

ORAL ARGUMENT NOT YET SCHEDULED
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE)	No. 14-73353
COUNCIL, INC.,)	
)	
<i>Petitioner,</i>)	
)	
v.)	
)	
UNITED STATES ENVIRONMENTAL)	
PROTECTION AGENCY,)	
)	
<i>Respondent,</i>)	
)	
DOW AGROSCIENCES LLC,)	
)	
<i>Respondent-Intervenor.</i>)	

CENTER FOR FOOD SAFETY, <i>et al.</i>)	No. 14-73359
)	
<i>Petitioners,</i>)	
)	
v.)	
)	
UNITED STATES ENVIRONMENTAL)	
PROTECTION AGENCY, and GINA)	
MCCARTHY, in her official capacity)	
as Administrator,)	
)	
<i>Respondents,</i>)	
)	
DOW AGROSCIENCES LLC,)	
)	
<i>Respondent-Intervenor.</i>)	

**RESPONDENTS' MOTION FOR VOLUNTARY VACATUR AND
REMAND**

Respondent United States Environmental Protection Agency (“EPA”) hereby moves for voluntary vacatur and remand of EPA’s registration, as amended, of Dow AgroSciences’ (“Dow”) “Enlist Duo” herbicide under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). Enlist Duo is an herbicide developed for use on corn and soybean crops that are genetically engineered to be resistant to the two active ingredients in Enlist Duo. As explained below, because EPA is in receipt of new information regarding potential synergistic effects between the two ingredients on non-target plants, EPA seeks a voluntary remand in order to reconsider the Enlist Duo registration in light of the new information. EPA also seeks vacatur of the registration because EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA.

On November 24, 2015, Counsel for EPA informed counsel for all parties of EPA’s intention to file this motion. Counsel for Petitioners in these consolidated Petitions have indicated that their respective clients do not oppose this motion. Counsel for Dow has indicated that Dow intends to file a response to this motion.

BACKGROUND

FIFRA generally governs pesticide regulation in the United States. *See generally* 7 U.S.C. §§ 136-136y. It regulates the sale, distribution, labeling, and use of pesticides while protecting human health and the environment from associated unreasonable

adverse effects. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984). To that end, FIFRA establishes a federal registration scheme that generally precludes distributing or selling any pesticide that has not been “registered” by EPA. 7 U.S.C. § 136a(a); *Fairhurst v. Hager*, 422 F.3d 1146, 1151 (9th Cir. 2005). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used. *See* 7 U.S.C. §§ 136a(c)(1)(A)-(F), 136a(d)(1). Applicants for pesticide registrations must submit proposed label language addressing a number of different topics, including ingredients, directions for use, and adverse effects of the products. *See* 7 U.S.C. § 136a(c); 40 C.F.R. § 152.50 & Part 156. *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69, 71 (8th Cir. 1995).

FIFRA authorizes EPA to issue registrations for new active ingredients under section 3(c)(5) or “conditional” registrations under section 3(c)(7). 7 U.S.C. §§ 136a(c)(5), (c)(7). To support either type of registration, applicants must submit or cite studies intended to identify potential effects on human health and the environment. 7 U.S.C. § 136a(c); 40 C.F.R. Part 158. EPA approves each registration only after a careful review of the submitted product data and label. *See Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995). To register a pesticide under section 3(c)(5), as EPA did here, EPA must determine that (1) the pesticide’s composition warrants the proposed claims for it, (2) the pesticide’s labeling complies with the requirements of FIFRA, (3) the pesticide will perform its intended function

“without unreasonable adverse effects on the environment,” and (4) when used in accordance with widespread and commonly recognized practice, the pesticide “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5). As relevant here, the phrase “unreasonable adverse effects on the environment” is defined within FIFRA to mean “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide.” 7 U.S.C. § 136(bb)(1).

In November 2011, Dow applied to EPA for registration of Enlist Duo under FIFRA. ER 8. On October 15, 2014, EPA granted Dow’s request and issued a registration for Enlist Duo for use in Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. *See* ER 7-8. Additionally, on March 31, 2015, EPA issued a final decision amending the registration to allow Enlist Duo use in Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, and North Dakota. *See* ER 1-2. As part of the registration, EPA required certain drift reduction measures, including a 30-foot downwind in-field buffer from “sensitive areas” in order to avoid effects on non-target organisms, including endangered plant species, located off the field. ER 34-35. “Sensitive Areas” are defined by the label as any areas other than roads, paved, or gravel surfaces; planted agricultural fields (with the exception of certain crops susceptible to the herbicide); agricultural fields that have been prepared for planting; and areas covered by the footprint of a building, shade house, green

house, silo, feed crib, or other man-made structure with walls and or roof. *See* ER 498.

In response to comments contending that EPA did not address the potential synergistic effects of Enlist Duo's two active ingredients, EPA stated that it "adequately addressed the issue of synergism between [the two Enlist Duo ingredients] by evaluating data on the chemicals individually as well as with formulation-specific information." ER 19. After reviewing that information, EPA concluded that "[g]iven that there is no indication of synergism between [the two Enlist Duo ingredients] for mammals, freshwater fish, and freshwater invertebrates, EPA believes it is reasonable to assume that there are no synergistic interactions for the taxonomic groups that were not tested, including plants." *Id.* EPA also stated that "[t]he mixture [of the two ingredients] does not show a greater toxicity compared to either parent compound alone." ER 561.

Recently, however, EPA discovered that Dow made claims of "synergistic herbicidal weed control" in its Provisional and Non-provisional patent applications for Enlist Duo. The Provisional application was filed on December 20, 2013, and the final application was filed on December 11, 2014. *See* <http://portal.uspto.gov/pair/PublicPair> (Provisional App. No. 61919135; Non-provisional App. No. 14567574); Ex. 1 (October 13, 2015, Letter from EPA to Dow). On October 13, 2015, after reviewing the patent application, EPA sent Dow a letter

pursuant to 40 CFR §159.195(c) (implementing FIFRA section 6(a)(2), 7 U.S.C. § 136d(a)(2)), advising Dow that the claimed “synergism” could affect the Agency’s assessment of drift reduction measures for avoiding impacts to non-target organisms, including those listed as endangered, and requesting all available information within 30 days of the letter. *Id.* EPA received Dow’s response on November 9, 2015. EPA is still evaluating the extensive information contained in Dow’s response, but an initial review indicates that the 30-foot buffer included in the registration may not be adequate. Ex. 2 (Declaration of Donald Brady, Ph.D. ¶¶ 11-12.) Accordingly, in light of the new information regarding the potential synergism of the two Enlist Duo ingredients, EPA seeks a voluntary remand with vacatur to reconsider the Enlist Duo registration.

ARGUMENT

Agency decisions are not carved in stone. Instead, an agency must consider the “wisdom of its policy on a continuing basis,” for example, “in response to changed factual circumstances.” *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (citations omitted). “[W]hen an agency action is reviewed by the courts the agency may take one of five positions,” one of which is “seek[ing] a remand to reconsider its decision because of intervening events outside of the agency’s control” *SKF USA, Inc. v. United States*, 254 F.3d 1022, 1027-28 (Fed. Cir. 2001); *see also California Communities Against Toxics v. EPA*, 688 F.3d 989 (9th Cir.

2012) (citing *SKF*, 254 F.3d at 1029). Indeed, courts generally only “refuse voluntarily requested remand when the agency’s request is frivolous or made in bad faith.”

California Communities, 688 F.3d at 992. “Administrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts.” *B.J. Alan Co. v. ICC*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990) (quoting *Commonwealth of Pennsylvania v. ICC*, 590 F.2d 1187, 1194 (D.C. Cir. 1978)).

Here, EPA has learned that it did not have all relevant information at the time it made its registration decision. Specifically, Dow did not submit to EPA during the registration process the extensive information relating to potential synergism it cited to the Patent Office; EPA only learned of the existence of that information after the registrations were issued and only recently obtained the information. Ex. 2 (Brady Declaration ¶¶ 4, 5, 8). EPA’s scientists have preliminarily reviewed this data over the last two weeks, and believe, based on that review, that the data indicate that the 30-foot buffer on the approved label may not be adequate to protect non-target plant species located outside the treated fields. *Id.* ¶ 11. EPA requires additional time in which to fully assess the new information. *Id.* ¶ 12.

Because EPA has become aware of previously-existing information about possible synergistic effects that it did not consider, the Agency can no longer represent to the Court that its conclusions were correct regarding whether issuance

of the registration met the standard in FIFRA and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. EPA therefore consents to vacatur as well as remand of the Enlist Duo registration. Following remand and vacatur of the Enlist Duo registration, EPA would fully evaluate the new information and determine whether a new registration could be issued and, if so, whether additional terms and conditions would be necessary for the new registration.¹ To the extent that any interested party is not satisfied with any final action on remand, that party may obtain review of that agency action in this Court in accordance with FIFRA section 16, 7 U.S.C. § 136n.

In environmental cases, to decide whether remand with or without vacatur is the appropriate remedy, a factor this Court considers is the extent to which vacatur would cause or prevent possible environmental harm. *See Pollinator Stewardship Council v. EPA*, ___ F.3d ___, 2015 WL 7003600 at *12 (9th Cir. Nov. 12, 2015) (collecting cases). In *Pollinator Stewardship*, for example, this Court concluded that because of possible adverse effects on bee populations from the pesticide at issue in the

¹ In addition to its FIFRA-related concerns, EPA seeks vacatur and remand in light of the new information that came to light in Dow's patent application in order to review its determination that Enlist Duo would have no effect on species listed as endangered or threatened under the Endangered Species Act. In particular, EPA is concerned about the potential effects of Enlist Duo on certain plant species.

registration under review, “leaving the EPA’s registration . . . in place risks more potential environmental harm than vacating it.” *Id.* In light of that consideration, and because EPA could reach a different result on remand after obtaining the studies that the Court found were lacking, this Court vacated the registration. *Id.* A similar analysis applies here in that EPA may determine that changes to the registration are necessary to adequately protect non-target plant species, including those listed as endangered.

Specifically, before EPA can register a pesticide under FIFRA, FIFRA section 3(c)(5) requires that EPA determine, in part, that the pesticide “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(D). EPA made such a finding here, supported by the 30-foot in-field buffer requirement. *See* ER 1, 8, 30, 34. However, the new information obtained from Dow calls that finding into question—the information suggests that EPA’s analysis may have understated the phytotoxicity of the product, therefore EPA can no longer be confident that Enlist Duo will not cause risks of concern to non-target organisms, including those listed as endangered, when used according to the approved label. Ex. 2 (Brady Declaration ¶¶ 10-12). And, based on the initial review of the new information, EPA believes that the 30-foot in-field buffer may not be adequate, thereby allowing a registration only on terms potentially different from those of the registration currently in effect. *Id.* Accordingly, keeping the registration in effect may

risk more environmental harm than vacating it, and it is possible that EPA's action on remand will result in a change to the registration.

A second factor courts consider in determining whether vacatur is appropriate is whether such relief (which constitutes an “interim change that may itself be changed”) would cause “disruptive consequences.” *California Communities*, 688 F.3d at 992 (quoting *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C.Cir. 1993)). While there may be some economic impacts to Dow from a vacatur, the extent of such impacts is unclear, and EPA believes that vacatur is appropriate in light of the potential environmental impacts and the fact that EPA's action on remand may result in a change to the registration. *See Pollinator Stewardship*, ___ F.3d ___, 2015 WL 7003600 at *12 (determining that vacatur is appropriate in light of potential environmental harm and fact that EPA may change registration on remand).

Thus, remand with vacatur is appropriate here. If this Court vacates this registration, EPA will then issue a cancellation order to regulate the sale, distribution, and use of existing stocks of Enlist Duo pursuant to FIFRA. *See* 7 U.S.C. § 136d(a)(1).

CONCLUSION

In summary, EPA has provided a reasonable basis for seeking voluntary remand. As the supporting EPA Declaration explains, the new information cited

above has called into question the validity of the Agency's earlier conclusion that use of Enlist Duo will not cause "unreasonable adverse effects on the environment."

Because remand with vacatur will be more protective of the environment and because EPA might not have issued the existing registration had it been aware of the potential synergy information at the time the initial registration was issued, vacatur is appropriate in this case. Thus, EPA respectfully requests that the Court vacate the Enlist Duo registration and to remand it to the Agency for further consideration.

DATED: November 24, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I served a copy of RESPONDENT'S MOTION FOR VOLUNTARY VACATUR AND REMAND via Notice of Docket Activity by the Court's CM/ECF system, on November 24, 2015, on all counsel of record:

/s/ David A. Carson
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