

No. 13-303

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IN THE  
**Supreme Court of the United States**

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ORGANIC SEED GROWERS AND TRADE ASSOCIATION,  
*et al.*,  
*Petitioners,*  
*v.*  
MONSANTO COMPANY, *et al.*,  
*Respondents.*

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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**BRIEF IN OPPOSITION**

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## QUESTION PRESENTED

Whether the court of appeals correctly ruled that petitioners' declaratory-judgment complaint—which asked the courts to declare 23 Monsanto patents invalid and unenforceable in their totality under a panoply of theories and also asked the courts to declare that petitioners were not engaging in infringing conduct—did not present a justiciable case or controversy, given that (a) petitioners disclaim any current use of, as well as any future intention to use, Monsanto's patented biotechnology, and (b) Monsanto has never enforced its patents against any petitioner, and has disclaimed any intent to enforce its patents against petitioners based on their representations about their own activities.

## **CORPORATE DISCLOSURE STATEMENT**

Monsanto Company, a publicly held corporation, has no parent corporation, and no other publicly held corporation owns 10% or more of its stock. Monsanto Technology LLC is a wholly owned subsidiary of Monsanto Company.

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**STATEMENT**

1. Monsanto Company develops, manufactures, licenses, and sells agricultural seeds, including many that incorporate innovations through biotechnology. After investing substantial time, expense, and expertise, Monsanto developed new seed technology through the identification, isolation, and carefully controlled transfer of novel genes into crop seed. These transgenic seeds give the resulting plants various beneficial traits, including herbicide tolerance, pest resistance, increased yield potential, improved nutritional content, more efficient conversion of solar energy, and drought tolerance. Perhaps the best known of these technologies is Mon-

santo's Roundup Ready<sup>®</sup> technology, which enables seeds to tolerate exposure to the herbicide glyphosate, allowing growers to control weeds by applying glyphosate to their fields without damaging their valuable crops. *See generally* *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1764 (2013); *see also* Pet. App. 5a-6a, 32a; C.A. App. A510-511.

Monsanto spends over one billion dollars annually on research and development (C.A. App. A268, A270), and to protect its significant investments in these popular technologies, Monsanto relies on the patent system. Monsanto has obtained several patents covering both traits and seeds, as well as methods for their creation and use. *See* Pet. App. 5a n.1 (listing 23 patents challenged by petitioners). Monsanto authorizes growers to use its patented biotechnology under a limited-use license, which permits a grower to plant seeds containing that technology in one season. The grower can then consume the resulting crop or sell it as a commodity, usually to a grain elevator or agricultural processor, but he may not save any of the harvested crop for replanting nor supply it to anyone else for that purpose. *See Bowman*, 133 S. Ct. at 1764-1765.

Although Monsanto has enforced its patents against growers who intentionally infringe—for example, by planting seed containing Monsanto's patented traits without obtaining a license, or by replanting harvested seed from crops containing those traits, *see, e.g., Bowman*, 133 S. Ct. at 1764-1765—Monsanto has explicitly stated its commitment not to take legal action against growers whose fields might inadvertently contain traces of Monsanto's patented traits. Monsanto's website includes "Monsanto's Commitment: Farmers and Patents," which states: "It has never been, nor will it be Monsanto policy to exercise its patent rights

where trace amounts of our patented seed or traits are present in [a] farmer’s fields as a result of inadvertent means.” Pet. App. 8a. This statement is meant to assure growers that Monsanto will not assert a patent-infringement claim where Monsanto’s patented traits might appear inadvertently (for example, through gene flow from nearby fields where biotech crops are grown, or residue from equipment that was not sufficiently cleaned) and thus are present only in minimal quantities. Pet. App. 17a. Consistent with its stated policy, Monsanto has never filed a patent-infringement lawsuit against a USDA-certified organic farm or handling operation for the presence of patented traits in its certified organic operations. Pet. App. 34a-35a.

Agricultural biotechnology such as Monsanto’s is regulated by the Department of Agriculture under the Plant Protection Act, 7 U.S.C. §§ 7701 *et seq.* The USDA has consistently concluded that safe and sustainable coexistence among organic, conventional, and biotech agriculture is possible and should be promoted. *See, e.g.*, C.A. App. A478 (U.S. Dep’t of Agriculture, Record of Decision: Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status 4 (Jan. 27, 2011)) (USDA “values and promotes coexistence ... [and its] purpose and need is to promote programs that support coexistence of all types of agricultural practices,” including biotech, conventional, and organic).

The USDA also regulates organic agriculture under the Organic Food Production Act, 7 U.S.C. §§ 6501 *et seq.*, and through the USDA’s National Organic Program, which regulates growers that wish to market agricultural products as organically produced. The USDA has specifically considered the issue of gene flow. Under its regulations, the inadvertent presence

of biotech traits in crops does not prevent organic certification, as long as organic farms and handling operations follow the appropriate production processes. Department of Agriculture, National Organic Program, 65 Fed. Reg. 80548, 80556 (Dec. 21, 2000); *id.* at 80632.

2. Petitioners are growers, growers' associations, seed businesses, and advocacy groups—claiming to represent as many as 300,000 individuals and 4,500 farms or growers—who do not wish to “possess, use or sell any transgenic seed, including any transgenic seed potentially covered by Monsanto’s patents.” Pet. App. 35a. Petitioners do not claim that they have ever used, or are using, Monsanto’s biotechnology. Monsanto has no information suggesting that any of the named petitioners has used or is using its technology, with or without authorization, and Monsanto has never claimed that any petitioner infringes its patents or indicated an intention to bring suit against any petitioner. *See* Pet. App. 11a.

Petitioners nonetheless claim to be concerned that, should genetic material containing Monsanto’s technology find its way into their operations even inadvertently, Monsanto could potentially sue them for patent infringement. *See* C.A. App. A109, A134-135, A141-142. Three among the hundreds of thousands of individuals supposedly represented by petitioners also assert that they have taken affirmative steps to avoid contact with Monsanto’s biotechnology in their operations. Petitioner Donald Patterson, a grower committed to organic agriculture, claims to have stopped cultivating alfalfa because of concerns about gene flow by transgenic alfalfa. C.A. App. A718-720.<sup>1</sup> Petitioner Fedco Seeds, a

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<sup>1</sup> Two other plaintiffs named in the amended complaint—Kirschenmann Family Farms, Inc., and Bryce Stephens—made

seed distributor that claims to have “made its reputation by having zero tolerance for transgenic” presence in its seed, asserts that it spends \$2,000 annually on testing to ensure that its seed does not contain transgenic material. C.A. App. A714-717. Petitioner Chuck Noble, a grower who does not use transgenic seed because he “believe[s] it poses a great risk for society,” claims to test seed that he purchases for the presence of transgenic material. C.A. App. A721-723.

Petitioners filed a complaint seeking a declaratory judgment that all claims of 23 Monsanto patents are invalid, unenforceable, and not infringed by petitioners, and that Monsanto would not be entitled to any remedy should infringement be proven. Pet. App. 35a. Petitioners’ amended complaint alleges that the more than 600 claims of those 23 patents “are all invalid[.]” under virtually every possible theory of invalidity available under the Patent Act. Petitioners’ “principal” argument is that all of Monsanto’s patents are invalid under 35 U.S.C. § 101 for failing to be “useful.” C.A. App. A110; *see* C.A. App. A142-151, A161. Plaintiffs, however, also broadly allege anticipation, obviousness, and double-patenting under Sections 102 and 103 of the Patent Act, and failure to satisfy the requirements of written description, enablement, and best mode under Section 112. C.A. App. A110-111, A161-162, A167-168.

The amended complaint does not allege that Monsanto’s transgenic traits have actually entered petition-

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similar statements in the district court. Kirschenmann did not join in the appeal from the dismissal, and Stephens withdrew from the appeal while it was pending, so those statements are not before this Court. *See* Pet. App. 3a (caption noting that Kirschenmann did not appeal), 27a-28a (correcting opinion to reflect withdrawal of Stephens from appeal).

ers' operations by gene flow or other inadvertent means. Petitioners likewise do not allege that Monsanto has ever contacted any of them, much less indicated an intent to bring suit, in connection with Monsanto's patents. Rather, petitioners' alleged fear of suit stems solely from Monsanto's alleged "investigation, accusation and litigation of patent infringement claims against *other* farmers," including those who allegedly "did not want to be contaminated by transgenic seed[.]" C.A. App. A155 (emphasis added).

On April 18, 2011—after the filing of the original complaint—petitioners' counsel sent a letter to Monsanto's counsel, stating that, while "none of [the petitioners] intend to possess, use or sell any transgenic seed, including any transgenic seed potentially covered by Monsanto's patents," they nonetheless fear that future "contamination" by such seed "could then subject them to claims of patent infringement by Monsanto." C.A. App. A180; *see* Pet. App. 35a-36a. Petitioners' counsel requested that "Monsanto expressly waive any claim for patent infringement it may ever have against [petitioners] and memorialize that waiver by providing a written covenant not to sue." Pet. App. 36a. He asserted that, if Monsanto did not respond, it would then be "reasonable for [petitioners] to feel that they would be at risk of having Monsanto assert claims of patent infringement against them should they ever become contaminated by transgenic seed potentially covered by Monsanto's patents." Pet. App. 36a, 43a n.6.

In a responsive letter, Monsanto's counsel reiterated that "it is not [Monsanto's] policy to exercise [its] patent rights against farmers whose fields inadvertently contain trace amounts of patented seeds or traits." Pet. App. 36a. Monsanto further assured petitioners that

Monsanto is unaware of any circumstances that would give rise to any claim for patent infringement or any lawsuit against your clients. Monsanto therefore does not assert and has no intention of asserting patent infringement claims against your clients.... Taking your representation [that petitioners did not wish to use Monsanto's biotechnology] as true, any fear of suit or other action is unreasonable....

Pet. App. 9a.

3. Monsanto moved to dismiss for lack of subject-matter jurisdiction, arguing that petitioners had failed to allege an actual case or controversy. The district court agreed with Monsanto and dismissed the case.

The district court considered whether, under *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007), "all the circumstances[] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Pet. App. 37a. It observed that petitioners "do not allege that [Monsanto has] ever demanded royalty payments from [petitioners], identified any of [petitioners'] conduct as potentially infringing, or even initiated any contact with [petitioners] whatsoever." Pet. App. 40a. Rather, the court noted, petitioners base their argument for jurisdiction on three types of alleged actions by Monsanto: (1) a purported "pattern of enforcing [Monsanto's] patent rights against non-[petitioner] farmers through litigation or threats of litigation," (2) a supposed "implicit threat' in [Monsanto's] statement that it is not their policy to enforce their patent rights against farmers whose crops inadvertently acquire trace amounts of patented seeds or traits," and (3)

Monsanto’s “refusal to provide [petitioners] with a blanket covenant not to sue.” *Id.* The district court ruled that these allegations were insufficient to establish jurisdiction.

First, although the court suggested that, in some circumstances, “suits brought by the patentee against parties other than the declaratory judgment plaintiffs may suffice to establish a case or controversy,” it found that possibility inapplicable in this case, because suits against nonparties could establish a case or controversy “only if those suits are sufficiently similar to the one that the patentee may potentially bring against the declaratory judgment plaintiffs.” Pet. App. 41a. Here, the court stressed, petitioners had failed to show that Monsanto’s prior patent infringement suits were brought against “similarly situated parties.” *See* Pet. App. 41a-42a. Although petitioners alleged that Monsanto had previously sued inadvertent users of Monsanto’s patented traits, Monsanto specifically denied that contention, and the court found that petitioners’ allegations were “belied by the decisions in the suits against the referenced individuals.” Pet. App. 42a-43a. The court further found that petitioners “overstate[d] the magnitude of [Monsanto’s] patent enforcement,” and that the handful of lawsuits Monsanto has filed against infringing growers is “hardly significant when compared to the number of farms in the United States.” Pet. App. 42a. Thus, Monsanto’s prior patent infringement suits were “at best, [] only minimal evidence of any objective threat of injury to plaintiffs” and “insufficient” to create a case or controversy. Pet. App. 43a.

Second, the district court found it “objectively unreasonable for petitioners to read [Monsanto’s Commitment] as a threat.” Pet. App. 44a. The court rejected petitioners’ “deliberate misreading” of the Commit-

ment and found that petitioners' post-filing letter to Monsanto "was clearly intended to be used as a prop in this litigation" (Pet. App. 47a) and "seems to have been nothing more than an attempt to create a controversy where none exists" (Pet. App. 45a).

Third, the district court rejected petitioners' attempt to base jurisdiction on Monsanto's refusal to provide them with a blanket covenant not to sue. The court found that the requested waiver "was so broadly framed as to preclude any realistic chance of [Monsanto's] acceptance," especially since it asked Monsanto "to accept as wholly accurate the complaint's description of [petitioners'] activities and intentions." Pet. App. 47a.

The district court also considered the contention that certain petitioners already were suffering "immediate injury" because they had "stopped farming certain crops for fear of patent infringement suits brought by defendants." Pet. App. 48a n.8. The court found these assertions insufficient because the alleged fear of patent litigation by Monsanto was "not reasonable based on the objective words and actions of the patentee." *Id.* (internal quotation marks omitted). In addition, the court noted, "the relevant concern is of *infringement*, not simply altered behavior." *Id.* (emphasis added). Thus, even if petitioners might have changed their farming practices because they were concerned about avoiding possible gene drift from transgenic seeds or crops, petitioners had not shown that it was reasonable for them to fear that they would be sued for patent infringement by Monsanto.

The court therefore dismissed the matter for lack of subject-matter jurisdiction: "[t]aken together, it is clear that these circumstances do not amount to a sub-

stantial controversy and that there has been no injury traceable to defendants.” Pet. App. 50a-51a.

4. The court of appeals affirmed the dismissal. Pet. App. 1a-24a. The court of appeals held that no case or controversy was present “[b]ecause Monsanto has made binding assurances that it will not take legal action against growers whose crops might inadvertently contain traces of Monsanto biotech genes,” and petitioners “have not alleged any circumstances placing them beyond the scope of these assurances.” Pet. App. 4a-5a (internal quotation marks omitted).

Applying *MedImmune* and other recent decisions of this Court concerning Article III jurisdiction, including *Clapper v. Amnesty International USA*, 133 S. Ct. 1138 (2013), and *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010), the court of appeals considered whether petitioners “have demonstrated a ‘substantial risk’ that the harm [of being found liable for patent infringement in an enforcement action brought by Monsanto] will occur, which may prompt [them] to reasonably incur costs to mitigate or avoid that harm.” Pet. App. 11a (first bracketed language added). The court assumed, for purposes of its decision, that (1) petitioners might theoretically be subject to patent-infringement liability if they inadvertently used trace amounts of Monsanto’s patented technology in their operations (Pet. App. 13a-14a), and (2) petitioners’ operations would inevitably come into contact with pollen or seeds from genetically modified crops or other sources (Pet. App. 15a-16a). But “[d]espite this possibility of infringement,” the court nonetheless ruled that Monsanto’s representations that it will not bring an infringement suit based on the inadvertent presence of trace amounts of its genetic material “moot any potential controversy.” Pet. App. 16a, 18a.

Although the court noted that Monsanto had not given petitioners a blanket covenant not to sue—given that Monsanto had no factual information about petitioners’ operations and the covenant petitioners demanded would effectively immunize them from suit even if they changed their operations to include growing crops containing Monsanto’s technology—it stressed that Monsanto “has given them something equally effective”: its commitment, placed on its website and reiterated by counsel during this litigation, that it will not take legal action based on the inadvertent presence of trace amounts of transgenic seed or genes. Pet. App. 17a. Those representations, the court stressed, “unequivocally disclaim any intent to sue [petitioners]” based on their assertions about the nature of their operations. Pet. App. 18a. The court concluded that, although Monsanto’s representations “are not a covenant not to sue, they have a similar effect,” because, given the court’s reliance on those representations, principles of judicial estoppel would preclude Monsanto from changing its position in a future case and suing petitioners for patent infringement if they were only inadvertently using trace amounts of Monsanto’s biotechnology. *See* Pet. App. 19a-20a.

The court identified some ambiguity in the scope of Monsanto’s commitment in that it extended to “trace” amounts of genetic material. Pet. App. 20a. The court concluded that, because Monsanto had disclaimed an intent to sue USDA-certified organic farms, which are prohibited from using transgenic seed, and because various (non-USDA) organic seed and product certification standards use a level of “approximately one per-

cent” to define trace amounts,<sup>2</sup> Monsanto’s commitment should be construed to disclaim suit against inadvertent users or sellers of seeds that contain “up to one percent of seeds carrying Monsanto’s patented traits.” Pet. App. 18a-19a. In light of that commitment, the court concluded that no petitioner had established a reasonable apprehension of being held liable to Monsanto in a patent-infringement suit, because no petitioner had alleged that its operations contained more than one percent of transgenic material or that it was taking any steps that put would it above that threshold. *See* Pet. App. 21a.

The court also rejected petitioners’ argument that Monsanto’s “refusal to provide a blanket covenant not to sue” had a “chilling effect” that forced petitioners “to forgo farming or other seed distribution activities that they otherwise would very much like to pursue.” Pet. App. 22a. The court acknowledged that, “[u]nder some circumstances, forgoing activities or taking costly precautions may be reasonable responses to a substantial risk of future harm, and may therefore be cognizable injuries.” *Id.* But the court concluded that this case does not present that circumstance, because the possibility that petitioners might grow greater than trace amounts” of transgenic seed *and* “be sued for infringement by Monsanto” “is too speculative to justify their present actions.” Pet. App. 23a.

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<sup>2</sup> USDA’s standards for organic certification are process-based and do not employ a numerical disqualification for organic certification. Other organizations, such as the Non-GMO Project, use levels of approximately one percent presence of transgenic material. *See, e.g.*, <http://www.nongmoproject.org/learn-more/understanding-our-seal/> (employing an “Action Threshold” of 0.9%).

Finally, the court observed that petitioners' concerns about exposure to transgenic material are fundamentally environmental in nature or rooted in other financial worries not related to patent infringement. Thus, the court noted that petitioners had taken precautions against transgenic presence in their operations "for purposes other than avoiding suit (i.e., to maintain organic certification)." Pet. App. 23a. None of those harms, the court stressed, "is traceable to Monsanto's enforcement of its patents"; those harms "could not be remedied by a declaratory judgment, and they cannot serve as a basis for jurisdiction in this case." Pet. App. 23a-24a.

### ARGUMENT

The lower courts, faithfully applying the framework this Court set forth in *MedImmune* for determining whether a declaratory judgment action presents a justiciable case or controversy, concluded that petitioners' complaint does not. Those rulings are plainly correct.

Although petitioners claim to be concerned that their operations might inadvertently come into contact with transgenic material, petitioners have not established a patent dispute—*i.e.*, that they have a reasonable, legitimate concern that Monsanto might attempt to assert its patents against them should that inadvertent contact occur. Petitioners adamantly state that they do not desire to make use of Monsanto's biotechnology, and Monsanto has no information that they are doing so. Indeed, Monsanto has assured petitioners that, taking as true their representations about their activities, they have no reason to fear patent enforcement by Monsanto.

Petitioners are attempting to manufacture a patent dispute where one does not exist. Petitioners plainly have a policy disagreement with transgenic agriculture, but their claimed concern about potential *patent-infringement* liability does not satisfy the fundamental requirement for Article III jurisdiction: an actual controversy. Neither the Constitution nor the Declaratory Judgment Act gives federal courts the power to issue opinions about policy disagreements based on hypothetical disputes.

**I. THE LOWER COURTS CORRECTLY CONCLUDED THAT THERE IS NO JUSTICIABLE CASE OR CONTROVERSY BETWEEN THE PARTIES**

The decisions of the district court and court of appeals reflect an unexceptionable application of this Court’s declaratory-judgment jurisprudence. This Court’s decision in *MedImmune* requires a declaratory-judgment plaintiff to demonstrate that “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune*, 549 U.S. at 127. *MedImmune* further explains that “the dispute [must] be ‘definite and concrete’” and “admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *Id.* (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937)); *see also* 28 U.S.C. § 2201 (requiring an “actual controversy”).

Further, as the lower courts recognized (*see* Pet. App. 23a, 37a-38a), to establish Article III standing, a declaratory-judgment plaintiff must show that it is presently suffering or will imminently suffer a “person-

al injury fairly traceable to the defendant’s allegedly unlawful conduct[.]” *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726 (2013) (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). Where the plaintiff’s alleged injury is that it has been forced to alter its behavior in response to the defendant’s legal claim or position, the plaintiff must show that that claim or position—and not some other independent factor—is causing the altered behavior. *See MedImmune*, 549 U.S. at 130 (discussing “situations in which the plaintiff’s self-avoidance of imminent injury is coerced by *threatened enforcement action*” (emphasis added)); *see also Clapper v. Amnesty Int’l USA*, 133 S. Ct. 1138, 1150-1153 (2013); *Already*, 133 S. Ct. at 730-731. Otherwise, the alleged injury will not be “redressed by a favorable decision.” *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)). This Court therefore has required the plaintiff to demonstrate that its avoidance efforts were a “reasonable” response to a “concrete,” “particularized,” and “imminent” risk of harm from a potential enforcement action by the defendant. *See Clapper*, 133 S. Ct. at 1147, 1150 n.5 (collecting cases).

Petitioners have failed to meet their burden of establishing a justiciable controversy in this case. *See Clapper*, 133 S. Ct. at 1148-1149; *Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 570-571 (2004). Petitioners have consistently conceded that Monsanto has not asserted—and could not currently assert—a patent-infringement claim against any of them, because no petitioner is using Monsanto’s biotechnology. *See* Pet. 6; C.A. Opening Br. 15. Petitioners also expressly disclaim any intent to plant transgenic crops. Further, Monsanto has repeatedly stated that it knows of no basis to sue petitioners and has no intention to do so. C.A. App. A183, A255. Petitioners therefore have no basis

to claim that Monsanto will seek to enforce its patents against them. Moreover, although petitioners allege that they have been injured by their efforts to avoid gene flow of transgenic material into their crops, the record makes clear that they undertake these efforts for reasons independent of any fear of patent liability to Monsanto. Thus, petitioners' actions to avoid gene flow are insufficient to confer declaratory-judgment jurisdiction.

**A. There Is No Concrete Patent Dispute Between The Parties**

Petitioners do not allege having conducted *any* past or present infringing activity. Indeed, petitioners explicitly profess that they do *not* currently make, sell, or use Monsanto's patented technology, and that they have no desire to do so in the future. Pet. 2; Pet. App. 7a; C.A. Opening Br. 15. And despite alleging that more than 600 claims of 23 separate Monsanto patents are entirely invalid, unenforceable, and not infringed, petitioners fail to specify which of these claims they fear they might someday be accused of infringing. C.A. App. A144, A152-153. Petitioners' vague and speculative concerns about future patent enforcement by Monsanto thus fall well short of demonstrating a "definite" and "concrete" controversy under the federal patent laws.

Petitioners do not—and cannot—claim that their alleged fear of patent enforcement is based on any action taken by Monsanto against any petitioner. As petitioners concede, Monsanto has never initiated, threatened, or even suggested any patent-enforcement action against any of the petitioners here. Pet. App. 11a (petitioners "concede that Monsanto has never specifically alleged that [petitioners] infringe its patents, nor

threatened suit against them”). Indeed, when petitioners’ original complaint was filed, Monsanto had no information whatsoever about petitioners or their farming and seed operations. And since this action was initiated, Monsanto has repeatedly told petitioners that Monsanto has no reason, desire, or intent to enforce its patents against them (*see* C.A. App. A183, A255; Pet. App. 17a)—assurances that the Federal Circuit has held to be “binding as a matter of judicial estoppel.” Pet. App. 17a-19a, 24a.<sup>3</sup> Without any basis to conclude that Monsanto will move to enforce its patents against any them, petitioners certainly have no basis to demand that Monsanto go even further and provide them and all of their thousands of members with an “unconditional and irrevocable” covenant not to sue.<sup>4</sup>

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<sup>3</sup> Although Monsanto does not dispute that its assertions to petitioners in this case are binding, Monsanto neither proposed nor conceded (*contra* Pet. App. 18a) that “trace amounts” can be no greater than one percent. That figure was offered by petitioners’ counsel on rebuttal at oral argument. *See* C.A. Oral Arg. Recording, at 37:11-38:32, *available at* <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2012-1298.mp3>.

<sup>4</sup> Monsanto’s unwillingness to provide a covenant not to sue to the “more than 300,000 individuals and 4,500 farms or farmers” allegedly represented by the petitioners is entirely reasonable. C.A. Opening Br. 1. Monsanto has no information about petitioners beyond what they have alleged in their complaint, nor could it predict what individuals and entities might choose to join the petitioner organizations in the future. A blanket covenant not to sue any present or future member of petitioners’ organizations would enable virtually anyone to commit intentional infringement. No authority suggests Monsanto must give a license to infringe in the future in order to avoid a lawsuit by parties who in the present claim no intent to practice its patents and with whom Monsanto has no dispute.

Nor can petitioners establish a concrete patent dispute based on Monsanto's history of patent assertion against *other* parties. Although Monsanto filed approximately 13 lawsuits per year between 1997 and 2010—a figure the district court found to be “hardly significant” when compared to the millions of farms in the United States—every one of those suits was based on allegations of *deliberate* use of Monsanto's patented technology. As Monsanto's counsel explained below, Monsanto has “never brought legal action ... against somebody who didn't want to make use of the traits that are manifested in [Monsanto's] transgenic products.” C.A. App. A835(10:3-5). That is consistent with Monsanto's publicized policy that it will not “exercise its patent rights where trace amounts of [its] patented seed or traits are present in [a] farmer's fields as a result of inadvertent means.” *See* C.A. App. A508, A512-513.

Moreover, as the district court found (Pet. App. 42a-43a), publicly available information undermines petitioners' contention that Monsanto targets inadvertent users of its biotechnology. Petitioners refer to four supposedly inadvertent users that Monsanto has sued, but two of those—Maurice Parr and Percy Schmeiser—were found by courts to be *intentionally* infringing and inducing infringement. *See, e.g., Monsanto Co. v. Parr*, 545 F. Supp. 2d 836, 844 (N.D. Ind. 2008); *Monsanto Can. Inc. v. Schmeiser*, 2001 FCT 256 [120] (Can.); *Monsanto Can. Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 ¶¶ 87, 97 (Can.). The other two cases similarly involved licensees of Monsanto's patented technology who Monsanto alleged were intentionally planting second-generation seed in violation of their licenses. *See Monsanto Co. v. Nelson*, 2001 U.S. Dist. LEXIS 25132, at \*2 (E.D. Mo. Sept. 10, 2001); Pet. App. 42a-43a (discussing news coverage of Roush litigation). Thus, all the al-

leged lawsuits over supposedly inadvertent infringement did not in fact involve allegations of inadvertent use; to the contrary, they involved allegations of deliberate activity. Moreover, those lawsuits are vanishingly few in number and remote in time from the present. *See* Pet. App. 42a-43a. Thus, Monsanto's prior patent-enforcement actions involving other, *dissimilar* parties do not establish a concrete threat of similar action against these petitioners.

Petitioners fail to put forward any plausible reason why Monsanto would pursue its patent rights against growers like petitioners, who have no desire to use the technology of the 23 Monsanto patents at issue. C.A. App. A835(10:2-5). Because such growers do not apply herbicides such as glyphosate directly to their crops, any inadvertent presence of Monsanto's patented genetic material in their fields would provide no benefit to those growers, and any damages that Monsanto could collect for such minimal use would be trivial and not worth the cost of a patent suit. Nor, as a practical matter, could Monsanto even detect such minimal use of its technology. *See* Pet. 3. Petitioners' suggestion that Monsanto will someday assert its patents against them—contrary to Monsanto's policy and economic incentives—is purely speculative.<sup>5</sup>

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<sup>5</sup> Petitioners also argue (Pet. 9-10) that the Federal Circuit's post-*MedImmune* declaratory-judgment jurisprudence is generally not faithful to that decision, but that contention provides no basis for review in this case. The Federal Circuit in this case relied almost entirely on Supreme Court precedent—not Federal Circuit precedent—in reaching its decision. *See* Pet. App. 18a-23a (relying heavily on *Already* and *Clapper*). Moreover, in each instance where the Federal Circuit did cite a Federal Circuit decision with which petitioners take issue, it relied on it only for the most basic propositions that petitioners themselves do not dispute. *See* Pet.

### **B. The Actions Of A Few Petitioners To Avoid Gene Flow Do Not Establish Declaratory-Judgment Standing**

Unable to assert any concrete patent dispute with Monsanto under *MedImmune*, petitioners attempt to reframe the central inquiry as one of “standing,” in which petitioners’ “injury” is *not* the risk of patent-enforcement action by Monsanto, but rather, the costs petitioners have already incurred to avoid gene flow from Monsanto’s patented products, *e.g.*, by forgoing the farming of certain crops or by undertaking genetic testing of seed supplies (Pet. 10-11). But even when viewed through the lens of standing, petitioners’ complaint falls well short of establishing a justiciable case or controversy.

To establish Article III standing, petitioners’ alleged injury must be (1) concrete, particularized, and actual or imminent; (2) fairly traceable to Monsanto’s challenged action; and (3) redressable by a favorable ruling. *See Clapper*, 133 S. Ct. at 1147. Moreover, petitioners cannot rely on “self-inflicted injuries” to establish their standing: the alleged injury must have been “reasonably incur[red]” in response to a “concrete,” “particularized,” and “certainly impending” risk of “future harm” from Monsanto’s patent-enforcement activities. *See id.* at

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App. 11a (citing *Matthews Int’l Corp. v. Biosafe Eng’g, LLC*, 695 F.3d 1322 (Fed. Cir. 2012), solely for the general proposition that the jurisdictional inquiry “must be calibrated to the particular facts of each case”); Pet. App. 12a n.3 (citing *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), solely for the proposition that “an amorphous, ‘widespread understanding’ of a risk of suit is not sufficient” to establish declaratory-judgment jurisdiction). This case therefore presents no occasion for this Court to review any supposed divergence between this Court’s decisions and Federal Circuit law.

1147, 1150-1153 (rejecting alternative “injury” theory based solely on costs incurred to avoid government enforcement of surveillance statute, where the “future harm” of government action was merely “speculative” and “not certainly impending”)<sup>6</sup>; *Laird v. Tatum*, 408 U.S. 1, 13-14 (1972) (rejecting allegations of a “subjective ‘chill’” on First Amendment rights as an inadequate substitute for a claim that a party “has sustained, or is immediately in danger of sustaining, a direct injury as the result of [defendant’s enforcement] action”).

Petitioners have failed to establish these fundamental prerequisites to standing. First, their alleged injuries—their alleged actions taken to avoid genetic drift—are not a “reasonable” response to the highly remote possibility of liability for patent infringement. As the Federal Circuit held, the risk that petitioners “will grow greater than trace amounts” of Monsanto’s patented seed *and* “be sued for infringement by Monsanto” is “too speculative to justify their present actions.” Pet. App. 22a-23a. Second, because petitioners have reasons to avoid gene flow that are entirely independent of any potential patent liability to Monsanto, petitioners’ avoidance actions are likewise not “fairly traceable” to Monsanto, nor could the requested declarations redress petitioners’ alleged “injury” of having to undertake costly avoidance measures.

As explained in Section I.A above, there is no “concrete,” “particularized,” or “certainly impending” risk of “future harm” from Monsanto’s patent-enforcement activities. As an initial matter, petitioners do not sug-

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<sup>6</sup> In *Clapper*, this Court explained that, while literal “certainty” may not be required, the declaratory-judgment plaintiff must at least establish a “substantial risk” that harm will occur as a direct result of the defendant’s enforcement action. 133 S. Ct. at 1150 n.5.

gest that they have ever experienced gene flow into their fields of more than a trace amount. Rather, in arguing that they someday “will experience contamination over 1%,” petitioners cite only a single study, conducted in Canada, regarding non-organic varieties of a single crop (canola) that none of the remaining declarants professes to grow or sell.<sup>7</sup> Pet. 15 (citing C.A. App. A630-651). Such general statistics regarding gene flow—untied to the situation of any particular petitioner’s location, crops, or practices—are insufficient to demonstrate an imminent threat to *these petitioners’* crops or seed.<sup>8</sup> It is entirely speculative whether any petitioner would experience gene flow affecting more than 1% of his fields—much less that such gene flow would involve *Monsanto’s* patented genes.

Moreover, it is insufficient for petitioners to establish that gene flow in more than a trace amount is imminent (which they cannot do). To establish standing in this context of an intellectual property dispute—where petitioners seek to be shielded from the prospect that they might be found liable to Monsanto for patent infringement and therefore seek invalidation of all of Monsanto’s patents—petitioners must demonstrate

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<sup>7</sup> See C.A. App. A714-715 (discussing only corn, soybeans, alfalfa, sweet corn, and beets), A718-720 (discussing only alfalfa), A721 (discussing only alfalfa and wheat).

<sup>8</sup> Nor does that single study establish that gene flow above 1% is “certainly impending” in any sense. Only 3 of the 27 unique seed lots sampled exhibited gene flow of over 2% (and only 1 of 13 *conventional* canola seed lots—the others were genetically modified varieties). The remaining lots exhibited significantly smaller percentages of gene flow—ranging from 0.05% to 0.67%. See C.A. App. A638-640, A649-651. The authors of the study further acknowledged that “it is unlikely that pollen flow would cause greater than 0.1% contamination in a single generation of pedigreed seed production.” C.A. App. A640.

that their alleged injury is caused by a concrete threat of *patent-enforcement action* by Monsanto.<sup>9</sup> Petitioners cannot do so here. *Even if* the threat of gene flow to petitioners' crops or seed is itself sufficiently imminent absent petitioners' precautionary measures, and *even if* such gene flow will reach more than trace levels, petitioners cannot establish that *patent-enforcement action* by Monsanto against any petitioner is imminent—or even remotely likely. *See supra* Section I.A.

This Court made clear in *Clapper* that parties “cannot manufacture standing by incurring costs in anticipation of non-imminent harm. *Clapper*, 133 S. Ct. at 1155. As in *Clapper*, none of the petitioners here can satisfy “the highly attenuated chain of possibilities” necessary to demonstrate an imminent threat of harm from potential Monsanto action, and petitioners' efforts, allegedly undertaken out of “fear” of such harm, are insufficient to establish Article III standing. *Id.* at 1148, 1152; *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983) (“It is the *reality* of the threat of [] injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions.”); *Laird*, 408 U.S. at 13-14 (“speculative apprehensiveness” of enforcement action “at some future date” is insufficient to create an Article III case or controversy).

Furthermore, petitioners' actions to avoid gene flow cannot constitute an injury that is “fairly traceable” to Monsanto or “redressable by a favorable deci-

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<sup>9</sup> *See MedImmune*, 549 U.S. at 128-130 & n.8 (describing the “threat of harm” or “complained-of injury” as the potential suit by respondents to enjoin petitioner's sales if petitioner stopped paying royalties); *cf. Already*, 133 S. Ct. at 730-732 (describing the declaratory-judgment claimant's “only legally cognizable injury” as its opponent's efforts “to enforce its trademark”—the removal of which eliminated any injury and mooted the case).

sion,” because no petitioner has shown it has taken any action that it would not have taken in the absence of Monsanto’s patent rights. To the contrary, the declarations and amended complaint underscore that these petitioners would continue to test seed for transgenic traits or avoid planting certain crops *regardless* of potential patent liability to Monsanto, because they have philosophical or economic reasons to avoid contact with transgenic material to the greatest extent possible.

For example, petitioner Fedco professes that it has a business policy and a reputation for having “zero tolerance” for transgenic traits in its seed, and “[t]his zero tolerance policy has contributed significantly to [its] success.” C.A. App. A716. Likewise, petitioner OS-GATA has a policy “that transgenic contamination of organic seed constitutes irreparable harm to the organic seed industry ... and that any detectable level is unacceptable.” C.A. App. A113. Petitioner Noble similarly states that he “purposefully do[es] not use genetically engineered (GE) seeds” and “do[es] everything [he] can to avoid having *any* contact with Monsanto’s GE alfalfa seed, as [he] believe[s] it poses a great risk for society.” C.A. App. A721 (emphasis added); *see also* C.A. App. A720 (Patterson, discussing his “lifelong commitment to the organic agricultural ideal,” his “dedication to food integrity,” and the “economic considerations” which require him to pursue farming activities that are not “ultimately doomed” to experience gene flow). In addition, although the National Organic Program does not withhold “certified organic” status as a result of inadvertent gene flow, organic growers and handling operations are nevertheless required to “take[] reasonable steps to avoid contact with [any] products of excluded methods,” including transgenic seed. Department of Agriculture, National Organic

Program, 65 Fed. Reg. 80548, 80556 (Dec. 21, 2000); *see also id.* (“Organic operations have always had to worry about the potential for drift from neighboring operations.... It has always been the responsibility of organic operations to manage potential contact of organic products with other substances not approved for use in organic production systems[.]”). And no petitioner has alleged that it will immediately begin farming the avoided crops or cease genetic testing of seed if granted a declaration of patent invalidity or noninfringement.

Petitioners argue that the Federal Circuit “used [their] efforts to avoid infringement against them” (Pet. 16), but there is no substance to that contention. The Federal Circuit correctly held that petitioners had failed to allege any concrete plans to engage in activity that would lead them “to use or sell greater than trace amounts of modified seed” and thus place them “outside the scope of Monsanto’s binding disclaimer.” Pet App. 21a. In reaching that conclusion, it properly relied upon petitioners’ own representations that they “us[e] their best efforts to avoid” gene flow because they “do not want to use or sell transgenic seed” for various business and personal reasons *even apart from* the possibility of patent-enforcement action by Monsanto. *Id.* (quoting C.A. App. A108-109). Because petitioners profess to avoid gene flow for reasons that are entirely *independent* of any threat of suit by Monsanto—and thus, may *never* (let alone imminently or even “some day”) cease their avoidance efforts—the Federal Circuit properly declined to assess the likelihood of gene flow in the entirely hypothetical event that petitioners *did* cease such efforts.

Any harm petitioners claim to have experienced from their voluntary actions is not concretely connected to any alleged patent dispute, and the relief petitioners

request would not eliminate that alleged coercion. In fact, petitioners' requested relief—which includes a declaration of invalidity of Monsanto's patents—could well *increase* the use of Monsanto's biotechnology, which then would be freely available to growers for use without any patent-law restrictions. This would only increase any perceived need for testing or avoidance of planting particular crops. The Federal Circuit thus correctly affirmed the district court's dismissal of this action for lack of subject-matter jurisdiction. Pet. App. 23a-24a.

## II. PETITIONERS' PHILOSOPHICAL OPPOSITION TO BIOTECHNOLOGY GIVES THEM NO BASIS TO INVOKE THE JURISDICTION OF THE FEDERAL COURTS TO ADVOCATE THEIR VIEWS

Petitioners have an obvious disagreement with United States policy permitting agricultural biotechnology under appropriate circumstances. They disagree with the judgment of Congress and the U.S. Patent and Trademark Office, which this Court has affirmed, that transgenic plants are patentable subject matter. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145-146 (2001). And petitioners are unhappy that government agencies such as the USDA have repeatedly affirmed the benefits and safety of these products and permitted their use in the United States. Neither the Patent Act nor the Declaratory Judgment Act, however, makes a patent-infringement case in the federal courts a proper forum for petitioners' anti-biotechnology campaign.

This Court should therefore decline petitioners' invitation to "usurp the powers of the political branches." *Clapper*, 133 S. Ct. at 1146-1147. Federal agencies like the USDA, EPA, and FDA—through the powers

granted to them by Congress and the President—are expressly charged with addressing the core policy issues underlying petitioners’ lawsuit.<sup>10</sup> And petitioners’ “principal” invalidity argument—that all 600-plus claims of 23 Monsanto patents are invalid under Section 101 because they may be “injurious” to society (C.A. App. A110)—involves policy questions that must be directed to Congress, which is better positioned than this Court to evaluate petitioners’ concerns. *See Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980); *see also Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F. 3d 1364, 1366-1368 (Fed. Cir. 1999).

The Declaratory Judgment Act does not give courts power to issue opinions on broad policy issues based on hypothetical disputes. The constitutional requirement of a case or controversy “assure[s] that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action.... The federal courts have abjured appeals to their authority which would convert the judicial process into no more than a vehicle for the vindication of the value interests of concerned bystanders.” *Valley Forge Christian Coll. v. Americans United for Separation of Church &*

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<sup>10</sup> *See, e.g.*, Executive Office of the President, Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23302, 23302 (June 26, 1986); *see also* C.A. App. A493 (U.S. Dep’t of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services, Program Aid No. 1862, *Coordinated Framework for the Regulation of Biotechnology 2-3* (Apr. 2006)) (“Together, [the USDA, EPA, and FDA] ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment.”).

*State, Inc.*, 454 U.S. 464, 472-473 (1982) (internal quotation marks omitted).

**CONCLUSION**

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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