**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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Argued March 24, 2015 Decided June 9, 2015

No. 14-5182

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
APPELLANT

v.

FEDERAL TRADE COMMISSION,
APPELLEE

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

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*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 was passed [t]o improve and facilitate the

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 or ), 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 . Premerger Notification; Reporting and Waiting Period Requirements , 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 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

It is noteworthy that PhRMA does not challenge 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 s 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 here, a gap [in the statute] for the agency to fill. *Chevron*, 467 U.S. at 843. Therefore,

*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 explanation for its promulgation of the Rule is perfectly reasonable and supported by the record.

We also 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).
requirements if one of the parties is engaged in commerce or

financial values defined in the Act is met. *Id.* § 18a(a)(1), (2).
The HSR []
It does, however, list a number of exempt transactions, *id.* § 18a(c), none of which are relevant here.

extensive. The Act provides in relevant part that:

equitable relief as the court in its discretion determines *Id.* § 18a(g)(2)(A), (C). It also provides for civil penalties of up to $10,000 for each day son, 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 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 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 e,

license is substantively the same as buying the patent or part of the patent outright, and carries the same potential anticompetit
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
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> license, such

longer adequate in evaluating the repo(quaating)8( )-5ab8( )ility ofxa

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context of an exclusive transfer of rights to a pharmaceutical patent. *Id.* at 68,712 13. The Rule also provides that a

- *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.

rights to a patent or part of a patent, in a situation in which the li -
is a reportable asset acquisition under the HSR Act is not in

focus on the pharmaceutical industry.

**C.** ***Rulemaking***

During the rulemaking proceedings, PhRMA opposed the Rule on the grounds that it . . . only a single industry to the exclusion of all

because the Rule applies only to that industry. Comments of PhRMA on Notice of Proposed Rulemaking, *reprinted in* 13. In support of its position, PhRMA submitted the declaration of an economic consultantu28P6171}TJETBTFim3>26001

that exclusive patent licensing agreements that transfer all of the rights to commercially use a patent or part of a patent alm *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] *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 a
the agency lacked statutory authority to promulgate the Rule. The FTC said that its action was justified by its authority to

*Id.* at 68,709. The FTC -or-nothing

PhRMA filed suit in the District Court, arguing that the limited application of the Rule to the pharmaceutical industry

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) *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 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*
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 Cour *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
set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, 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

*Chevron*, 467 U.S. at 842. If not, we then proceed to *Chevron*

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

*Id.* at 843–44.

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

of this section. *Id.* § 18a(d)(2)(C) (emphasis added). In other words, the Act does not compel the FTC to cabin regulated ing 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)

which includes many industry- . for
hus aware of extant industry-specific antitrust laws when it drafted the HSR Act and intentionally imposed a *general* *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 must show that the statute *unambiguously* *Vill. of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 661 (D.C. Cir. 2011). argument fails to do this.

PhRMA additionally contends that the legislative history

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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

The most telling response to 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 grantin

rules as may be necessary and appropriate to carry out the

. . . gap[s] for

*Chevron*, 467 U.S. at 843. 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 *Chevron* Step One.

**C.**

There is no doubt that 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 ,

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 tly 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 expanding the HSR [ ] requirements to parties or transactions not covered by the clarifying the types of transactions that constitute asset transfers for which the Act requires prior 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,

adequate to evaluate the HSR reportability of exclusive patent

> the 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 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 *Id.*

The FT interpretation of the Act reflected in the Rule is obviously rationally related to *See Vill. of Barrington*, 636 F.3d at 665 (internal quotation marks omitted). And for focusing on the pharmaceutical industry is perfectly reasonable. *See Animal Legal Def. Fund v. Glickman*, 204 F.3d 229, 235

choosing the level of generality at which to articulate .

industry-targeted manner, but rejected that heretofore

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

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

### D. *The Survives Review Under the Arbitrary and Capricious Standard*

Section 706(2)(A) of the APA provides that a reviewing

findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in

PhRMA
departure from past agency practice. Moreover, *West Deptford Energy, LLC v. FERC*

> documentary material filed . . . pursuant to this section shall be exempt from disclosure . . . and no such information or documentary material may be made
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> umstances 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 PhRMA4(t )0rl364(nd )-339(p)-3(hRM)-3(A4t )0rl3dos not Pvean phontendh

document is often quite clear from reading the documents. *See* FEDERAL TRADE COMMISSION, PREMERGER NOTIFICATION PROGRAM: INFORMAL INTERPRETATIONS, *available at* www.ftc.gov.

PhRMA itself *actually used it* in formulating its comments on

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on proposed Rule). Thus, it is clear that

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

them. The FTC did much more in this case in receiving and

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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.

procedural regularity and substantive rationality attaches to