

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ORGANIC SEED GROWERS AND
TRADE ASSOCIATION, et al.,
Plaintiffs,

v.

MONSANTO COMPANY AND
MONSANTO TECHNOLOGY LLC
Defendants.

Case No. 1:11-cv-2163-NRB-RLE

ECF Case

BRIEF FOR AMICI CURIAE

**Farm and Ranch Freedom Alliance, Biodynamic Farming and Gardening Association,
Carolina Farm Stewardship Association, Ecological Famers of Ontario, Fair Food Matters,
International Organic Inspectors Association, Michigan Land Trustees, Natural
Environment Ecological Management, Nebraska Sustainable Agriculture Association,
Organic Council of Ontario, Slow Food USA, and Virginia Independent Consumers and
Farmers Association**

**IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO
DISMISS**

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STATEMENT OF INTEREST OF *AMICI CURIAE*

This case presents several issues of first impression, and the outcome will have repercussions for almost every American. While the Plaintiffs are at the most immediate risk of suit for patent infringement by Monsanto, the legal principles involved in this Court's decision will have even broader ramifications. For example, livestock and poultry farmers who feed grain to their animals face issues of GM-contaminated feed. Organic certifiers must make decisions about whether or not, and under what conditions, to require testing for GM contamination as part of the certification process. Food processors, whether they operate on a large-scale or simply bake a few loaves of bread for a local farmers market, use ingredients that may be contaminated with Monsanto's patented products. And, ultimately, almost every American consumer somehow makes use products made from corn, soybeans, canola, sugar beets, or cotton, all of which may implicate the scope and enforceability of Monsanto's patents. The entire food chain is impacted by the spread of Monsanto's patented crops.

Amici organizations include members who feed grain to livestock and poultry, who certify organic production of crops, who use grains or cotton as raw ingredients for other products, and who consume or use products made from these crops. Some of the members of *Amici* are in privity with the affected farmers, either by buying their crops or otherwise conducting business with them such as through organic certification of the crops. All of these individuals have an interest in having the scope and enforceability of Monsanto's patents determined by this Court, both because of the direct issue of their own liability and because of the indirect impact the decision will have on the availability of these crops.

The Farm and Ranch Freedom Alliance (FARFA) advocates for farmers, ranchers, and homesteaders to assure their independence in the production and marketing of their food,

including their right to farm without fear of prosecution for patent infringement. FARFA also advocates for consumers' access to information and resources to obtain healthy foods of their choice, including mandatory labeling of genetically modified (GM) foods.

The Biodynamic Farming and Gardening Association (BDA) is a nonprofit membership association of individuals and organizations in North America who are committed to the transformation of the whole food system, from farm to table, and who draw inspiration from the spiritual-scientific insights of Rudolf Steiner. The BDA's membership includes biodynamic farmers and seed growers who are at risk of being contaminated by genetically modified seed, as well as farmers who feed such crops to their livestock and make other uses of such crops.

Carolina Farm Stewardship Association's (CFSA) mission is to promote local and organic agriculture in the Carolinas by inspiring, educating and organizing farmers and consumers. CFSA is deeply committed to advancing the interests of organic producers in the Carolinas and strenuously opposes any corporate action that would unfairly threaten, hinder, limit, or otherwise impose additional costs on organic agriculture operations. CFSA's membership includes farmers, gardeners, consumers and businesses in North and South Carolina. These members are committed to sustainable agriculture and the development of locally-based, organic food systems.

The Ecological Farmers of Ontario (EFO) develops and provides programs to promote the practice and advancement of ecological agriculture to maintain and enhance the health of the soil, water, crops, livestock and the diversity of the environment. As organic and ecological farmers, committed to growing crops which are free from contamination by genetically modified organisms, its members face the burdens of maintaining buffer zones around corn crops, genetic testing of corn crops and ensuring all equipment from seed cleaning to harvest to storage is free

of any potential GM contamination for both corn and soybeans. With the release of GM alfalfa in the U.S., Ontario's ecological farmers are becoming ever more concerned about the potential genetic contamination of their crops and livestock feed.

Fair Food Matters (FFM) is a Michigan-based nonprofit organization that helps increase awareness of and appreciation for local foods and organic and sustainable production. In doing so, FFM is helping consumers make better choices about what to feed themselves, their families and their communities, and helping those who produce that food to enjoy safe working conditions and a living wage.

The International Organic Inspectors Association (IOIA) is a nonprofit, professional association of organic farm, livestock, and processing inspectors that provides comprehensive organic inspector training worldwide. IOIA promotes consistency and integrity in the certification process, and addresses issues and concerns relevant to organic inspectors, including promoting public confidence in organic agriculture and products. IOIA also serves the Organic Sector by working closely with numerous regional, state, provincial, and international certification agencies, as well as with governmental agencies and IFOAM (International Federation of Organic Agricultural Movements), to develop policies and publications relating to organic inspection and inspector training.

Michigan Land Trustees (MLT) promotes sustainable land management and organic agriculture. MLT helps educate small-scale homesteaders and beginning farmers, while also supporting the development of local and organic-based food systems by providing start up grants to a variety of organizations and projects. Its diverse membership favors the preservation of biodiversity—especially of non-GM crop seeds—as a key element of the social and ecological resilience that is needed to address the challenges of peak oil and climate change.

Natural Environmental and Ecological Management (NEEM) believes that no company should be allowed to irrevocably manipulate the DNA make up of any natural item and commodities level products that make up our basic food supply. NEEM has conducted research that indicates GM crops are unhealthy for humans and damaging to the infrastructure that supports an already fragile industrial food system.

The Nebraska Sustainable Agriculture Society's (NSAS) mission since the 1970's has been to promote agriculture and food systems that build healthy land, people, communities & quality of life, for present and future generations. NSAS has a diverse membership that includes farmers and ranchers, rural and urban consumers, market gardeners, educators, families and restaurateurs.

The Organic Council of Ontario is a membership-based trade organization championing organics in Ontario. A full value-chain organization, OCO has a deep interest in this court case. Many of our members, and the broader organic sector in general, are impacted along the value chain — from seed supplier to producer to processor to retailer — by the inappropriate application of patents for GMOs in food production.

Slow Food USA is a national nonprofit that believes in protecting the diversity of life, including seeds. Slow Food represents a network of both farmers and consumers who are concerned that patents on seed violate several basic truths and who support the rights of farmers to control their own farms.

The Virginia Independent Consumers and Farmers Association's (VICFA) mission is to promote and preserve unregulated direct farmer-to-consumer trade that fosters the availability of locally grown of home-produced food products. VICFA believes Monsanto's patented seeds work contrary to the achievement of its goals.

SUMMARY

Monsanto has a track record of aggressive enforcement of its patent rights. Monsanto has sued or settled with hundreds of farmers, and investigated unknown numbers more. Because of the nature of Monsanto's patented seeds, the individual Plaintiffs and the farmer members of Plaintiff organizations (hereinafter collectively "Plaintiff farmers") cannot avoid infringing on Monsanto's patents unless they entirely abandon growing corn, soybeans, canola, cotton, sugar beets, and, as of this year, alfalfa. While Monsanto tries to downplay the threat of enforcement by pointing to its "commitment" not to sue farmers for "trace" infringement, this provides no enforceable protections for Plaintiffs. Because of the nature of the patented seeds and the realities of farming, it is certain that at least some of the Plaintiff farmers already have more than trace contamination, and the number of such affected farmers will only grow over time. While many of the Plaintiff farmers are certified organic, not all are, so the simple fact that Monsanto has yet to sue a certified organic farmer has no impact on their standing.

Not only does Monsanto's patented technology inevitably lead to infringement through no fault of the Plaintiffs, but, by their design, the majority of Monsanto's patented crops only provide the alleged benefits if a farmer applies herbicides, specifically Roundup®, directly to the crop. Monsanto could easily protect its patent rights by agreeing not to sue for unintentional contamination absent an affirmative action by the farmer to make use of the patented traits. By failing to do so, and instead offering an ambiguous and ultimately meaningless commitment, Monsanto has made it clear that it intends to maintain the threat of patent infringement lawsuits against Plaintiff farmers and those similarly situated.

Plaintiff farmers have, by the simple act of farming corn, soybeans, canola, cotton, sugar beets, or alfalfa crops, undertaken meaningful steps towards infringement. Due to Monsanto's

decision to release patented seeds and market them for widespread planting, it is now impossible for farmers to remain 100% free of genetically modified crops because of the multitude of ways that contamination can occur.

Given the difficulties in minimizing GM contamination, farmers must make numerous decisions about which steps are worthwhile for them and which steps are not. They are not able to make these decisions based on their own and their customers' interests, but must instead make these decisions with the threat of litigation against a giant corporation looming over their heads. The constant threat of a patent infringement suit by Monsanto creates significant, unquantifiable costs for the Plaintiff farmers and similarly situated farmers. Unless this Court allows this case to proceed, the Plaintiff farmers will face the choice of abandoning growing such crops or risking prosecution whenever Monsanto chooses.

ARGUMENT

Monsanto's motion to dismiss notes that its patented technology is self-replicating. *See* Monsanto Br. at p.5. Yet Monsanto wants the court to ignore the real-world repercussions of this fact. Monsanto seeks to reap all of the benefits of a patented seed – particularly the necessity for farmers to buy their products year after year indefinitely, since new seed is needed every single year – but to take no responsibility for the reality that its technology, by its very nature, induces others to infringe.

In *MedImmune*, the Supreme Court recognized that the test for standing to bring suit under the Declaratory Judgment Act involved an analysis of “all the circumstances.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127, 127 S.Ct. 764, 771 (2007). Following *MedImmune*, the Federal Circuit has held that, to establish an injury in fact traceable to the

patentee, a declaratory judgment plaintiff must allege both (1) an affirmative act by the patentee related to the enforcement of his patent rights, *SanDisk Corp. v. STMicroelecs., Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007), and (2) meaningful preparation to conduct potentially infringing activity, *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008). As the Federal Circuit recently stated, “no bright-line rule exists for determining whether a declaratory judgment action satisfies Article III’s case-or-controversy requirement.” *Association for Molecular Pathology v. Myriad Genetics*, No. 2010–1406, 2011 WL 3211513, at *9 (Fed. Cir. 2011) (citing *MedImmune*).

A. Monsanto Has Taken Affirmative Action to Enforce Its Patent Rights.

By patenting a self-replicating product, one virulent in its spread, Monsanto has created a situation in which it can pick and choose targets for enforcement activity. Monsanto has, by its own admission, implemented an aggressive campaign to enforce its patent rights. According to Monsanto’s website, in the section addressing lawsuits against farmers for patent infringement, the company has filed 128 lawsuits and settled “almost 700 matters” out of court. *See E. Freeman, Settling the Matter - Part 5*, MONSANTO, Nov. 11 2008, <http://www.monsanto.com/newsviews/Pages/Settling-the-Matter-Part-5.aspx> (last visited Aug. 1, 2011). Monsanto states that only a “rare few choose to seek a resolution in the courts,” which would logically imply that it has conducted hundreds, if not thousands, of additional investigations. *See E. Freeman, Monsanto Seed Police?*, MONSANTO, Nov. 10 2008, <http://www.monsanto.com/newsviews/Pages/Seed-Police-Part-4.aspx> (last visited Aug. 1, 2011). Only Monsanto knows how many farmers it has investigated or the harm caused to these farmers.

Monsanto cites *Creative Compounds, LLC v. Starmark Laboratories*, No. 2010–1445, 2011 WL 25195313 (Fed Cir. 2011), in support of its assertion that the court should require

plaintiffs to show action by the patentee directed at the plaintiffs themselves. *See Monsanto Br.* at p.14. But *Creative Compounds* does not stand for such a broad, bright-line rule. Rather, *Creative Compounds* stands for the narrow proposition that one cannot bring a declaratory judgment action to invalidate a patent merely for **economic** gain, such as invalidating a potentially competing patent to reassure one's customers. *See* 2011 WL 25195313 at *11-12.

In contrast, in the case before this Court, there is a clear dispute over legal rights, namely whether Monsanto is legally able to enforce its patent rights against the Plaintiffs. There is an underlying legal cause of action that the declaratory judgment defendant (Monsanto) could bring or threaten to bring, if not for the fact that the declaratory judgment plaintiffs had preempted it. *See Arris Grp., Inc. v. British Telecomm. PLC*, 639 F.3d 1368, 1374-75 (Fed. Cir. 2011).

As discussed in detail below, many Plaintiff farmers undoubtedly have a non-negligible level of GM contamination in their fields because it is simply impossible to remain 100% GM free if one is growing corn, canola, soybeans, cotton, sugar beets, or alfalfa. The exact level of contamination is often unknown because most farmers do not test, possibly in fear of treble damages imposed on "willful" infringers. But, whether they test or not, they remain vulnerable to a patent infringement suit by Monsanto, creating a legal dispute that is properly addressed through the Declaratory Judgment Act.

B. Monsanto's Pledge Not to Sue for "Trace Contamination" is Neither Enforceable Nor Meaningful.

Monsanto seeks to have the court ignore its track record of aggressive enforcement based on an unenforceable "commitment" that Monsanto's policy is to not sue "where trace amounts of our patented seeds or traits are present in [a] farmer's fields as a result of inadvertent means." *Monsanto Br.* at p.5. The term "trace," however, is ambiguous and unenforceable. Are Plaintiffs and other farmers to assume it means less than 0.9%, the standard in the European Union to

avoid labeling? Two percent? Five percent? Given the realities of farming, as discussed next, it is certain that at least some of the Plaintiff farmers already have contamination that exceeds any of those levels. Moreover, the passage of time and natural biological processes will inevitably lead to higher contamination levels, at which point Monsanto will have created a target-rich environment for its patent enforcement activities.

As a hypothetical, Farmer Smith buys soybean, corn or canola seed from a local seed dealer. Even if the seed is not labeled as GM, there is a very high probability that it is already contaminated to some degree. As another district court found:

Monsanto's domination of the soybean seed market, combined with the regeneration of the Roundup Ready® trait and the lack of any restriction against the mixing of soybeans harvested from a Roundup Ready® crop from those that are harvested from a crop that was not grown from Roundup Ready® seed, has resulted in the commodity soybeans sold by grain dealers *necessarily carrying the patented trait* ...

Monsanto Co. v. Bowman, 686 F. Supp. 2d 834, 836 (S.D. Ind. 2009) (emphasis added). See also **Attachment E**, L.F. Friesen et al., *Evidence of Contamination of Pedigreed Canola (Brassica napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits*, 95 AGRONOMY J. 1342-1347 (2003); **Attachment F**, B.L. Ma et al., *Extent of Cross-Fertilization in Maize by Pollen from Neighboring Transgenic Hybrids*, 44 CROP SCI. 1273-1282 (2004). Assume a relatively low level of contamination of 0.5%. Farmer Smith plants the seed in a 20-acre field without a significant buffer zone because, as discussed below in Section E, the recommended buffer zones are too expensive. His neighbor plants a GM variety of the same crop, and cross-pollination causes an additional 2% of Farmer Smith's field to be contaminated. Cf. **Attachment G**, PETER THOMISON, OHIO STATE UNIVERSITY EXTENSION, FACT SHEET, MANAGING "POLLEN DRIFT" TO MINIMIZE CONTAMINATION OF NON-GMO CORN (2004),

available at <http://ohioline.osu.edu/agf-fact/0153.html>. (noting that research has indicated that a buffer of 660 ft is needed to limit cross-pollination to 1% or less).¹

Farmer Smith, unaware of the now 2.5% contamination in his field, decides to save seed for next year and hires a local seed cleaner. The seed cleaner does not perfectly clean his machinery in between fields and has some GM grains from a previous field caught in his machinery when he comes to Farmer Smith's farm, adding another 0.5% of contamination. The saved seed now has 3% contamination. If Farmer Smith sells some of the seed, additional contamination can occur due to the transport vehicles and storage facilities. If Farmers Smith plants his saved seed next year, he *starts* with 3% GM contamination, which is then subject to cross-pollination and other vectors of contamination, even though he has never intentionally planted and has always avoided GM seed.

If Farmer Smith tests his seed and finds out that he has 3% contamination, he faces a dilemma. He must choose between planting the contaminated seed (and risking a patent infringement lawsuit by Monsanto, with potentially treble damages for willful infringement since he now knows of the contamination), or disposing of all the seed, a significant loss, and seeking out uncontaminated seed at significant trouble and expense.

The dilemma is inescapable because there is no effective way for a farmer to save seed only from the non-GM portion of his field because the plants intermingle. There are two ways to detect GM contamination. The first is to test a sample of the grain. Such testing will tell the farmer whether or not there is GM contamination, but it will *not* enable the farmer to segregate the GM portion from the non-GM portion because, in order to be a representative sample, the sample must include grains from multiple plants from throughout the field. The second way to

¹ One acre equals 43,650 square feet. A 20 acre-field is 934' x 934', so the recommended buffer zone on two sides would encompass the entire field.

determine GM contamination is to spray Roundup® on the field, killing everything *except* the GM Roundup-Ready® plants and leaving the farmer with no non-GM grain or seed. For farmers wishing to avoid planting GM crops, this second option is entirely counter-productive. Moreover, it only works with crops engineered to be resistant to herbicides, not insecticide-producing GM crops. Thus, Monsanto's threatened enforcement of its patent rights places the burden on the farmer not only to test the seed, but to then either risk a patent infringement suit or bear significant burdens to find non-contaminated seed.

By its very nature, GM technology contaminates non-GM crops. Efforts by the farmers, undertaken at significant expense and burden, can only minimize contamination, not stop it completely. As the contamination compounds, it is reasonable to ask how long it will take for the farmer to have 10% or 20% contamination in his fields, whether he is saving his own seed or buying increasingly contaminated seed because no commercial company can guarantee 100% non-GM seed. At what point does Monsanto contend that this is no longer "trace" contamination, even though it occurred entirely without the farmer's knowledge or intent? Monsanto's pledge not to sue for "trace" contamination is meaningless given the real-world conditions farmers operate under.

By patenting a self-replicating product, one virulent in its spread, Monsanto has created a situation in which infringement is a certainty and occurs at ever-increasing levels. By deliberately keeping their pledge vague, Monsanto perversely expects human error and biological realities to compound the amount of contamination to the point where seed contamination is substantial and near-universal, making infringement unavoidable. A product that, by its very nature, creates inevitable infringement is a case of first impression, and Plaintiffs

have a concrete, tangible, and immediate need to know the scope of their legal rights such that they can plan their activities accordingly.

C. Monsanto's Claim to Have Never Sued a Certified Organic Producer Also Does Not Protect the Plaintiffs

Monsanto expands on its so-called commitment by noting that it has never sued a certified organic producer for GM contamination. But bringing a suit is the final step in a long process that can be used to intimidate and harass farmers, starting with investigations, accusations, harassment, and the threat to file a suit. *Cf. Monsanto v. Scruggs*, 342 F. Supp.2d 602, 605-06 (N.D. Miss. 2004) (Monsanto's investigator placed defendant under video and binocular surveillance, followed defendant and his family members, and questioned defendant's customers). Monsanto can cause significant harm to the Plaintiff farmers without ever filing a lawsuit.

Moreover, certified organic farmers already must answer to their certifiers. While the organic regulations technically require only that certified organic farmers not knowingly plant GM seed, certifiers may spot-check crops and, if GM contamination is found, require the farmer to take steps to reduce contamination. Moreover, certified organic farmers face significant economic losses if they cannot sell their crops as certified organic, or have to pull land out of the program. So they would have a potentially expensive counter-claim against Monsanto for the loss of organic markets from contamination, making it logical that Monsanto has so far hesitated to sue a certified organic producer. *Cf. Johnson v. Paynesville Farmers Union Coop. Oil Co.*, Nos. A10-1596 & A10-2135, 2011 WL 2982473 (Minn. Ct. App., July 25, 2011) (holding that a pesticide applicator was liable to a certified organic producer for damages for trespass connected with the loss of certification). Note that Monsanto has not actually committed that it won't sue certified organic farmers in the future, but merely states that it has not yet done so.

Even if Monsanto were to make an enforceable commitment (which it has not), thousands of farmers would then face the choice of risking infringement suits or becoming certified organic simply to avoid lawsuits. Many farmers around the country are not certified organic, but use organic and sustainable practices. Many other farmers raise conventional crops but have no desire to raise GM crops. Neither category of farmers should be forced to become certified organic, with its attendant expenses and burdens, simply in the hopes of avoiding a patent lawsuit. Monsanto's restraint in the courtroom so far with respect to certified organic farmers does not protect Plaintiff farmers from liability.

D. Monsanto Could Have Offered Enforceable Protections While Still Protecting Its Patent Rights, and Chose Not To.

The ambiguity and narrowness of Monsanto's alleged assurances become even more apparent when considered against the backdrop of the technology at issue. All of Monsanto's GM soybeans and the majority of its other GM crops have been modified to confer resistance to herbicides, specifically Roundup®. See U.S. DEPARTMENT OF AGRICULTURE, ECONOMIC RESEARCH SERVICE, ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S., <http://ers.usda.gov/data/BiotechCrops/adoption.htm> (providing a graph of the adoption of different GM varieties and noting that "soybeans have only HT varieties"). This trait is only useful when the vast majority of the crop is GM. Consider a farmer whose corn field is 50% contaminated with GM Roundup-Ready® corn. If he or she were to spray Roundup® – which is the way Monsanto intends for its technology to be used – then the half of the crop that is **not** GM Roundup-Ready® would be killed along with the weeds.

Amici fully agree with the Plaintiffs that Monsanto's patented technology does far more harm than good. But, just for purposes of this argument over standing, assume that the GM traits confer the benefits Monsanto claims for its products. A farmer gets *none* of those benefits unless

his crop is almost entirely GM. Even when the contamination reaches 30% or 40%, the farmer is unable to make use of it even if he or she is using chemical herbicides. And organic farmers, who do not use Roundup, never receive any benefit at all from Roundup-Ready® crops, even assuming Monsanto's claims were true.

Monsanto is well aware of the uses of its own technology. So why would it limit its alleged assurance not to sue to "trace" contamination when the inadvertent infringer receives absolutely no benefits far past that point? Monsanto could still protect its patent rights by suing only those farmers who make affirmative use of its GM traits, such as by spraying a field with Roundup® and harvesting the resulting crop. Instead, Monsanto has chosen to maintain the threat that it will sue whether or not the farmer intended to use the patented product and whether or not the farmer makes any actual use of the GM traits.

Monsanto's ambiguous, unenforceable pledge does not counter the affirmative steps it has taken in aggressively investigating and harassing farmers for alleged patent infringement.

E. Plaintiff Farmers Have Undertaken Meaningful Preparation to Conduct Potentially Infringing Activity.

Unlike most patented products, patented seeds are not self-limiting. They will, by their very nature, spread even to land where no patented seeds were ever planted. The simple act of farming a wide variety of crops, such as corn, soybeans, canola, cotton, sugar beets, or alfalfa, involves meaningful, if inadvertent, steps towards infringement of Monsanto's patents. In all likelihood, many of Plaintiff farmers have significant levels of GM contamination already in their fields, although they may not have tested for it and definitely do not desire it. While the fault for such GM contamination lies with Monsanto's decision to create and market this self-replicating, uncontrollable technology, the patent doctrine of strict liability means that the farmers still face liability.

Many farmers take steps to avoid contamination because they affirmatively wish to avoid any presence of GM in their crops. Contrary to Monsanto's claims in support of their products, there is a growing body of evidence on the problems caused by both the GM crops themselves and the resulting over-use of the herbicide Roundup®. For example, a recent evaluation of studies on crops genetically modified to produce the insecticide *Bacillus thuringiensis* ("Bt")² in India concluded that the studies, which Monsanto claimed supported the safety of its crops, "ignored toxic endpoints" that may have significant implications for human health. Rats fed the GM grain showed damage to the animals' ovaries, livers, and immune systems. See **Attachment A**, L. GALLAGHER, BT BRINJAL EVENT EE1: THE SCOPE AND ADEQUACY OF THE GEAC TOXICOLOGICAL RISK ASSESSMENT: REVIEW OF ORAL TOXICITY STUDIES IN RATS (2010) at p.2. Another recent review of the studies on GM crop feeding trials found that the trials used "controversial protocols" and ignored statistically significant results indicating the potential for chronic diseases in the liver and kidney. See **Attachment B**, G. Seralini et al., *Genetically Modified Crops Safety Assessments: Present Limits and Possible Improvements*, ENVTL SCI. EUR. 2011, 23:10. The active ingredient of Roundup®, glyphosate, has been found to cause damage to human embryonic and placental cells, and to make plants more susceptible to disease. See **Attachment C**, N. Benachour et al., *Time- and Dose-Dependent Effects of Roundup on Human Embryonic and Placental Cells*, ARCH. ENVTL. CONTAM. TOXICOL. 53, 126-133 (2007); **Attachment D**, G.S. Johal and D.M. Huber, *Glyphosate Effects on Diseases of Plants*, 31 EUR. J. AGRONOMY 144-152 (2009).

For these and other reasons unrelated to patent liability, many people are not interested in including Monsanto's products in the food chain. Unfortunately for both farmers and

² Strains of the bacteria *Bacillus thuringiensis* ("Bt") produce proteins, known as Bt toxins, that are toxic to certain crop-destroying insects.

consumers, however, avoiding GM contamination is effectively impossible. While Monsanto's brief leaves the impression that avoiding contamination is simple and easy, GM contamination can occur at any stage of the food chain as a result of both natural processes and human intervention: from seed production to crop growing to harvesting to cleaning to storage and transport. To minimize contamination, a farmer must undertake expensive and burdensome measures at every step of production:

- 1) having the seed tested;
- 2) implementing buffer zones to avoid cross-pollination;
- 3) paying for extra time and equipment to ensure that the harvester and cleaner do not contaminate the crop from previous jobs;
- 4) testing after harvest to check for contamination from events such as seed blowing from a passing truck (a frequent occurrence in an agricultural area);
- 5) paying to have the truck cleaned prior to hauling non-GM grain to market;
- 6) paying extra for special storage or storing the grain on the farm after harvest.

Consider the cost of just one of these steps, the buffer zone. According to the Ohio State University Extension, for corn, a buffer zone of 660 feet is required to limit cross-pollination to 1% or less. With a buffer zone of less than 165 feet, the Extension recommends removal of several rows of corn. The actual impact on a small farmer raising 20 acres of corn is significant. Incorporating a 165-foot buffer zone on two sides of a 20-acre field would result in the loss of the use of 35% of that field.³ The alternative, according to the Extension, is to remove 16 border rows on each side, resulting in losses from the expense of planting that corn, harvesting it

³ One acre equals 43,650 square feet. A 20 acre-field is 934' x 934'. Incorporating a 165' buffer zone on two sides would reduce the field to 604' x 934', or 564,136 sq. ft or 12.9 acres.

separately and disposing of it. *See Attachment G*, PETER THOMISON, OHIO STATE UNIVERSITY EXTENSION, FACT SHEET, MANAGING “POLLEN DRIFT” TO MINIMIZE CONTAMINATION OF NON-GMO CORN (2004), available at <http://ohioline.osu.edu/agf-fact/0153.html>.

And even with these extensive precautions, GM contamination cannot be wholly prevented. For example, gene flow from a GM bentgrass patented by Scotts was observed to have spread as far as 21 kilometers (13 miles) away from the experimental plantings in the direction of prevailing winds. *See Attachment H*, L.S. Watrud et al., *Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker*, PROC. NAT’L ACAD. SCI. U.S. 101: 14533-14538 (2004). *See also* U.S. ENVIRONMENTAL PROTECTION AGENCY, WIND MOVES POLLEN WITH ALTERED GENETIC TRAITS BEYOND FIELDS OF EXPERIMENTAL BENTGRASS, <http://www.epa.gov/wed/pages/news/04Nov/lead.htm>. In Canada, testing of canola seeds from “certified seedlots” revealed GM contamination in all but one seedlot, with approximately 10% of the seedlots showing “very high levels” of contamination, namely greater than 2.0%. *See Attachment E*, Friesen et al. at p.9-10. Notably, the seed samples in the Canadian study were taken in 2002, when only 40% of the Canadian canola was estimated to be GM, and the pedigreed crops were required to have extensive isolation distances to try to minimize contamination. *See* Friesen et al. at p.3 & 11. In contrast, 94% of all soybeans, 90% of all cotton, and 88% of all corn planted in the U.S. is currently genetically modified, vastly increasing the probable extent and levels of contamination. *See* U.S. DEPARTMENT OF AGRICULTURE, ECONOMIC RESEARCH SERVICE, ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S., <http://ers.usda.gov/data/BiotechCrops/adoption.htm>.

The biological reality is that a farmer who raises corn, cotton, soybeans, canola, sugar beets, or alfalfa cannot reliably avoid infringing on Monsanto’s patent. The farmer is left with a

choice: risk infringement or refrain from raising these crops at all. That is precisely the type of dilemma that the Declaratory Judgment Act is meant to address. *See MedImmune*, 127 S.Ct. at 773, 549 U.S. at 130 (“The dilemma posed by that coercion – putting the challenger to the choice between abandoning his rights or risking prosecution—is a ‘dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.’”).

CONCLUSION

This problem is of Monsanto’s making. By developing a product that is self-replicating, and then marketing it to farmers across the country, Monsanto has ensured that no farmer can entirely avoid infringing. Monsanto has chosen to exploit this problem by an aggressive pattern of enforcement that has left farmers across the country in fear of an enforcement lawsuit even if they have no desire or intent to use the patented seeds. These farmers are placed in the position of abandoning growing valuable crops or investing significant time and effort in protective measures to try to minimize contamination. In the latter case, no matter what measures they take, the farmers still face the threat of a patent infringement lawsuit because of the impossibility of remaining completely GM-free. It is critical for both these farmers and for all the parties involved in the food chain, including the *Amici*, that this Court consider this case and provide a clear declaration of their rights.

Respectfully submitted,

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