United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 14, 2010 Decided July 16, 2010

No. 09-1314

RECKITT BENCKISER INC.,
PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

Consolidated with No. 09-5437

On Petition for Review of a Final Action
of the Environmental Protection Agency and
Appeal from the United States District Court
for the District of Columbia
(1:09-cv-00445)

Lisa S. Blatt argued the cause for petitioner/appellant. With her on the briefs were *Ronald A. Schechter*, *Lawrence E. Culleen*, and *Michael R. Hartman*.

Lynn L. Bergeson, *Timothy D. Backstrom*, and *Steven Schatzow* were on the brief for *amici curiae* Liphatech, Inc. and Woodstream Corporation in support of petitioner/appellant.

Sambhav N. Sankar, Attorney, U.S. Department of Justice, argued the cause for respondent/appellee. With him on the brief were *Lisa E. Jones*, *Robert P. Stockman*, and *Stephanie J. Talbert,* Attorneys. *R. Craig Lawrence,* Assistant U.S. Attorney, entered an appearance.

Before: ROGERS, TATEL and GRIFFITH, *Circuit Judges* .

Opinion for the Court by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: Reckitt Benckiser, Inc. manufactures pesticides that are subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136–136y. On May 28, 2008, the Environmental Protection Agency issued a Risk Mitigation Decision for Ten Rodenticides (the "RMD," revised June 24, 2008)[1] and notified the company in August 2008 that its registered products containing these rodenticides would be considered misbranded on June 14, 2011, unless certain product changes were made. The company notified EPA that it did not intend to make the changes and instead intended to challenge the RMD through the registration cancellation procedures of FIFRA Section 6, 7 U.S.C. § 136d. When EPA did not expeditiously commence cancellation proceedings, the company filed suit seeking declaratory and injunctive relief on the ground EPA could not bypass such proceedings and treat registered products as

[1] The RMD is available at http://www.regulations.gov/search/Regs/home.html#documentDetail?D=EPA-HQ-OPP-2006-0955-0764. The revision of June 24, 2008, which included a revised timeline, is also available at this website.

misbranded for failure to comply with the RMD. The district court dismissed the complaint for lack of subject matter jurisdiction. The company appeals, and we hold that there was sufficiently final agency action ripe for review, *see Ciba-Geigy Corp. v. U.S. EPA*, 801 F.2d 430 (D.C. Cir. 1986), and also that the district court had jurisdiction pursuant to FIFRA Section 16(a), 7 U.S.C. § 136n(a). Accordingly, we reverse and remand.

I.

The statutory framework for EPA's issuance of the RMD is as follows. FIFRA provides that pesticides sold or distributed in the United States must be registered with EPA. *Id.* § 136a(a). A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used. *See id.* § 136a(a), (c)–(e). EPA can only register a pesticide upon determining that "it will perform its intended function without unreasonable adverse effects on the environment" and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(C), (D).

In 1978, Congress required EPA to "reregister" all pesticides "in the most expeditious manner practicable" and to give priority to food applications. Act of Sept. 30, 1978, Pub. L. 95-396, § 8, 92 Stat. 819, 827 (1978) (amending FIFRA). Congress enacted FIFRA Section 4 in 1988, setting out the detailed reregistration procedures for pesticides whose active ingredients were first registered in a pesticide before November 1, 1984. *See* 7 U.S.C. 136a-1(a). Reregistration under Section 4 involves five phases, and in phase five EPA determines whether a particular active ingredient is eligible for reregistration. *See id.* § 136a-1(g)(2)(A). If EPA determines not to reregister a pesticide, it "shall take appropriate regulatory

action . . . as expeditiously as possible." *Id.* § 136a-1(g)(2)(D). "Any failure of the Administrator to take any action required by" Section 4 is subject to judicial review "under the procedures prescribed by section 136n(b)" for review in a court of appeals. *Id.* § 136a-1(m)[2]; *see infra* note 3.

A pesticide product remains registered until EPA or the registrant cancels it pursuant to Section 6, 7 U.S.C. § 136d. Under Section 6, when it appears to EPA that a registered pesticide or its labeling does not comply with FIFRA or "generally causes unreasonable adverse effects on the environment," EPA "may" bring cancellation proceedings, *id.* § 136d(b), in which the registrant has the right to demand a hearing before an Administrative Law Judge ("ALJ") and can present evidence and argue for continued registration of its product, *id*. § 136d(b), (d); *see* 40 C.F.R. § 164.80(b). Registrants can seek review of a cancellation decision by filing a petition for review in a court of appeals pursuant to Section 16,

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[2] Section 4(m) provides:

> Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 136n(b) of this title.

7 U.S.C. § 136a-1(m).

see 7 U.S.C. § 136n(b).[3] Subject to certain exceptions, Section

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[3] Section 16 provides:

> (a) District court review
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> Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.
>
> (b) Review by court of appeals
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> In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. . . . The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. . . . The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.
>
> (c) Jurisdiction of district courts
>
> The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

7 U.S.C. § 136n.

16 provides that parties may obtain district court review of EPA's refusal to cancel a registration. *See id.* § 136n(a).

FIFRA Section 12 prohibits the sale or distribution of registered but "misbranded" pesticides, *id.* § 136j(a)(1)(E), defined to include registered pesticides whose packaging does not adequately prevent against accidental ingestion, *see id.* § 136(q)(1)(B), or whose labels do not contain directions or warnings "adequate to protect health and the environment," *id.* § 136(q)(1)(F), (G). EPA has several options for addressing pesticide products it concludes are misbranded: EPA can assess civil administrative penalties against anyone who distributes a misbranded pesticide, *see id.* § 136*l*(a); the charged party has a right to hearing in which EPA must persuade an ALJ that the person violated FIFRA, *see id.* § 136*l*(a)(3); 40 C.F.R. § 22.24. EPA can pursue a criminal misbranding action, in which it bears the burden to prove a violation beyond a reasonable doubt. *See id.* § 136*l*(b). EPA also can issue, pursuant to FIFRA Section 13, "stop sale, use, or removal" orders and can commence court proceedings to seize the pesticide. *See id.* § 136k(a), (b).[4]

EPA issued the RMD on May 28, 2010 (as revised June 24, 2008) as "the Agency's final decision on the reregistration eligibility of rodenticide products" that contained "one or more"

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[4] EPA has generally limited use of such stop sale orders to "relatively serious" FIFRA violations. *See* EPA OFFICE OF COMPLIANCE MONITORING, OFFICE OF PESTICIDES & TOXIC SUBSTANCES, ENFORCEMENT RESPONSE POLICY FOR THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) 7 (1990), *available at* http://www.epa.gov/compliance/resources/policies/civil/fifra/fifraerp.pdf.

of ten active ingredients,[5] and also "the Agency's final action in response to the remand order" in *West Harlem Environmental Action v. EPA*, 380 F. Supp. 2d 289, 296 (S.D.N.Y. 2005). RMD at 1. In seeking to minimize children's exposure to rodenticide products containing the ingredients, the RMD required such products to be marketed in bait stations, e.g., as solid bait in tamper-resistant containers, rather than as loose pellets or meal. *See* RMD at 1, 11. Seeking to minimize wildlife exposure to and ecological risks from the ingredients, the RMD prohibited marketing to general consumers for residential use any rodenticide containing the second-generation anticoagulants brodifacoum, bromadiolone, difenacoum, or difethialone. *See id.* at 2, 16. The RMD also set restrictions on the weight, labeling, and distribution of products containing one of the ten rodenticides. *See, e.g.*, *id.* at 17–19. The RMD stated that affected products otherwise "would present unreasonable risks inconsistent with FIFRA." *Id.* at 25. The RMD warned that EPA "may take regulatory action to address the risk concerns from the use of the affected products" if a registrant failed to comply with the RMD, and that while EPA "may initiate cancellation actions" against products whose manufacturers did not voluntarily comply with the RMD, "[r]odenticide products that do not comply with this Risk Mitigation Decision that a registrant releases for shipment after June 4, 2011, *would be considered misbranded*." *Id*. at 25–26 (emphasis added). In other words, EPA considered products covered by the RMD misbranded as of the date of the RMD, but provided a three-year "grace period" for compliance before

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[5] The ten rodenticide ingredients covered by the RMD were: the "first-generation" anticoagulants warfarin (and its sodium salt), chlorophacinone, and diphacinone (and its sodium salt); the "second-generation" anticoagulants brodifacoum, bromadiolone, difenacoum, and difethialone; and the non-anticoagulants bromethalin, cholecalciferol, and zinc phosphide. RMD at 2.

registrants would be subject to misbranding actions. Oral Arg. 12:55–13:28; 25:35–52.

Reckitt Benckiser markets to consumers, under the brand name d-CON®, registered rodenticide products that contain ingredients prohibited by the RMD or contain ingredients allowed by the RMD but in a pellet form prohibited by the RMD. On June 18, 2008, by certified mail, EPA notified the company of the RMD, described procedures for responding, and repeated the RMD's warnings that "[r]odenticide products that do not comply . . . that a registrant releases for shipment after June 4, 2011, *would be considered misbranded*" (emphasis added) and that EPA "will initiate cancellation actions against products for which it does not receive notification of the registrant's intent to comply."[6] The company responded that it did not intend to comply with the RMD,[7] and requested that EPA "expeditiously commence" cancellation pursuant to Section 6 for Reckitt Benckiser's products affected by the RMD.[8] When EPA did not do so, the company filed suit on March 3, 2009, for injunctive and declaratory relief, seeking an order directing EPA to begin cancellation proceedings and

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[6] Letter from Steven Bradbury, Ph.D., Director of the Special Review and Reregistration Division, EPA Office of Prevention, Pesticides, and Toxic Substances, to Linda Jenkins, Reckitt Benckiser Inc., at 2, 5 (June 18, 2008) ("2008 Letter") (emphasis added).

[7] Letter from Liane Jenkins, Senior Regulatory Specialist, Reckitt Benckiser Inc., to Susan Lewis, Branch Chief, Special Review & Reregistration Division, EPA Office of Pesticide Programs (Aug. 28, 2008).

[8] Letter from Ronald A. Schechter and Lawrence E. Culleen, Arnold & Porter LLP, to Susan Lewis, Branch Chief, Special Review & Reregistration Division, EPA Office of Pesticide Programs (Jan. 9, 2009).

enjoining EPA from beginning misbranding proceedings prior to their completion. The district court dismissed the complaint for lack of subject matter jurisdiction, concluding that the company's claims arose under the reregistration provisions of Section 4 and thus invoked the judicial review provisions of Section 4(m), 7 U.S.C. § 136a-1(m), which provides for initial review in the court of appeals.

The company appeals, and in the alternative filed a petition in this court seeking review of EPA's failure to act pursuant to FIFRA; this court consolidated the cases. Our review of the dismissal of the complaint is *de novo*. *See Am. Fed'n of Gov't Employees*, 475 F.3d 341, 347 (D.C. Cir. 2007).

II.

Reckitt Benckiser's lawsuit challenges neither the substance of the RMD nor EPA's authority to bring certain misbranding actions instead of or before Section 6 cancellation where a product fails to bear a label consistent with the terms of that product's registration. *See* Appellant's Br. 7, 8 & n.1. Instead the company challenges EPA's interpretation that under FIFRA it has authority to commence enforcement proceedings for misbranding against the company's non–RMD-conforming products without first cancelling their registrations pursuant to Section 6, in effect canceling the registrations without following the regulatory procedures provided in Section 6. EPA maintains its misbranding threat is neither final agency action nor ripe for review. We first address the threshold question of whether EPA's interpretation of its FIFRA misbranding enforcement authority is ripe for judicial review. *See Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 47–50 (D.C. Cir. 1999). We conclude that our decision in *Ciba-Geigy*, 801 F.2d 430, controls.

In *Ciba-Geigy*, much as here, the "principal issue" was whether EPA's interpretation of FIFRA as allowing misbranding proceedings upon bypassing cancellation proceedings for failure to comply with labeling changes was ripe for review. *Id*. at 435. EPA had issued a "Registration Standard" for the registered pesticide simazine and notified Ciba-Geigy and other simazine registrants that EPA "intends to institute cancellation proceedings" against products that did not comply with the Registration Standard within nine months, and that non-compliant products "*will be considered misbranded*" after the deadline. *Id*. at 432 (emphasis added). Ciba-Geigy informed EPA it did not intend to comply voluntarily with the Registration Standard. *Id.* at 433. After the compliance deadline had passed, EPA responded that "[i]t is the Agency's position" that products not complying with the Registration Standard "are misbranded" under FIFRA, and that "the Agency does not agree with [Ciba-Geigy's] interpretation" of FIFRA that cancellation proceedings were required before misbranding proceedings. *Id.* (first alteration in *Ciba-Geigy*). Ciba-Geigy filed suit seeking a declaration that EPA had failed to follow procedures required by law when requiring labeling changes and use restrictions. The district court dismissed the complaint for lack of subject matter jurisdiction, concluding EPA had neither issued a final order nor taken any other final action reviewable by a court. Reversing, this court held that under *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), *abrogated on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977), the challenge to EPA's interpretation of its FIFRA misbranding authority was ripe for judicial review in the district court. *Ciba-Geigy*, 801 F.2d at 434–39.

Determining ripeness requires a court to evaluate "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.*, 387 U.S. at 149. In addition to evaluating "whether delayed review

would cause hardship" to Reckitt Benckiser, this court must consider "whether judicial intervention would inappropriately interfere with further administrative action" and "whether the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998). Thus the fitness of an issue for review depends on whether (1) "the issue presented is a purely legal one," (2) "consideration of that issue would benefit from a more concrete setting," and (3) "the agency's action is sufficiently final." *Ciba-Geigy*, 801 F.2d at 435; *see Abbott Labs.*, 387 U.S. at 148; *Nevada v. Dep't of Energy*, 457 F.3d 78, 85 (D.C. Cir. 2006). In *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997), the Supreme Court, in interpreting the Administrative Procedure Act ("APA"), 5 U.S.C. § 704, held that the finality of an agency's action depends on whether it marks the "consummation of the agency's decisionmaking process" and is not "of a merely tentative or interlocutory nature," and determines "rights or obligations" or is otherwise an action "from which legal consequences will flow" (quotation marks omitted). Although the court's ripeness analysis in *Ciba-Geigy* predated *Bennett v. Spear*, this court has treated the analysis of finality in relation to ripeness in *Ciba-Geigy* as "complementary" to that of *Bennett*. *John Doe, Inc. v. DEA*, 484 F.3d 561, 566 (D.C. Cir. 2007).

EPA's interpretation of FIFRA as providing authority to bypass Section 6 regulatory cancellation proceedings and commence misbranding enforcement proceedings for failure to comply with the RMD is fit for judicial review. First, EPA's interpretation raises "a pure legal question as to what procedures EPA [i]s obliged to follow" under FIFRA when implementing the RMD. *Ciba-Geigy*, 801 F.2d at 435. As counsel for EPA explained at oral argument, "it is EPA's view that we do not need to bring a cancellation procedure before bringing a misbranding action." Oral Arg. 35:48–54. EPA "has not sought to justify its interpretation of [FIFRA] on the basis of the specific

facts of the case," *Ciba-Geigy*, 801 F.2d at 435, but has instead adopted an interpretation of FIFRA that would apply in many situations involving a labeling change to a registered pesticide.

Second, although EPA had identified the specific FIFRA misbranding provisions it considered Ciba-Geigy products to be violating, *id.* at 433, the lack of such factual development regarding which specific FIFRA misbranding provisions EPA might apply to Reckitt Benckiser's products does not make EPA's interpretation unripe for review. Specification of the misbranding provisions EPA considers a product to be violating would not change EPA's interpretation of FIFRA in the reregistration RMD situation here. EPA has informed the company of its interpretation and "steadfast[ly]" declined to bring cancellation proceedings, as the company requested. *Id.* at 437. As in *Ciba-Geigy*, the court "has no reason to believe that our consideration of the issue would be facilitated by further factual developments." *Id.* at 433.

Third, for similar reasons, EPA's interpretation of its misbranding authority under FIFRA is "sufficiently final" agency action. *Id.* at 435. As in *Ciba-Geigy*, where EPA unambiguously stated that the registrant was not entitled to a cancellation proceeding before complying with proposed pesticide labeling changes, *id.* at 437, EPA's interpretation of its authority here is definitive. EPA unequivocally informed Reckitt Benckiser that its non–RMD-complying products "*would be considered misbranded*" after June 4, 2011, *see* 2008 Letter at 2 (emphasis added), *supra* note 6, without regard to whether EPA would have initiated or completed Section 6 proceedings to cancel those products' registrations. EPA suggests this statement "assumes for now that the agency could bring a misbranding action against the company's products," Appellee's Br. 41, and confirmed at oral argument that it had taken the position that "we do not need to bring a cancellation procedure before bringing a

misbranding action," Oral Arg. 35:48–54. As in *Ciba-Geigy*, 801 F.2d at 437, EPA's statements "gave no indication that [they] w[ere] subject to further agency consideration or possible modification." There is thus little chance that "judicial review will disrupt the orderly process of administrative decisionmaking" regarding EPA's interpretation of its FIFRA misbranding authority. *Id.* Furthermore, as the court explained in *Ciba-Geigy*, 801 F.2d at 437, EPA, which is charged with administering FIFRA, has made an authoritative interpretation of its FIFRA misbranding authority that has practical and significant legal effects.

With respect to hardship, EPA's interpretation of its FIFRA misbranding authority, as with the registrant in *Ciba-Geigy*, 801 F.2d at 438–39, has had a "direct effect" on Reckitt Benckiser's "day-to-day business." *Abbott Labs.*, 387 U.S. at 152. According to sworn declarations by company officials, the company has been forced to spend hundreds of thousands of dollars on research and development of RMD-compliant products and expects it will cost an additional one million dollars to conclude development of these products by the June 4, 2011 deadline.[9] The company also anticipates continued loss of sales and sales opportunities as customers stop carrying its products and it is forced to offer other products containing what the company views as less effective active ingredients.[10] *See also Envtl. Def. Fund v. Ruckelshaus*, 439 F.2d 584, 591–92 (D.C. Cir. 1971).

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[9] Pet. for Review Ex. 8, Decl. of David Long, Reckitt Benckiser Inc., Vice President of Regional Regulatory and Medical Affairs for North America, ¶ 7 (Dec. 17, 2009).

[10] Long Decl. ¶ 11, *supra* note 9; Pet. for Review Ex. 9, Decl. of Debra Eible, Reckitt Benckiser Inc., U.S. Multi-Surface and Pest Control Marketing Director ¶¶ 7, 10 (Dec. 17, 2009).

The factual distinctions from *Ciby-Geigy* on which EPA relies are immaterial. Here, unlike in *Ciba-Geigy*, the compliance deadline has not passed. This distinction is attributable to the shorter nine-month compliance deadline in *Ciba-Geigy*, 801 F.2d at 432–33, while the RMD provided a three-year grace period. Also here, unlike in *Ciba-Geigy*, EPA has not decided whether to bring proceedings against Reckitt Benckiser's products, nor whether to bring misbranding proceedings before or instead of Section 6 cancellation proceedings. Even assuming Section 4 affords EPA discretion upon deciding not to reregister a product to choose which "appropriate regulatory action" to take "as expeditiously as possible," 7 U.S.C. § 136a-1(g)(2)(D), the issue raised by the company is whether EPA has properly interpreted FIFRA to allow enforcement proceedings for misbranding to bypass cancellation proceedings as a means of implementing the RMD. *See Ciba-Geigy*, 801 F.2d at 435. Regardless of whether Congress broadened EPA's enforcement discretion in Section 4, because EPA has provided a definitive and sufficiently final interpretation of its FIFRA misbranding authority, judicial review of that interpretation would not interfere with EPA's administrative decisionmaking processes.

EPA's view that its statement that non–RMD-complying products "would be considered misbranded" after June 4, 2011 is not reviewable final agency action fails to address the finality of EPA's interpretation of FIFRA as allowing it to bypass Section 6 cancellation proceedings in the implementation of the RMD. The cases on which EPA relies address the finality of EPA's decision whether or not to bring enforcement proceedings for misbranding rather than the finality of EPA's interpretation of its procedural FIFRA misbranding authority. EPA's interpretation is not less final because the court "do[es] not know" whether, *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 733 (2003), or "ha[s] no

idea whether or when," *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163 (1967), EPA will bring enforcement proceedings for misbranding bypassing regulatory cancellation proceedings. Neither does EPA's interpretation "merely express[] its view of what the law requires of a party," *Indep. Equip. Dealers v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004) (quoting *AT&T Co. v. EEOC*, 270 F.3d 973, 975 (D.C. Cir. 2001)). Instead, EPA's interpretation had the "definitiveness and direct and immediate effect" that the court in *Ciba-Geigy*, 801 F.2d at 436 (quotation marks omitted), held was dispositive of finality. As the court discussed in *Ciba-Geigy*, *id.* at 435, while the Supreme Court in *FTC v. Standard Oil Co. of California*, 449 U.S. 232, 241–42 (1980), held that the issuance of a complaint was not reviewable final agency action, the Court reiterated that *Abbott Laboratories* holds that regulations that were "definitive" statements of the agency's position that had a "direct and immediate. . . effect on the day-to-day business" of the parties were sufficiently final to be judicially reviewable before enforcement, *Standard Oil*, 449 U.S. at 239 (quoting *Abbott Labs.*, 387 U.S. at 152–53).

EPA's other attempts to distinguish *Ciby Geigy* are also unpersuasive. Reckitt Benckiser's challenge to EPA's interpretation of its misbranding authority under FIFRA is not untimely for failing to challenge EPA's similar interpretation in *Ciba-Geigy*, as EPA urges, because the company was not a party in *Ciba-Geigy*, *see* Reply Br. 23–24. Although EPA claims its interpretation of its FIFRA misbranding authority "left the world just as it found it" by restating its interpretation from *Ciba-Geigy* rather than "implementing, interpreting, or prescribing law or policy," EPA does not show its interpretation was sufficiently "established" as a policy by or after *Ciba-Geigy*. *Indep. Equip. Dealers Ass'n*, 372 F.3d at 428. As the company responds, EPA has not cited one instance where it brought a misbranding action to enforce compliance with a pronouncement such as the RMD without first taking any of the steps to cancel a registration

pursuant to Section 6. And although EPA suggests that any hardship the company suffers from EPA's interpretation of its misbranding authority for implementing the RMD does not meet the hardship component in *Abbott Laboratories*, 387 U.S. at 149, the company's hardships are indistinguishable from those this court found dispositive of ripeness when applying the *Abbott Laboratories* test in *Ciba-Geigy*. Like Ciba-Geigy, as a result of EPA's interpretation of FIFRA, the company has stated it faces a drop in sales and a choice between "costly compliance" and "the risk of serious civil and criminal penalties for unlawful distribution of 'misbranded' products." *Ciba-Geigy*, 801 F.2d at 438–39; *see* Long Decl. ¶¶ 7–9, Eible Decl. ¶¶ 7–9, *supra* notes 8 & 9.

EPA's reliance on *Munsell v. Department of Agriculture*, 509 F.3d 572, 586 (D.C. Cir. 2007), for the proposition that "[m]ere uncertainty as to the validity of a legal rule" does not qualify as hardship in a ripeness analysis, is misplaced. The court was quoting the Supreme Court's determination in *National Park Hospitality Association v. Department of the Interior*, 538 U.S. 803, 810–11 (2003), that where parties "suffer no practical harm as a result" of an agency's statement of policy regarding a statute the agency was not charged with administering, uncertainty regarding the legality of the policy does not qualify as a hardship. EPA is charged with administering FIFRA and its interpretation is having the "practical effect" on Reckitt Benckiser as occurred in *Ciba-Geigy*, 801 F.2d at 437. The hardship that makes Reckitt Benckiser's challenge ripe for review is not that it faces "the prospect of having to defend itself in an administrative hearing should the agency actually decide to pursue enforcement," *Reliable Automatic Sprinkler*, 324 F.2d at 732, but rather the compliance "dilemma" it faces as a result of EPA's interpretation "purport[ing] to give an authoritative interpretation of a statutory provision that has a direct effect on the [company's] day-to-day

business," *Ciba-Geigy*, 801 F.2d at 438 (quoting *Abbott Labs.*, 387 U.S. at 152)). In addition, unlike *Standard Oil*, 449 U.S. at 243, or *Ticor Title Insurance Co. v. FTC*, 814 F.2d 731, 742 (D.C. Cir. 1987) (opinion of Edwards, J.), the company is not challenging the legality of a complaint EPA has issued.

Finally, under the two-prong analysis in *Bennett*, 520 U.S. at 177–78, EPA's interpretation of its misbranding authority under FIFRA represents "final agency action" under the APA, 5 U.S.C. § 704. First, for the reasons discussed regarding the third prong of the fitness analysis for purposes of ripeness, EPA's interpretation represents the "consummation of the agency's decision making process" regarding its legal authority. *Bennett*, 520 U.S. at 178 (quotation marks omitted). Second, EPA stated in the RMD and the letter of June 18, 2008 to Reckitt Benckiser obligations with which the company must comply or risk misbranding enforcement proceedings. Having made a binding procedural determination that, in the absence of compliance with the RMD, the company is not entitled to a Section 6 cancellation proceeding before being subject to a misbranding proceeding, EPA has determined it has the discretion to deny the company a right it claims to possess under FIFRA. *See id.*

III.

On the question of jurisdiction, EPA maintains that because the RMD is a Section 4(g)(2)(A) determination of the reregistration eligibility of active ingredients, any challenge to EPA's implementation of it necessarily arises under Section 4 as well. However, EPA's interpretation of its FIFRA misbranding enforcement authority to implement the RMD cannot properly be viewed as a form of "appropriate regulatory action" under Section 4(g)(2)(D)(i), 7 U.S.C. § 136a-1(g)(2)(D)(i). An agency's exercise of its regulatory authority is related to but distinct from an agency's interpretation of a statute it

administers. *Compare* 5 U.S.C. § 706 *with Chevron*, 467 U.S. at 842–45; *see Eagle Broad. Group, Ltd. v. FCC*, 563 F.3d 543, 551 (D.C. Cir. 2009). Reckitt Benckiser has no remedy under Section 4 to challenge EPA's statutory interpretation. This court, therefore, lacks jurisdiction pursuant to Section 4(m), 7 U.S.C. § 136a-1(m), *supra* note 2.

Neither does this court have jurisdiction under Section 16(b), 7 U.S.C. § 136n(b), *supra* note 3. EPA's interpretation is not an "order . . . following a public hearing" giving rise to court of appeals rather than district court jurisdiction. 7 U.S.C. § 136n(b); *cf. Humane Soc'y v. EPA*, 790 F.2d 106, 110–11 (D.C. Cir. 1986); *Envtl. Def. Fund v. Costle*, 631 F.2d 922, 925–32 (D.C. Cir. 1980); *see also United Farmworkers v. EPA*, 592 F.3d 1080, 1082–83 (9th Cir. 2010).

However, the district court has jurisdiction over Reckitt Benckiser's challenge to EPA's interpretation of its FIFRA misbranding authority. EPA's interpretation is an "other final action[] of the Administrator not committed to the discretion of the Administrator by law" and is judicially reviewable in the district court under Section 16(a), 7 U.S.C. § 136n(a), *supra* note 3. *Cf. Ciba-Geigy*, 801 F.2d at 434, 437 n.8 (citing *Heckler v. Chaney*, 470 U.S. 821, 834 (1984)). Because evaluating EPA's interpretation of its authority under FIFRA to implement the RMD through enforcement proceedings for misbranding is a prerequisite to evaluating Reckitt Benckiser's contentions that EPA improperly delayed or refused to initiate Section 6 cancellation proceedings, we do not reach the question of whether these contentions provide additional bases of jurisdiction. In view of our disposition, we also do not reach the company's contention that the district court has jurisdiction over its claims under Section 16(c), 7 U.S.C. § 136n(c), *supra* note 3.

Accordingly, we reverse the dismissal of Reckitt Benckiser's complaint and remand the case to the district court to address the company's challenge to EPA's interpretation of its authority under FIFRA to bring enforcement proceedings for misbranding before, or rather than, regulatory cancellation proceedings under Section 6 against products not voluntarily complying with a reregistration RMD. We, therefore, do not reach the company's contentions that EPA's non-initiation of Section 6 cancellation proceedings was arbitrary and capricious or unreasonably delayed under the APA, 5 U.S.C. § 706. We dismiss the petition for review for lack of jurisdiction.