rules to facilitate Government identification of mergers and acquisitions likely to violate federal antitrust laws before the mergers and acquisitions are consummated. PhRMA has not identified any statutory language that unambiguously limits the FTC's great discretion in any way relevant to this case.

It is true that Section 18a(c) lists certain "classes of transactions" that are exempt from the filing requirements of the Act, but the exemptions do not, as PhRMA claims, purport to limit or otherwise define "person" in the phrase "no person shall acquire" in Section 18a(a). Rather, the reference to "no person shall acquire" reasonably can be construed to refer to persons who are not exempt and who are otherwise subject to the regulations promulgated by the FTC to enforce the terms of the Act. The Commission was not obliged to "exempt" any industries when it adopted the Rule. Indeed, the record indicates that the FTC did not mean to exempt other industries from the Rule because it recognized that the problem uncovered in the pharmaceutical industry might one day appear in other industries and remain potentially reportable.

This view of the statute is reinforced by the provisions of Subsection (d), which addresses "Commission rules." 15 U.S.C. § 18a(d). The statute makes it clear that the Commission "*may*" "exempt . . . classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws." *Id.* § 18a(d)(2)(B) (emphasis added). However, as noted above, the statute also makes it clear that the Commission "*may*" "prescribe *such other rules* as may be necessary and appropriate to carry out the purposes

of this section." *Id.* § 18a(d)(2)(C) (emphasis added). In other words, the Act does not compel the FTC to cabin regulated "persons" solely by resorting to exemptions from generally applicable rules.

Given this reasonable view of the Act, it is fairly plain that the statute did not unambiguously prohibit the FTC from focusing on the pharmaceutical industry in its 2013 rulemaking action. The Rule at issue was adopted to address a problem that was specific only to the pharmaceutical industry. And the FTC acted within the compass of the statutory authority given to the agency pursuant to Section 18a(d)(2)(C) when it adopted a rule focused on that group.

Furthermore, the Rule is perfectly consistent with the purposes of the Act. The HSR Act was enacted to assist the FTC in enforcing other provisions of the Clayton Act, and to give the FTC and the Department of Justice a tool to identify problematic mergers and acquisitions before they were consummated. S. REP. NO. 94-803, at 1, 7 (stating that the purpose of the Act "is to support and invigorate effective and expeditious enforcement of antitrust laws, to improve and modernize antitrust investigation and enforcement mechanisms," and "to facilitate [the antitrust authorities in] enjoining illegal mergers before they are consummated."); H.R. REP. NO. 94-1373, at 8–10 (explaining the difficulties for the government in challenging anti-competitive mergers after they have been completed and stating that the advance notification requirements will both improve enforcement efficacy and save resources wasted in post-merger enforcement proceedings). Given these purposes, it would have made no sense for Congress to restrict the FTC from focusing on review of particular types of transactions that the agency determines occur only in one industry.

PhRMA advances an entirely unconvincing argument that the FTC's action should be vacated because the agency acted outside the bounds of its delegated authority when it promulgated the Rule. The argument is specious because it wrongly assumes that Congress intended to compel the FTC to issue only rules of general applicability across industries except when exempting certain industries from coverage. As shown above, this is not what the statute says. The Act is at worst ambiguous on this point, but the provisions of 15 U.S.C. § 18a certainly do not unambiguously limit the authority of the FTC in the way that PhRMA contends. And, as the Supreme Court has made clear, a court must defer under *Chevron* to an agency's reasonable interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority. *City of Arlington v. FCC*, 133 S. Ct. 1863 (2013). We do so here.

In another vain effort to support its argument that the statute precludes the Rule, PhRMA asserts that the Rule "imposes notification requirements on persons in the pharmaceutical industry who propose certain transactions but not on persons in other industries proposing identical transactions." Br. for Appellant 19. This assertion finds no support in the record. The Rule focuses on the pharmaceutical industry because that was the only industry in which the FTC had seen such arrangements. Moreover, as noted above, the Commission has repeatedly explained that if such arrangements arise in other industries, they too will be potentially reportable under the Act. Notice of Final Rulemaking, 78 Fed. Reg. at 68,706, 68,709.

PhRMA also argues that the statute viewed in context supports its view that the Rule violates the plain terms of the Act. According to PhRMA, "the HSR Act is a component of a far larger, and quite complex, antitrust statutory scheme,

which includes many industry-specific statutes." Br. for Appellant 24. "Congress was thus aware of extant industry-specific antitrust laws when it drafted the HSR Act and intentionally imposed a *general* notification requirement." *Id.* at 25. We disagree. As explained above, the provisions of 15 U.S.C. § 18a simply do not support this construction of the Act. To prevail on its *Chevron* Step One argument, PhRMA has to do better than concoct an interpretation purportedly based on the statute's context. PhRMA "must show that the statute *unambiguously* forecloses the [agency's] interpretation." *Vill. of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 661 (D.C. Cir. 2011). PhRMA's "context" argument fails to do this.

PhRMA additionally contends that the legislative history of the Act demonstrates Congress's intent to restrict the FTC's authority to impose reporting requirements upon specific industries to the exclusion of others. It attempts to support this claim by arguing that a Senate bill that was before Congress, which did not pass, would have given the FTC "*carte blanche* power to impose or withhold notification requirements." Br. for Appellant 30 (citing S. 1284, 94th Cong. § (b)(3) (1975)). According to PhRMA, the law that was enacted is less sweeping in its terms than the Senate bill that did not pass, and "[t]his history demonstrates that Congress specifically contemplated – and declined – giving FTC the authority that it now illicitly claims as its own." *Id.* at 31. The District Court thoroughly and convincingly debunked PhRMA's legislative history argument, finding that the legislative history shows only Congress's concern that small businesses and mergers not be burdened with the notification requirements. *Pharm. Research*, 44 F. Supp. 3d at 119–22; *see also* Earl W. Kintner et al., *The Hart-Scott-Rodino Antitrust Improvements Act of 1976: An Analysis*, 46 GEO. WASH. L. REV. 1, 13 n.72 (1977).

The most telling response to PhRMA's legislative history argument is that the enacted provisions of 15 U.S.C. § 18a, read together, did not preclude the FTC from adopting the Rule. By expressly granting the FTC the authority to "define the terms used in this section" and 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)(A), (C), Congress "explicitly left . . . gap[s] for the agency to fill." *Chevron*, 467 U.S. at 843. PhRMA's claim that the Act unambiguously bars the FTC from promulgating a rule, which in substance is within its delegated authority, if the rule focuses on a specific industry that is the sole source of the problem being addressed is fanciful. We therefore reject PhRMA's invocation of *Chevron* Step One.

C. *This Court Owes Deference to the FTC Because the Contested Rule Embodies a Permissible Construction of the Act (***Chevron** *Step Two)*

If, as we have found in this case, "the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. And if, as we have found, "Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843–44. Thus, at *Chevron* Step Two, our focus is on "whether the [agency] has reasonably explained how the permissible interpretation it chose is rationally related to the goals of the statute." *Vill. of Barrington*, 636 F.3d at 665 (internal quotation marks omitted).

There is no doubt that the Commission's action was taken pursuant to express delegations of authority. The Act grants the FTC the authority to act by rulemaking, 15 U.S.C. § 18a(d), to "define the terms used in this section," and to "prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section," *id.* § 18a(d)(2)(A), (C). Given the terms of the Act, and for the reasons enunciated in part II.B and articulated below, we have little trouble in concluding that the Rule is not "manifestly contrary to the statute." *Chevron*, 467 U.S. at 844.

There is also no doubt that the Commission clearly and reasonably explained why it adopted the Rule. The FTC importantly noted that it was "not expanding the HSR [Act's] 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." Notice of Final Rulemaking, 78 Fed. Reg. at 68,709. The FTC determined that the Rule reflected a necessary and important clarification of its regulatory policy because, "due to the evolution of pharmaceutical patent licenses, the 'make, use, and sell' approach [was] no longer adequate to evaluate the HSR reportability of exclusive patent licenses in the pharmaceutical industry." *Id.* at 68,707. Such exclusive patent licenses, the FTC explained, are reportable asset acquisitions under the Act "even if the licensor retains the limited right to manufacture under the patent or part of a patent for the licensee." *Id.*

The FTC further explained that, in its experience, these types of arrangements had only occurred in the pharmaceutical industry. Specifically, in the five years prior to the rulemaking,

> the [FTC's Premerger Notification Office] 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. . . . In addition, requests for guidance on the treatment of exclusive patent licensing transactions have generally been limited to the pharmaceutical industry.

Id. at 68,708.

Finally, the Commission explained that the agency's "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 therapeutic area." *Id.*

The FTC's interpretation of the Act reflected in the Rule is obviously "rationally related to the goals of" the statute. *See Vill. of Barrington*, 636 F.3d at 665 (internal quotation marks omitted). And the Commission's explanation for focusing on the pharmaceutical industry is perfectly reasonable. *See Animal Legal Def. Fund v. Glickman*, 204 F.3d 229, 235 (D.C. Cir. 2000) ("[W]e accord agencies broad deference in choosing the level of generality at which to articulate rules."). It is not the role of this court to second-guess the agency on these matters.

PhRMA contends that the FTC's interpretation of its authority under the Act is not entitled to deference under *Chevron* Step Two because "[i]n thirty-seven years of administering the HSR Act, [the] FTC not only never claimed authority to impose the notification requirements in an

industry-targeted manner, but rejected that heretofore undiscovered carte blanche grant of authority from § 18a." Br. for Appellant 37 (internal quotation marks omitted). This argument cannot carry the day. PhRMA quotes language from a 1978 FTC notice of final rules implementing the pre-merger notification requirements of the HSR Act, in which the FTC declined to exempt joint ventures in specific industries from the Act's reporting requirements. *Id.* at 37–38 (quoting Premerger Notification; Reporting and Waiting Period Requirements, 43 Fed. Reg. 33,450, 33,496 (July 31, 1978)). However, the FTC's reasoning in this notice regarding its exemption authority says nothing about the FTC's interpretation of its separate authority to *define* when an asset acquisition is reportable under the Act; thus, we are hardly persuaded by PhRMA's argument that the Rule represents a departure from past practice. The record does not indicate that the FTC has ever previously indicated that it lacked the authority to act as it did when it promulgated the Rule.

Furthermore, even if the FTC had viewed its authority under the Act differently in the past and then expressed an intention to embrace a different construction of the Act when it adopted the Rule, the prior interpretation of the Act would not foreclose it from changing its position. *Rust v. Sullivan*, 500 U.S. 173, 186–87 (1991) (the Supreme Court "has rejected the argument that an agency's interpretation 'is not entitled to deference because it represents a sharp break with prior interpretations' of the statute in question"). That is not the situation in this case, however, because the position that PhRMA now attempts to attribute to the FTC is not one that the agency has ever expressed. Thus, PhRMA's argument rests on nothing more than the faulty suggestion that, although this is the first time that the FTC has taken a position on the matter in dispute, it was precluded from adopting the Rule by a "past practice" emanating from prior agency inaction. This

is an absurd proposition and it certainly finds no support in the law.

D. *The Commission's Action Also Survives Review Under the Arbitrary and Capricious Standard*

Section 706(2)(A) of the APA provides that 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). "[T]he touchstone of arbitrary and capricious review is reasoned decisionmaking." EDWARDS, ELLIOTT, & LEVY, *supra*, at 203.

> Normally, an agency rule would be arbitrary and capricious if the agency 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.

State Farm, 463 U.S. at 43.

The analysis of disputed agency action under *Chevron* Step Two and arbitrary and capricious review is often "the same, because under *Chevron* step two, [the court asks] whether an agency interpretation is 'arbitrary or capricious in substance.'" *Judulang v. Holder*, 132 S. Ct. 476, 483 n.7 (2011) (citing *Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 53 (2011) (quoting *Household Credit Servs., Inc. v. Pfennig*, 541 U.S. 232, 242 (2004))). Therefore, the analysis in part II.C, *supra*, rejecting PhRMA's

Chevron Step Two arguments applies here as well in our rejection of PhRMA's claims resting on Section 706(2)(A).

PhRMA raises a number of points in support of its claim that the FTC's adoption of the Rule was arbitrary and capricious. First, PhRMA argues that there is no rational basis for the Rule because the FTC only invoked its "experience" as justification for "target[ing]" transactions in the pharmaceutical industry, without describing or explaining what that experience was. Br. for Appellant 39–40. Along these same lines, PhRMA also contends that "the Rule is arbitrary and capricious because it is based on considerations [*i.e.*, the "prevalence" of the transactions in the pharmaceutical industry] which Congress has not intended [the FTC] to consider." *Id.* at 47 (internal quotation marks omitted). These claims are unconvincing. The FTC's basis for the Rule was its *unchallenged* determination that patent transfers covered by the Rule are asset acquisitions under the Act. *See* Notice of Final Rulemaking, 78 Fed. Reg. at 67,706–07. As explained earlier in this opinion, the FTC adequately explained why the Rule focused on the pharmaceutical industry. We need not cover this ground again. The FTC's cumulative experience with filings and fielding informal requests for guidance was a valid basis for its decision to promulgate a rule focused on the pharmaceutical industry. *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 known to the agency through its cumulative experience and consequent expertise." (citations omitted)).

PhRMA additionally asserts that the "FTC offered no reasoned basis for departing from its own longstanding views." Br. for Appellant 41. As discussed above, we reject

PhRMA's claim that the Rule constitutes an impermissible departure from past agency practice. Moreover, *West Deptford Energy, LLC v. FERC*, which PhRMA relies on, is inapposite. *See* 766 F.3d 10, 20–21 (D.C. Cir. 2014) (FERC's sudden departure from "unbroken Commission practice," without explanation and relying on patently unsupportive agency precedent, was unjustified). In contrast to that case, here, the FTC explained its reasons for crafting the Rule with an industry-specific focus.

PhRMA makes two final arguments attacking the FTC's rulemaking process. First, PhRMA argues that "[b]y withholding . . . source information, [the] FTC impeded PhRMA's ability to challenge the agency's basis for the Final Rule and the courts' ability to meaningfully review it." Br. for Appellant 48. Specifically, PhRMA objects that the FTC did not produce the 66 filings received by the PNO that the FTC described as involving exclusive patent licensing arrangements in the pharmaceutical industry, and that the FTC's public database of informal requests is unhelpful because it is incomplete and "heavily redacted." *Id.* at 48–53. Second, it argues that the FTC did not respond to the Varner Declaration. *Id.* at 55. Both of these arguments fail.

The FTC's response to PhRMA's objection that it did not have access to the 66 filings is telling:

> PhRMA also suggests in passing that the Commission should have divulged the 66 individual HSR filings that it cited for the observation that *pharmaceutical* patents accounted for every single instance over the preceding five years in which parties filed HSR notification involving exclusive patent licenses. The HSR Act, however, makes such filings confidential. It provides that "[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 in circumstances not present here. 15 U.S.C. § 18a(h); *see* JA 349–51 [citing the District Court opinion, *Pharm. Research*, 44 F. Supp. 3d at 131–32]. The FTC thus had no lawful basis for revealing these reports to PhRMA, and PhRMA does not even contend otherwise on appeal.
>
> In any event, keeping these HSR filings confidential did nothing to prejudice PhRMA, and that lack of prejudice is itself fatal to PhRMA's APA challenge. HSR filings do not represent the type of "technical studies and data" that aggrieved parties might wish to contest and that an agency might thus be required to make available for close scrutiny. And the Commission did not rely on these HSR filings to make a technical judgment or establish a technical standard. It used them only as a general source of background experience to inform its judgment that, in fact, exclusive patent licenses arise overwhelmingly in the pharmaceutical industry. The filings were relevant only because they involved exclusive licenses in the pharmaceutical industry, not because of their particular content.

Br. for FTC 42–43 (citations omitted). PhRMA's briefs to the court do not even address the disclosure exemption in 15 U.S.C. § 18a(h), and its Reply Brief offers no effective rebuttal to the FTC's additional points concerning the 66 filings.

Furthermore, the agency's database of informal guidance is available online and searchable. Although the names and contact information are redacted, the context of a guidance

document is often quite clear from reading the documents. *See* FEDERAL TRADE COMMISSION, PREMERGER NOTIFICATION PROGRAM: INFORMAL INTERPRETATIONS, *available at* www.ftc.gov. "Not only is the database publicly available, but PhRMA itself *actually used it* in formulating its comments on the Rule. JA 22." Br. for FTC 41 (citing PhRMA's comments on proposed Rule). Thus, it is clear that PhRMA had access to the guidance requests and its claims to the contrary are spurious.

On the record here, there is nothing to indicate that PhRMA was denied information to which it was entitled to participate in the rulemaking proceeding. Indeed, the record strongly reflects that PhRMA had ample opportunity to comment during the rulemaking proceeding, and its views were fully considered and addressed by the FTC. PhRMA submitted an expert's declaration with its comments. The comments and declaration purported to show that the kinds of exclusive rights transfers covered by the Rule also occurred in other industries. Comments of PhRMA on Notice of Proposed Rulemaking, JA 12–58. As noted above, the Commission reasonably rejected the expert's claims as being off point. Notice of Final Rulemaking, 78 Fed. Reg. at 68,708–09. PhRMA's representatives also met personally with FTC Commissioners four times to discuss their concerns about the Rule. *See* JA 65–70. Yet, PhRMA produced nothing to rebut the FTC's findings that, in its experience, the types of transactions covered by the Rule had arisen only in the pharmaceutical industry.

The cases cited by PhRMA involving agencies' failures to reasonably respond to public comment are readily distinguishable. *Business Roundtable v. SEC* is inapposite because the statute in that case expressly required the agency to consider "the economic effects of a new rule," which the

agency failed to do. *See* 647 F.3d 1144, 1148–49 (D.C. Cir. 2011). In both *Louisiana Federal Land Bank Association v. Farm Credit Administration*, 336 F.3d 1075, 1080 (D.C. Cir. 2003), and *PSEG Energy Resources & Trade LLC v. FERC*, 665 F.3d 203, 210 (D.C. Cir. 2011), the agency acknowledged the commenters' objections but provided no other response to them. The FTC did much more in this case in receiving and responding to PhRMA's objections.

Finally, some of PhRMA's arguments to this court might be read to suggest that the FTC was less than forthcoming during the rulemaking proceeding. As we have explained, the record belies any such contention. "Because a presumption of procedural regularity and substantive rationality attaches to final agency action, aggrieved parties bear the burden of demonstrating to a reviewing court that challenged agency action merits reversal." *Nat'l Small Shipments Traffic Conference, Inc. v. ICC*, 725 F.2d 1442, 1455 (D.C. Cir. 1984). PhRMA has offered no good reason to rebut the presumption of procedural regularity in the agency's handling of this case.

The FTC action is supported by reasoned decisionmaking; the agency did not rely on factors which Congress did not intend for it to consider; and the Rule was promulgated in observance of procedures required by law. In sum, there is nothing in the record to support PhRMA's claims that the FTC violated 5 U.S.C. § 706(2)(A) or (D) when it promulgated the Rule.

III. CONCLUSION

For the reasons set forth above, we affirm the judgment of the District Court.

So ordered.