United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
March 21, 2024
Lyle W. Cayce
Clerk

No. 23-60620

INHANCE TECHNOLOGIES, L.L.C.,

Petitioner,

versus

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; MICHAEL S. REGAN, *Administrator, United States Environmental Protection Agency*,

Respondents.

Appeal from the Environmental Protection Agency
Agency Nos. SN-23-0002, SN-23-0003,
SN-23-0004, SN-23-0005, SN-23-0006,
SN-23-0008, SN-23-0009, SN-23-0010,
SN-23-0011

Before RICHMAN, *Chief Judge,* and GRAVES and WILSON, *Circuit Judges*.*

CORY T. WILSON, *Circuit Judge*:

In March 2022, the EPA charged for the first time that Petitioner Inhance Technologies, L.L.C.'s (Inhance) fluorination process was subject

* JUDGE GRAVES concurs in the judgment only.

to a Significant New Use Rule regarding long-chain perfluoroalkyls (PFAS). The EPA issued two orders under Section 5 of the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601–2697, in December 2023, prohibiting Inhance from manufacturing or processing PFAS during its fluorination process. Because the EPA exceeded its statutory authority in doing so, we vacate the orders.

I.

Inhance is a Texas company that has been fluorinating plastic containers using the same process since 1983. The fluorination process creates a barrier that keeps dangerous substances from leaching out of their containers, and keeps outside substances from permeating in. The EPA began investigating Inhance after the presence of PFAS was detected in an insecticide that was stored in a container fluorinated by Inhance. PFAS are "widely used, long lasting chemicals, . . . which break down very slowly over time." EPA, *PFAS Explained*, www.epa.gov/pfas/pfas-explained (last visited Mar. 15, 2024). "There are thousands of PFAS chemicals, and they are found in many different consumer, commercial, and industrial products." *Id.* In recent years, research has shown that exposure to certain levels of PFAS may lead to cancer, cardiovascular disease, and developmental delays in children, among other things. EPA, *Our Current Understanding of the Human Health and Environmental Risks of PFAS*, www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas (last visited Mar. 15, 2024).

After confirming that Inhance's fluorination process resulted in the creation of PFAS, the EPA issued Inhance a Notice of Violation in March 2022. The Notice of Violation offered Inhance two options: (1) change its fluorination process so it no longer manufactured PFAS, or (2) temporarily halt the fluorination of any products that resulted in the creation of PFAS.

Though Inhance did not change its process or stop fluorinating containers, it submitted two Significant New Use Notices (SNUNs) to the EPA in December 2022.[1] After considering those SNUNs, the EPA issued the two orders at issue here in December 2023. Both orders prohibited Inhance from manufacturing or processing PFAS through their fluorination process. Inhance asserts that if the orders are allowed to take effect, they will shut down Inhance's fluorination process, bankrupting the company.

Inhance immediately petitioned this court for expedited review. We granted Inhance's unopposed motion for a stay pending appeal and expedited briefing and argument.

II.

A.

Before considering the parties' arguments regarding the EPA orders, it is necessary to sketch the statutory and regulatory background underlying the case. Congress enacted TSCA in 1976 to protect "human beings and the environment" from chemical substances that "present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2601(a). There are two ways the EPA may regulate chemical substances under TSCA.

First, Section 5 allows the EPA to regulate the use of "new chemical substance[s]" and any "significant new use" of a chemical substance. *Id.* § 2604(a)(1)(A). The EPA determines what constitutes a significant new use after consideration of four factors:

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[1] The United States filed an enforcement action in the United States District Court for the Eastern District of Pennsylvania in December 2022 after Inhance refused to comply with the Notice of Violation. *See* Complaint, *United States v. Inhance Techs. LLC*, 5:22-cv-05055, 2022 WL 17903769 (E.D. Pa. Dec. 19, 2022). That action remains pending.

> (1) the projected volume of manufacturing and processing of a chemical substance; (2) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance; (3) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and (4) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Id. § 2604(a)(2). If the EPA labels the use of a chemical substance as a significant new use, then it proposes a rule regulating that substance, and affected entities are allowed the opportunity for notice and comment. At the end of the comment period, the EPA promulgates a final rule known as a Significant New Use Rule (SNUR).[2]

If a company wants to manufacture or process a new chemical substance or a chemical substance that has been deemed a significant new use, it must submit a SNUN "at least 90 days before such manufacture or processing." *Id.* § 2604(a)(1)(B). After review, the EPA must make one of three findings: (1) the chemical substance or significant new use presents an unreasonable risk of injury to health or the environment; (2) there is insufficient evidence to determine an evaluation of the health and environmental effects of the chemical substance or significant new use; or (3) the relevant chemical substance is not likely to present an unreasonable risk of injury to health or the environment. *Id.* § 2604(a)(1)(B)(ii), (a)(3). If the EPA finds that there is insufficient evidence to determine the effects of

[2] SNUR and SNUN are terms of art not used in the statute. But they are commonly used by the EPA to describe the rule-making process under Section 5. *See, e.g.*, EPA, *Filing a Significant New Use Notice (SNUN) under TSCA*, www.epa.gov./reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-significant-new-use-notice (last visited Mar. 7, 2024).

the substance or the substance presents an unreasonable risk of injury, then it must issue an order prohibiting or limiting the manufacture of the substance.[3] *Id.* § 2604(e), (f). These are known as Section 5(e) orders and Section 5(f) orders, respectively, and they are the types of orders at issue in this case.

Second, the EPA may regulate chemical substances under Section 6. *See* 15 U.S.C. § 2605. The mandate of Section 6 is broader than Section 5, in that Section 6 applies to all chemical substances, not just new chemical substances or significant new uses of a chemical substance. *See id.* § 2605(a). However, the rulemaking process under Section 6 is also more rigorous than Section 5: It requires the EPA to conduct a cost-benefit analysis, weighing the negative effects of the chemical substance against the benefits of the substance and the economic consequences of prohibiting or limiting the substance. *See id.* § 2605(c)(2)(A)–(C). No such analysis is required under Section 5.

B.

In response to growing concerns about PFAS, the EPA proposed a new SNUR in January 2015, "designating as a significant new use manufacturing . . . or processing of an identified subset of [PFAS] for any use that will not be ongoing after December 31, 2015, and all other [PFAS] for which there are currently no ongoing uses." 80 Fed. Reg. 2885 (Jan. 21, 2015). Under the SNUR section entitled "Does this action apply to me?" the EPA included a non-exhaustive list of industries that might be affected by the SNUR. *Id.* at 2886. Those industries included fiber, yarn, and thread

[3] Alternatively, if the EPA finds that the substance is not likely to present an unreasonable risk of injury to health or the environment, then the SNUN submitter "may commence manufacture of the chemical substance or manufacture or processing for a significant new use." 15 U.S.C. § 2604(a)(3)(C).

mills; carpet and rug mills; home furnishing merchant wholesalers; carpet and upholstery cleaning services; and chemical manufacturing and petroleum refineries. *Id.* Notably, the fluorination industry was missing from the list, as was any industry with the same North American Industry Classification Code[4] as the fluorination industry. *See id.* The proposed rule also made clear that the SNUR would apply only to "any use not ongoing as of the date on which this proposed rule is published." *Id.*

In July 2020, the EPA promulgated the final SNUR. 85 Fed. Reg. 45109 (July 27, 2020). Like the proposed rule, it included a list of industries that might be affected by the SNUR. *Id.* at 45110. That list included other industries in addition to those already stated in the proposed rule, but it still did not include the fluorination industry. *See id.* The SNUR went into effect without any challenges.

C.

The EPA issued Inhance a Notice of Violation of the SNUR in March 2022 after confirming the presence of PFAS in a pesticide that had been stored in containers fluorinated by Inhance. Though Inhance did not stop fluorinating containers, it attempted to engage with the EPA through the SNUN process. Despite submitting SNUNs for its products, Inhance maintained that its fluorination process was not covered by the SNUR and that Inhance's SNUNs were not "admission[s] of fact" or a concession that the SNUR was "legally applicable to the Company's fluorination."

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[4] "The North American Industry Classification System (NAICS) is the standard used by . . . agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy." EPA, *NAICS*, rcrapublic.epa.gov/rcrainfoweb/action/modules/br/naics/view (last visited Mar. 15, 2024).

In December 2023, the EPA determined that three PFAS manufactured by Inhance presented an unreasonable risk of injury to human health and the environment and six additional PFAS manufactured by Inhance may do so. It therefore issued a Section 5(f) order for the first three PFAS, requiring Inhance to stop manufacturing and processing those PFAS. And it issued a Section 5(e) order for the remaining PFAS, requiring Inhance to stop manufacturing or processing the PFAS, "at least until Inhance completes further testing to address information gaps identified during the review." Inhance timely petitioned this court for expedited review of the EPA's orders.

III.

Generally, the Administrative Procedure Act (APA) "appl[ies] to review of a rule or order" under TSCA. 15 U.S.C. § 2618(c)(1)(B).[5] Under the APA, a "reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations . . . [or] without observance of procedure required by law . . . ." 5 U.S.C. § 706.

Inhance argues that the EPA exceeded its statutory authority by issuing orders under Section 5 instead of Section 6 because Inhance's forty-

[5] The exception to APA review in the TSCA context is that TSCA has its own "more rigorous" substantial evidence standard. *See* 15 U.S.C. § 2618(c)(1)(B)(i)(II); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1213–14 (5th Cir. 1991). Because we do not reach the EPA's argument that its orders were supported by substantial evidence, that exception is not relevant to our decision today.

year-old fluorination process is not a "significant new use" under TSCA.[6] We agree.

"[A]gencies, as mere creatures of statute, must point to explicit Congressional authority justifying their decisions." *Clean Water Action v. EPA*, 936 F.3d 308, 313 n.10 (5th Cir. 2019). To determine an agency's statutory authority, we consult the statute's text. *See Sackett v. EPA*, 598 U.S. 651, 671–74 (2023). "The appropriate starting point when interpreting any statute is its plain meaning." *Sample v. Morrison*, 406 F.3d 310, 312 (5th Cir. 2005). "In ascertaining the plain meaning of the statute, [we] must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." *Id.* (quoting *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988)). "When statutory language is susceptible of multiple interpretations, a court may shun an interpretation that raises serious constitutional doubts and instead may adopt an alternative that avoids those problems." *Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018).

Section 5 allows the EPA to regulate the manufacturing or processing of any chemical substance for a "a use which the [EPA] has determined . . . is a significant new use." 15 U.S.C. § 2604(a)(1)(A)(ii). But the statute defines neither "significant new use" nor "new." Thus, we "look first to the word[s'] ordinary meaning[s]." *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407 (2011).

Inhance asserts that "new" means "having recently come into existence," or "not previously existing." *See New*, MERRIAM-WEBSTER DICTIONARY, www.merriam-webster.com/dictionary/new (last visited

[6] Inhance makes several other arguments for why we should vacate the EPA's orders. Because we agree that the EPA exceeded its statutory authority by proceeding under Section 5, we do not reach those arguments.

Mar. 7, 2024); *New*, OXFORD ENGLISH DICTIONARY, www.oed.com /search/dictionary/?scope=Entries&q=new (last visited Mar. 7, 2024). Accordingly, Inhance urges that its fluorination process cannot be deemed "new" because its "decades-old" fluorination process did not "recently come into existence." By contrast, the EPA offers a different definition of "new," as meaning "not previously known" or "known but a short time although perhaps existing before." *See New*, OXFORD ENGLISH DICTIONARY (1978); *New*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1976). Based on those definitions, the EPA argues that a "significant new use" is any use "not previously known to the EPA."[7] And because Inhance did not identify its fluorination process as an "ongoing use" during the rulemaking process, the fluorination process qualifies as a significant new use under Section 5.

Inhance's interpretation of Section 5 is more persuasive, for two reasons. First, it more closely aligns with the text of Section 5 and the design of TSCA as a whole. *See* 15 U.S.C. § 2604; *Sample*, 406 F.3d at 312. The plain language of Section 5 requires a party to provide notice to the EPA "*before* . . . manufacturing or processing" of a new chemical substance can begin. *Id.* § 2604(a)(1)(B)(i) (emphasis added). Likewise, the four factors the EPA must consider in determining whether something is a significant new use are forward-looking. *See id.* § 2604(a)(2)(A)–(D) (stating that the EPA must consider the "*projected* volume of manufacturing and processing

[7] The EPA first argues that we should not reach Inhance's statutory argument because it is a "collateral attack[] on the SNUR," and thus not properly before this court. But the APA standard of review, which as explained in note 5 *supra* is largely incorporated by TSCA, requires us to "hold unlawful and set aside agency action . . . in excess of statutory jurisdiction, authority, or limitations . . . ." 5 U.S.C. § 706. The propriety of the EPA's orders necessarily involves EPA's authority under TSCA to issue both the orders and the SNUR.

of a chemical substance" and "*reasonably anticipated* manner and methods of manufacturing . . . [and] processing" (emphases added)). This suggests that Section 5 is intended to regulate covered substances prior to their initial manufacture, not decades after a manufacturing process has been in place.

Furthermore, TSCA's broader structure demonstrates that Section 5 is intended only to regulate significant new uses prior to first manufacture. As explained above, there are two ways the EPA can regulate chemical substances under TSCA: Section 5 applies (only) to new chemical substances and significant new uses; Section 6 applies to all chemical substances. *See id.* § 2605(a). Unlike Section 5, Section 6 requires the EPA to conduct a cost-benefit analysis, weighing the negative effects of the chemical substance against the benefits of the substance as well as the economic consequences of prohibiting or limiting the substance. *See id.* § 2605(c)(2)(A)–(C). This shows that Congress intended for the EPA to consider more carefully the effects of its regulations on manufacturing processes that have previously existed.

Contrarily, the EPA's interpretation of Section 5 distorts TSCA's framework and defies common sense. Under its approach, the agency can regulate a use under Section 5 anytime it "discovers" a use not previously known to the agency, even if that use has existed for decades. But that reading undermines Section 6 and shortcuts Congress's express directive to the agency to weigh the costs to businesses and the overall economy before shutting down an ongoing manufacturing process. More simply, the EPA's interpretation lacks intuitive force: A forty-year-old manufacturing process is not "new" in any pertinent sense of the word. At bottom, the EPA's attempt to redefine "new" to expand the reach of the SNUR does not pass muster because "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014).

Second, the EPA's definition of "significant new use" presents serious constitutional concerns. *See Jennings*, 583 U.S. at 286. It is well-established that administrative agencies must give the public fair notice of their rules before finding a violation of them. *See Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 374 (5th Cir. 2024) (en banc). This requirement is rooted in the Fifth Amendment's Due Process Clause. *See id.* at 374–76 (explaining the contours of the fair-notice doctrine). Thus, while companies are required to stay apprised of laws and regulations, they are not required to predict an agency's actions with "extraordinary intuition or with the aid of a psychic." *Id.* at 381 (quoting *United States v. Chrysler Corp.*, 158 F.3d 1350, 1357 (D.C. Cir. 1998)).

According to the EPA, "significant new use" is a "term of art that depends on EPA action, rather than a readily used term in common speech." During the rule-making process for PFAS, the EPA explained that it would "not designate ongoing uses as significant new uses when the final rule [was] promulgated." 80 Fed. Reg. 2887. But to be designated as an ongoing use the EPA required companies to submit their prior manufacture or use of PFAS for approval under the proposed SNUR. Ultimately, the EPA "reviewed all ongoing use claims . . . and excluded from the definition of 'significant new uses'" only those ongoing uses that had been submitted for approval. 85 Fed. Reg. 45118; *see also* 40 C.F.R. § 721.10536(b)(5).

Unfortunately for Inhance, neither it nor the EPA knew that its fluorination process resulted in the creation of PFAS until March 2022, nearly two years after the final SNUR was promulgated. Moreover, neither the 2015 proposed SNUR nor the 2020 final version included the fluorination industry as an industry that might be affected by the SNUR. *See* 80 Fed. Reg. 2886; 85 Fed. Reg. 45110. Thus, having no reason to know it would be subject to the new SNUR, Inhance did not submit its fluorination process as an ongoing use during the rule-making process. Nevertheless, under the EPA's

interpretation of Section 5, Inhance is still subject to the SNUR because its manufacture of PFAS was not known to the EPA until 2022 (making it "new" in the agency's eyes), and Inhance did not presciently submit an ongoing use for approval during the rule-making process.

But this court has recognized that federal agencies "cannot 'surprise' a party by penalizing it for 'good-faith' reliance on the agency's prior positions." *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 189 (5th Cir. 2023) (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–57 (2012)). Indeed, "[d]ealing with administrative agencies is all too often a complicated and expensive game, and players like [Inhance] are entitled to know the rules." *Id.* (internal quotations and citation omitted). Had Inhance—or the EPA—known that its fluorination process was implicated by the proposed SNUR, Inhance could have participated in the rule-making process and perhaps prevented its fluorination process from being deemed *post hoc* a significant new use by the EPA. Instead, because Inhance did not possess "extraordinary intuition" or the "aid of a psychic" to foresee that the EPA would regulate the fluorination industry, Inhance faces being shuttered by the agency's belated "discovery" of its process. *See Wages*, 90 F.4th at 376. Fortunately for Inhance, such foresight is "more than the law requires." *Id.* We therefore eschew the EPA's interpretation of "significant new use" and instead adopt Inhance's more straightforward interpretation of the statute. *See Jennings*, 583 U.S. at 286. And that dooms the EPA's orders at issue here, because Inhance's fluorination process was not a significant new use within the purview of Section 5.

IV.

The EPA may not contort the plain language of TSCA's Section 5 to deem a forty-year-old ongoing manufacturing process a "significant new use" subject to the accelerated regulatory process provided by that part of the statute. In other contexts, "new" may have nuanced meanings, but its meaning in the statute before us is plain, and plainly prohibits the EPA's December 2023 orders aimed at Inhance.

We hasten to add that our ruling to this effect does not render the EPA powerless to regulate Inhance's fluorination process. The agency can properly proceed, abiding the APA's procedural guardrails, under TSCA's Section 6 by conducting *inter alia* the appropriate cost-benefit analysis required for ongoing uses—a proposition even Inhance concedes. The EPA is just not allowed to skirt the framework set by Congress by arbitrarily deeming Inhance's decades-old fluorination process a "significant new use." *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 105–06 (2015).

Accordingly, the EPA's December 2023 orders are

VACATED.