United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 14, 2011 Decided June 17, 2011

No. 10-1142

IN RE: NATURAL RESOURCES DEFENSE COUNCIL,
PETITIONER

On Petition for Writ of Mandamus to the
Food and Drug Administration

Aaron Colangelo argued the cause for petitioner. With him on the briefs were *Levi Jones* and *Avinash Kar*.

Anne Murphy, Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the brief were *Tony West*, Assistant Attorney General, *Douglas N. Letter*, Attorney, *Eric M. Blumberg*, Deputy Chief Counsel, Food & Drug Administration, and *Karen E. Schifter*, Senior Counsel, Department of Health and Human Services.

Before: HENDERSON, ROGERS and KAVANAUGH, *Circuit Judges*.

Opinion for Court by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: This appeal concerns whether this court or the district court has jurisdiction over matters relating to a citizen petition filed pursuant to Food and Drug Administration ("FDA") regulations promulgated under the Food, Drug, and Cosmetic Act ("the Act") , 21 U.S.C. §§ 301 *et seq.* Because its citizen petition to revoke regulations permitting Bisphenol A ("BPA") to be used as a food additive, *see, e.g*, 21 C.F.R. § 177.1555; *id.* § 177.1595, has been pending since October 21, 2008, the Natural Resources Defense Council ("NRDC") seeks what amounts to a writ of mandamus directing the FDA to issue a final decision on its petition. We hold that exclusive jurisdiction over citizen petitions lies in the district court, and accordingly we dismiss the petition.

I.

Section 409 of the Act on "food additives" provides that "[a]ny person may, with respect to any intended use of a food additive, file with the Secretary [of the Department of Health and Human Services] a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(b)(1). The petition must include specified information and data, *id.* § 348(b)(2), and the Secretary must issue an order adopting a regulation or denying the petition within 180 days after the petition is filed, *id.* § 348(c)(2). Within 30 days of publication of such order, "any person adversely affected . . . may file objections," and the Secretary "shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections" and "[a]s soon as practicable after completion of the hearing . . . shall by order act upon such objections . . . ." *Id.* § 348(f)(1). Judicial review of an order amending or repealing a regulation is in the U.S. Court of Appeals, in the circuit where the

adversely affected petitioner resides or has his principal place of business, or in this court. *Id.* § 348(g).

Section 409 directs the Secretary by regulation to "prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." *Id.* § 348(i). Pursuant to this authority, FDA regulations provide two options for seeking repeal or amendment of a food additive regulation.[1] The first is a food additive petition. *See* 21 C.F.R. § 171.1. When a food additive petition seeks promulgation of a new regulation, the petitioner bears the burden of showing that the additive will have its "intended physical or other technical effect," *id.* § 171.1(c), and "will be safe for its intended use," *id.* The petitioner is required to submit a considerable amount of supporting data, including the additive's chemical properties, and data on quantity and proposed use. *See id.* When a food additive petition seeks to amend an existing regulation, the petitioner must include "full information on each proposed change," but may rely on statements in the original petition where no change is proposed. *Id.* The FDA must grant or deny a food additive petition in accordance with the statutory timeline in section 409(c)(2) of the Act. *See id.* § 171.100.

The second method to request amendment or repeal of a food additive regulation is by citizen petition. This is addressed in section 10.30 of Part 10, which contains the general administrative practices and procedures for the Act. A citizen petition is required to include far less supporting data than the food additive petition, and the petitioner does not bear the

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[1] The Secretary has redelegated authority under the Act to the FDA. *See* FDA Staff Manual Guide § 1410.10 (2005); 69 Fed. Reg. 17,285 (Apr. 2, 2004).

burden of establishing that an additive is safe or unsafe. *Compare* 21 C.F.R. § 10.30, *with id.* § 171.1. While the Act provides that a food additive petition can only be granted or denied, *see* 21 U.S.C. § 348(c), the regulation allows the FDA to grant or to deny a citizen petition or to "[p]rovide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information," 21 C.F.R. § 10.30(e)(2). In ruling on a citizen petition, the FDA is to take into consideration: "(i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute." *Id.* § 10.30(e)(1). The FDA is required to respond within 180 days of receipt of the petition, *id.* § 10.30(e)(2).

The provisions on citizen petitions apply "except to the extent that other sections of this chapter apply different requirements to a particular matter." *Id.* § 10.30(a). Thus, a petitioner submitting new data to support the amendment or repeal of a regulation must do so through a food additive petition. *Id.* § 171.130(b). When seeking to ban a substance from use in food, a petition must include "an adequate scientific basis." *Id.* § 189.1(c). In any event, the FDA can "publish a proposal to establish, amend, or repeal a regulation . . . on the basis of new scientific evaluation or information." *Id.*; *see id.* § 171.130(a); *see also id.* § 10.30(h).

II.

On October 21, 2008, the NRDC submitted a "Citizen Petition" to the FDA "under section 409 of [the Act], and pursuant to 21 C.F.R. §§ 10.30, 171.130, and 189.1." Citizen Petition 1 (Oct. 21, 2008). The petition asked the FDA to

"establish a regulation prohibiting the use of BPA . . . in human food and [to] revoke all regulations permitting the use of a food additive that results in BPA becoming a component of food." *Id.* The petition did not challenge the FDA's original decision to permit BPA to be used as a food additive; rather, it sought a change in the regulations based on new data. *See id.* at 6, 10. In support of its request, the NRDC relied on section 409(c)(3) and (c)(5) of the Act, which require that the safety of a food additive must be established before its use can be sanctioned by the FDA, *id.* at 5-6 (citing 21 U.S.C. § 348(c)(3), (5)), and on scientific data to show the dangers of BPA. For example, it pointed to animal and human tissue studies indicating that "levels of BPA ranging from 5 to 10 ppb leach[] from baby bottles heated with water," *id*. at 7–8, and otherwise indicating that humans are "widely exposed to BPA" at "levels . . . well within the range of concern based on animal studies." *Id*. at 8. In citing new studies, it noted the association of BPA exposure and disruption of female and male reproductive toxicity (even across generations), various forms of cancer, and interference with the thyroid hormone, as well as an association between BPA and diseases such as diabetes, cardiovascular disease, and obesity. *Id.* at 10–13. The NRDC asserted that "[t]he weight of the scientific evidence now shows that human exposure to BPA can not [sic] be confirmed safe," *id*. at 9, and, based on the studies by different laboratories unaffiliated with BPA manufacturers or users, "strongly disagree[d]" with the two studies on which the FDA relied in concluding that "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses." *Id.* at 14 (internal quotation marks omitted).

The FDA acknowledged receipt of the NRDC's citizen petition shortly after receiving it. When five months had passed without further response, the NRDC wrote to the Division of Dockets Management, inquiring when the FDA intended to respond and noting that under the Act "the FDA's final

determination of this petition was due within 90 days, and is now several months overdue." Letter from Aaron Colangelo, NRDC, to Lyle D. Jaffe, Division of Dockets Management, FDA (Apr. 20, 2009). Two weeks later, on May 6, 2009, the Office of Food Additive Safety provided a "tentative response" pursuant to 21 C.F.R. § 10.30(e), listing the "limited availability of resources and other agency priorities" as reasons for not reaching a final decision on the citizen petition. Letter from Laura Tarantino, Director, Office of Food Additive Safety, FDA, to Sarah Janssen & Aaron Colangelo, NRDC (May 6, 2009). Thirteen months passed and the NRDC received no further response to its citizen petition.

III.

The NRDC filed in this court on June 29, 2010, a petition seeking to have the court establish "an enforceable deadline" by which the FDA "must respond . . . with either a denial or a responsive rulemaking." Petition at 22. The FDA responded by maintaining that this court lacks jurisdiction over the petition because the FDA's final action on the citizen petition is reviewable in the district court and that court can also entertain an Administrative Procedure Act ("APA") claim for unreasonable delay.

In *Cutler v. Hayes*, 818 F.2d 879 (D.C. Cir. 1987), this court observed that the Act "contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions." *Id.* at 887 n.61. Although the Act has been amended since then, section 409 of the Act continues to vest exclusive jurisdiction over challenges to orders of the FDA, "including any order thereunder with respect to amendment or repeal of a regulation issued under this section . . . in the United States Court of Appeals for the circuit wherein [the "adversely affected"] person resides or has his

principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit." 21 U.S.C. § 348(g)(1). Because "courts of appeals have only such jurisdiction as Congress has chosen to confer upon them," *Cutler*, 818 F.2d at 887 n.61 (citations omitted), this court instructed that where a regulation is not based on a statutory provision vesting exclusive jurisdiction in the courts of appeals, jurisdiction lies in the district courts, *id*.; *see Wellife Products v. Shalala*, 52 F.3d 357, 358 (D.C. Cir. 1995); 28 U.S.C. § 1331. The only exception is when the final agency action will be exclusively reviewable in the courts of appeals and the court is acting to protect its future jurisdiction. *Telecomms. Research & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 78–79 (D.C. Cir. 1984). This is a narrow exception, however. This court will not "assert jurisdiction on the basis of hypothetical scenarios," and the exception "is not properly extended to cases where the basis of prospective jurisdiction is a speculative chain of events." *Moms Against Mercury v. FDA*, 483 F.3d 824, 827 (D.C. Cir. 2007); *see also Nat'l Mining Ass'n v. Mine Safety and Health Admin.*, 599 F.3d 662, 672–73 (D.C. Cir. 2010).

The FDA adopts this position in its Response to the Petition, maintaining that the citizen petition procedure is non-statutory and that judicial review of final agency action on a citizen petition is through APA review in the district court. It further maintains the *TRAC* exception does not apply because jurisdiction over its final action on the NRDC's citizen petition may well lie in the district court. It notes, as this court recently reaffirmed: "If judicial review of an FDA action or inaction is not provided for in the Act, challenges to such actions may be brought only in the district court." *Moms Against Mercury*, 483 F.3d at 827.

In reply, the NRDC argues that section 409 governs the FDA's response to its citizen petition. Although acknowledging

that its petition requesting the repeal of regulations allowing the use of BPA as a food additive was filed as a citizen petition under section 10.30 of the regulations, and not as a food additive petition under section 171.1, the NRDC nonetheless maintains that because the citizen petition regulation must conform to the requirements of section 409 of the Act, this court has jurisdiction. In particular, the NRDC maintains that because sections 171.130 and 189.1, which regulations were promulgated under section 409 of the Act, direct petitioners to "Part 10" of the regulations, and Part 10 contains the citizen petition provision, "[a] citizen petition seeking repeal of food additive regulations is authorized by [section 409(i),] 21 U.S.C. § 348(i)[,] and subject to the requirements of [section 409]." Reply Br. 5.

This argument fails for a number of reasons. First, it ignores the requirement in section 171.130(b) that a food additive petition must be filed when new data is presented to support a request for repeal of an existing regulation. Had the NRDC done so, then section 409 of the Act would apply. Second, the NRDC's argument overreads section 189.1(c), which provides only that a petition to "establish, amend, or repeal a regulation . . . shall include an adequate scientific basis to support the petition, pursuant to part 10 of this chapter"; it does not indicate that a citizen petition may be used to repeal a food additive regulation or ban a particular food additive. Third, the NRDC inaccurately states that Part 10 "relates to citizen petitions," Reply Br. 4, when section 10.25 in Part 10 recognizes food additive petitions as one way to request FDA action and Part 10 otherwise covers all administrative practices and procedures under the Act. There is, then, nothing in the regulations identified by the NRDC to support its position that the citizen petition process, which can be used for any type of petition under the Act (not just one relating to food additives), is governed by section 409 of the Act.

Further, as the FDA points out, lawsuits involving citizen petitions are regularly heard in the district courts. *See, e.g.*, *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008); *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). Much as the NRDC seeks through its current petition, this court has held that in cases brought under APA § 706(1) seeking to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), when the agency has failed to act within a "reasonable time," *id.* § 555(b), jurisdiction lies in the district court. *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1099–1100 (D.C. Cir. 2003). *Community Nutrition Institute v. Novitch*, 583 F. Supp 294 (D.D.C. 1984), upon which the NRDC relies, is not to the contrary; there the district court ruled this court had jurisdiction "because the FDA has issued final orders with respect to all of [plaintiffs'] requests," *id.* at 296, unlike in the instant case. To the extent the district court there suggested that if the plaintiffs sought reconsideration of the challenged regulation and the agency denied reconsideration, then the "plaintiffs *may* be able to seek review in the court of appeals at that time," *id.* (emphasis added), this hypothetical presumes the existence of a final agency order. The FDA's "tentative response" of May 6, 2009 is, by its plain terms, not such an order.

The *TRAC* exception, as the FDA suggests, is inapplicable because exclusive jurisdiction over any final agency action on the NRDC's citizen petition will not necessarily be in this court. The NRDC maintains that because submission of a citizen petition must invoke the regulatory process that section 409 mandates, any final order by the FDA would be exclusively reviewable in the courts of appeals. But the NRDC ignores the option that the FDA has to provide a tentative response to a citizen petition, *see* 21 C.F.R. § 10.30(e)(2)(iii), as occurred here. This does no more than set off a "speculative chain of

events," *Moms Against Mercury*, 483 F.3d at 827, that might or might not result in promulgation of a final regulation subject to this court's exclusive jurisdiction and as such does not give rise to jurisdiction under *TRAC*. Indeed, if the FDA were to deny the NRDC's citizen petition, then "no part of the statutory food additive petition process would be invoked and the denial would be reviewable only in district court." Respondent's Br. 21. It is true, as the NRDC points out, that in *DiCola v. FDA*, 77 F.3d 504 (D.C. Cir. 1996), the court suggested in the context of a *TRAC* type action in which final review would necessarily be in the courts of appeals, that if the petitioner submitted a citizen petition and the FDA unreasonably delayed its response, then the petitioner could file a mandamus petition in this court. *See id.* at 509–10. But here, where judicial review of the FDA's final action on the NRDC's citizen petition might be in the district court, the *TRAC* exception does not apply.

None of the NRDC's other arguments that section 409 of the Act governs the citizen petition process in section 10.30 of the FDA regulations is any more persuasive. Contrary to the NRDC's claim, the FDA has not "concede[d] that *other* provisions in [section 409] do apply to its consideration of NRDC's petition." Reply Br. 5 (emphasis in the original). Rather, the FDA acknowledged that were it to determine that a citizen petition warrants initiation of a rulemaking, then certain provisions of section 409 would apply. *See* Respondent's Br. 8, 20. This is but one of three possible responses to the filing of a citizen petition, and other responses – denial or "tentative response" – would not lead to a food additive regulation established under section 409. *See id.* 20–21. There is no inconsistency, much less concession by the FDA, between the FDA's acknowledgment that one possible response comes within section 409 of the Act while others do not.

Neither is the FDA's position that the NRDC was required to submit a food additive petition in order to obtain exclusive review in this court undercut by the NRDC's claim that the food additive petition seeks information only a food additive manufacturer would have. The regulations provide that petitions to amend food additive regulations "may omit statements made in the original petition concerning which no change is proposed." 21 C.F.R. § 171.1(c). Under section 171.130(b), a petitioner is to provide "an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal," but nothing requires petitioners to provide information that only the manufacturer would have.

Although this court has at times expressed the view that "bifurcated jurisdiction between District Court and Court of Appeals over identical litigation is not favored," *Environmental Defense Fund v. Gorsuch*, 713 F.2d 802, 813 (D.C. Cir. 1983) (quoting *Oljato Chapter of Navajo Tribe v. Train*, 515 F.2d 654, 660 (D.C. Cir. 1975)), that concern is not implicated here, contrary to the NRDC's suggestion. The FDA's regulations require that new data presented with the aim of amending or repealing a food additive regulation must be presented as a food additive petition, 21 C.F.R. § 171.130(b), and, consequently, exclusive jurisdiction over challenges relating to properly submitted food additive petitions will be in the courts of appeals pursuant to section 409(g) of the Act. The district courts will have jurisdiction over citizen petitions that do not request repeal or amendment of a food additive regulation based on new data. So far as the NRDC elaborates that such a bifurcation creates a conflict between the courts and "does not make sense," Reply

Br. 8, it fails to come to grips with the workings of the food additive process under the regulations.

Finally, during oral argument, counsel for the NRDC suggested that section 10.30(e)(1) of the regulations, providing that the FDA "shall . . . rule upon each petition . . . taking into consideration . . . time requirements established by statute," requires the FDA to comply with the statutory timeline in section 409(c)(2) of the Act, and thereby establishes that the citizen petition process is governed by the requirements of section 409 generally. Oral Arg. Recording at 3:02-3:23. The NRDC referred to section 10.30(e) in its Petition at 8, but only in the context of listing the three possible responses by the FDA to a citizen petition. This was insufficient to put the FDA on notice of the argument presented during oral argument. Ordinarily this would mean that the argument is forfeited. *Cf. U.S. v. Southerland*, 486 F.3d 1355, 1360 (D.C. Cir. 2007). Inasmuch as the NRDC's petition is filed as an original proceeding in this court and the issue goes to our jurisdiction, however, we reach the merits. *See Shays v. FEC*, 528 F.3d 914, 922–23 (D.C. Cir. 2008). The FDA correctly argued in its response that section 10.30(e)(1) does nothing more than make the statutory deadlines one of several factors that the FDA must consider and weigh in its discretion. This provision simply highlights the difference between the food additive petition review process, which is subject to the statutory timeline, and review of a citizen petition established by regulation, which treats the timeline as a guideline for the FDA to consider and allows for a "tentative response" by the FDA. The NRDC's reliance on section 10.30(e) is thus insufficient to support its position that section 409 applies generally to its citizen petition.

Accordingly, because the NRDC cannot show that jurisdiction over its citizen petition lies exclusively in this court, or that all final FDA action on its petition would be directly and

exclusively reviewable in this court, we dismiss the petition for lack of jurisdiction.