In The Supreme Court of the United States

MONSANTO COMPANY, et al.,

Petitioners.

v.

GEERTSON SEED FARMS, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF AMICI CURIAE CROPP COOPERATIVE;
MONTANA ORGANIC ASSOCIATION; NATIONAL
COOPERATIVE GROCERS' ASSOCIATION;
NATIONAL ORGANIC COALITION; ORGANIC
FARMING RESEARCH FOUNDATION; ORGANIC
SEED ALLIANCE; ORGANIC SEED GROWERS
AND TRADE ASSOCIATION; ORGANIC
TRADE ASSOCIATION; WESTERN
ORGANIC DAIRY PRODUCERS ALLIANCE;
UNITED NATURAL FOODS, INC.; ANNIE'S, INC.;
CLIF BAR & COMPANY; EDEN FOODS, INC.;
NATURE'S PATH FOODS, INC.; PURIST FOODS,
INC.; STONYFIELD FARM, INC.; AND STRAUS
FAMILY CREAMERY IN SUPPORT OF RESPONDENTS

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| reports/risky-business.pdf |
| Cal/West Seeds, CW News, Winter Issue 2010, available at http://www.regulations.gov/search/Regs/home.html#docketDetail?R=APHIS-2007-0044 (Docket Item No. APHIS-2007-0044- |
| 7617.2) |
| Consumer Reports National Research Center, <i>Organic Food Poll</i> (February 8, 2010), <i>available</i> <i>at</i> http://greenerchoices.org/pdf/OrganicFood%20 |
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INTEREST OF THE AMICI CURIAE

Amici are commercial and public interest members of the organic community, as either growers of organic grains, fruits, or vegetables; organic livestock owners; sellers of organic products; or organizations dedicated to the integrity of the organic label. As stakeholders whose livelihood or interests will be harmed by the release of Petitioner Monsanto's genetically engineered ("GE") alfalfa into the environment, amici have a strong interest in presenting their concerns regarding the unrestricted use of product lines J101 and J163 (collectively, Roundup® Ready Alfalfa or "RRA"), especially regarding their own or their members' ability to choose to produce or sell organic products. Thus, amici urge the Court to uphold the decision of the Ninth Circuit prohibiting the planting of RRA until the government has completed its Environmental Impact Statement ("EIS") and the U.S. Department of Agriculture ("USDA") has issued a new decision on whether to deregulate RRA based on the EIS.

¹ All parties have consented to the filing of this brief, and the consent letters are on file with the Clerk in accordance with Supreme Court Rule 37.2(a). No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici*, their institutions, or their counsel made a monetary contribution to its preparation or submission.

Amicus CROPP Cooperative is the nation's largest farmer-owned cooperative, with over 1,600 organic farmers located in 30 states. CROPP Cooperative's members include certified organic dairy farmers, beef and pork producers, and feed crop growers, all of which rely on the availability of certified organic alfalfa. CROPP Cooperative markets certified organic products under the brands Organic Valley Family of Farms® and Organic Prairie Family of Farms®. CROPP Cooperative's members face a significant decline in the marketability of organic products and a significant increase in production costs should RRA contaminate organic alfalfa crops.

Amicus Montana Organic Association ("MOA") is a nonprofit organization that provides education, information, and assistance to organic producers, processors, and related parties. MOA's members depend on ample supplies of certified organic alfalfa, and wish to grow crops and livestock feed without the threat of contamination by RRA.

Amicus National Cooperative Grocers' Association ("NCGA") is a business services cooperative that helps unify co-ops to optimize operational and marketing resources, strengthen purchasing power, and offer more value to natural food co-op shoppers. It comprises 114 food co-ops nationwide, with members operating more than 145 stores in 32 states with combined annual sales of nearly \$1.2 billion. NCGA supports consumers' right to have access to organic foods free from GE contamination, and believes that RRA stands not only

to compromise that right but also the integrity of the organic label.

Amicus National Organic Coalition ("NOC") is a national alliance of farmer and rancher associations, environmentalists, consumer and food safety groups, and progressive industry members involved in organic agriculture and in upholding the integrity of the organic label. NOC believes the integrity of the organic label and the ability of its members to meet consumer expectations and foster organic markets are dependent upon the exclusion of GE products, ingredients, and methods from organic products.

Amicus Organic Farming Research Foundation ("OFRF") is a national charitable foundation dedicated to the widespread adoption and improvement of organic farming systems. OFRF's policy objectives are to ensure that the public and policymakers are well informed about organic farming issues and to increase public institutional support for organic farming research and education. OFRF supports organic farmers' rights to grow and sell their products without the threat of contamination by GE products. By charter, the majority of OFRF's Directors are certified organic producers.

Amicus Organic Seed Alliance ("OSA") is a nonprofit organization with a mission to support the ethical development and stewardship of seed. OSA accomplishes its goals through advocacy, education, and research with organic farmers and other agricultural professionals. Amicus Organic Seed Growers and Trade Association ("OSGATA") is the trade association for organic seed farmers, breeders, companies, and supporters. OSGATA develops, protects and promotes the organic seed trade and its growers, and strives to ensure that the organic community has access to high quality organic seed. OSGATA believes that organic seed is the foundation of organic crop agriculture and that the integrity of the organic industry rests upon the availability of organic seed free from GE product contamination.

Amicus Organic Trade Association ("OTA") is the membership-based business association for the organic industry in North America focused on issues impacting organic agriculture and its products. OTA believes that organic stakeholders' livelihoods will be harmed by the release of GE alfalfa into the environment.

Amicus Western Organic Dairy Producers Alliance ("WODPA") is a membership organization whose mission is to preserve, protect, and ensure the sustainability and integrity of organic dairy farming across the West. WODPA believes that GE contamination of alfalfa will severely curtail the availability of organic hay used as forage to feed organic dairy cows, and will result in catastrophic impacts on the organic dairy industry and WODPA's member farmers.

Amicus United Natural Foods, Inc. ("UNFI") is the nation's leading distributor of natural, certified organic, and specialty foods with sales of nearly \$4 billion annually in the United States. UNFI operates 20 distribution centers serving 17,000 retail locations, and fears that its ability to meet market demand for products reliably free of GE organisms is at risk from the introduction of RRA.

Amicus Annie's, Inc. produces natural and certified organic food under two brands, Annie's Homegrown and Annie's Naturals. Annie's is concerned that customer expectation for certified organic foods to be completely free of genetically modified ingredients will be eroded by the introduction of RRA, threatening its business.

Amicus Clif Bar & Company is the leading maker of organic, natural energy bars and healthy snacks in North America. Clif Bar & Company is committed to protecting the integrity of the organic supply chain, from the farmer to the consumer, and its business depends on the availability of certified organic products.

Amicus Eden Foods, Inc. is the oldest natural foods company in the United States and the largest independent manufacturer of dry grocery organic foods. To satisfy customer demands, Eden Foods has been burdened with the enormous and costly responsibility of avoiding genetically modified organisms. Eden Foods believes the introduction of RRA will only increase this burden.

Amicus Nature's Path Foods, Inc. is North America's largest certified organic breakfast cereal manufacturer. Nature's Path is affected by organic consumer opinion, and believes consumer demand for its products will be impacted should organic alfalfa become contaminated by RRA.

Amicus Purist Foods, Inc. produces natural and certified organic food under the brand name White Mountain Foods. Purist Foods relies on certified organic milk to produce its line of organic yogurt, and fears that widespread introduction of RRA will lead to a significant decrease in the availability of certified organic milk as organic alfalfa supplies become contaminated.

Amicus Stonyfield Farm, Inc. is the largest organic yogurt manufacturer in the world, and the third largest yogurt brand in the U.S. Stonyfield Farm purchases certified organic milk from the member farmers of amicus CROPP Cooperative, and fears that the economic viability of its business will be in peril if supplies of organic alfalfa become contaminated by RRA.

Amicus Straus Family Creamery produces delicious, high quality certified organic dairy products from the Straus family dairy and two other organic dairy farms in California. Straus Family Creamery relies on organic alfalfa for feed, and is concerned that introduction of RRA will lead to widespread contamination of organic alfalfa supplies and weaken the integrity of the organic label.

SUMMARY OF ARGUMENT

Petitioner Monsanto Company ("Petitioner") wishes to sell a product unregulated in the market place, without concern that the product will, by Petitioner's own acknowledgement, contaminate the

products of a successful, \$25 billion industry. Petitioner desires this Court overturn the careful, cautious decision of the lower courts requiring the USDA to take a hard look at this question of contamination before allowing the unregulated sale of Petitioner's product. The role of the courts is to assure that government agencies avoid decisions which unintentionally harm existing stakeholders. In this case, the lower courts clearly found that the agency had not undertaken the requisite review, and that without that review, it would be irresponsible to allow the unregulated sale of Petitioner's products.

Petitioner's dual lines of RRA were developed by inserting a gene into an alfalfa plant. This gene was developed in a laboratory, and it makes the final product lines resistant to another one of Petitioner's products, a glyphosate herbicide marketed as Roundup®. Conventional alfalfa has no natural resistance to Roundup, but RRA can survive the herbicide application which is then used to kill all surrounding weeds.

This case raises important issues of the ability of courts to prevent irreparable harm to commercial stakeholders, such as *amici*, through the issuance of injunctive relief. In this case, Respondents Geertson Seed Farms and Trask Family Seeds, along with a number of environmental groups, filed suit in district court challenging the USDA's decision to deregulate Petitioner's RRA without issuing the requisite EIS under National Environmental Policy Act ("NEPA") for "major Federal actions significantly affecting

the quality of the human environment." 42 U.S.C. § 4332(2)(C). Based on an extensive review of the record, the district court concluded that the USDA, acting through the Animal and Plant Health Inspection Service ("APHIS") violated NEPA by failing to take the necessary "hard look" at the significant environmental consequences of deregulating RRA. As the district court correctly recognized, APHIS inadequately explained why cross-pollination of conventional and organic alfalfa by RRA would not create a significantly harmful impact on the environment. Pet.App. 38a. In particular, the district court pointed towards a number of decisional inadequacies: APHIS "made no inquiry into whether those farmers who do not want to grow genetically engineered alfalfa can, in fact, protect their crops from contamination, especially given the high geographic concentration of seed farms and the fact that alfalfa is pollinated by bees that can travel more than two miles," Pet.App. 38a; APHIS failed to consider whether, for climaterelated reasons, organic farmers might be forced to harvest forage alfalfa during a time when alfalfa seed might be subject to cross-contamination, Pet.App. 39a; and APHIS failed to adequately consider the effects on organic farmers' ability to continue to exercise their choice in marketing organic products. Pet.App. 40a.

The district court then issued a permanent injunction order, again evaluating the extensive record and ultimately concluding that "plaintiffs have sufficiently established irreparable injury and that the balance of the equities weighs in favor of

maintenance of the status quo and against allowing the continued expansion of the RRA market pending the government's completion of the EIS." Pet.App. 60a-79a. In reaching this conclusion, the district court recognized that contamination of organic crops by RRA has already occurred, and that this contamination "cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa." Pet.App. 71a. Moreover, the district court balanced the equities to all potential stakeholders, comparing the loss of anticipated revenue to Monsanto and farmers who desire to plant RRA against the harm faced by organic growers, Pet.App. 72a, and rejecting the argument that the use of RRA would promote the use of less-toxic herbicides, given the fact that most conventional forage alfalfa is grown without the use of any herbicides. Pet.App. 74a-75a.

The district's court's order was carefully tailored. It avoided expanding its injunction to encompass either RRA already planted in reliance on APHIS's deregulation decision, or even the harvesting and sale of already planted RRA seed, Pet.App. 76a, but instead limited its injunctive relief to future plantings of RRA – that is, a "maintenance of the status quo." Pet.App. 64a. Again, this decision was based on a comprehensive balancing of the equities involved in this case, considering the "drastic" nature of completely prohibiting the use of previously planted RRA. Pet.App. 76a.

The Ninth Circuit upheld this permanent injunction, recognizing the extensive review that the

district court already applied. Pet.App. 87a-88a. The Ninth Circuit observed that the district court engaged in the "traditional balance of harms analysis," Pet.App. 91a, and recognized that a NEPA violation alone was insufficient to establish irreparable harm. Moreover, the Ninth Circuit pointed out that the district court had found that existing instances of genetic contamination² demonstrated that some injunctive relief was warranted, "though narrower than the blanket injunction sought by the plaintiffs," Pet.App. 91a, and that the district court comprehensively balanced the hardships to Monsanto and GE growers against the harm faced by organic growers, consumers, and members of the public interested in a reasoned study of the impact of the deregulated use of RRA. Pet.App. 92a.

The Ninth Circuit's decision should be upheld.

² As the Ninth Circuit observed, the plaintiffs presented "declarations from seed growers whose crops had been contaminated with the Roundup Ready gene and scientists who opined that genetic contamination is likely to occur." Pet.App. 88a.

ARGUMENT

I. THE ORGANIC FOODS INDUSTRY FACES CATASTROPHIC MARKET COLLAPSE FROM THE SPREAD OF GENETICALLY ENGINEERED ALFALFA.

Since the dawn of agriculture – save for the last fourteen years - mankind has grown a variety of conventional crops with remarkable success without the use of transgenic organisms. Until the widespread introduction of synthetic fertilizers, herbicides and pesticides in the mid-twentieth century, all agriculture was in a sense "organic" because it relied upon natural biological processes for the successful propagation of crops for food. In this way, agriculture sustained human life for millennia before the introduction of genetically modified seed varieties such as RR alfalfa. The "relatively young . . . agricultural biotechnology industry," Brief of Amici American Farm Bureau, et al., at 21, represents a recent departure from the methods of crop production that farmers, retailers, and consumers have long successfully expected.

Today, markets and consumers clearly differentiate between "organic" and "conventional" products, and organic products comprise one of the fastest growing market segments in agriculture. JA 407, 823-25. Overall annual sales of certified organic products have approached \$25 billion in recent years, and the growth rate for organic foods remained in the double digits for the eleventh straight year in 2008. Organic Trade Association, 2009 Organic Industry Survey 2,

available at http://www.ota.com/pics/documents/01a_OTAExecutiveSummary.pdf. A stroll down the aisles of even the most widely recognized supermarkets reveals that certified organic foods have evolved from a small niche market to a mainstream, economically significant industry. Farmers, food processors, and retailers receive a price premium for certified organic products; alfalfa growers, for example can reap a 40% to 50% premium for certified organic alfalfa, up to \$200 per acre. JA 139, 988. CROPP Cooperative members receive similar premiums for certified organic milk. JA 646-47.

Organic dairy farming is central to this national growth, as consumer demand has driven a steady increase in production. Nationwide, the number of certified organic cows grew by an annual average of 25 percent between 2000 and 2005. The organic dairy industry has surpassed \$1 billion in annual sales for the past several years, and the sale of organic milk alone was \$750 million in 2007. U.S. Department of Agriculture, National Agricultural Statistics Service, Organic Production Survey 175 (2008), available at http://www.agcensus.usda.gov/Publications/2007/Online_ Highlights/Organics/ORGANICS.pdf. Amicus CROPP Cooperative, which sells certified organic milk under the brand name Organic Valley® and to third parties, saw certified organic milk sales reach \$333 million in 2007. JA 646.

Consumers choose organic products in large part due to the decreased environmental impact of organic production. *See, e.g.*, Organic Trade Association, Consumer Profile Facts, http://www.ota.com/organic/mt/

consumer.html. Organic agriculture results in decreased off-farm inputs; reduced use of pesticides; and increased biodiversity through a holistic production management system. Indeed, the very definition of organic production is a system that integrates "cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity." 7 C.F.R. § 205.2. These ecological benefits lie at the core of the organics industry and drive consumer choices.

The continuing viability of this billion dollar industry depends in large part upon the availability of certified organic alfalfa. Much of the alfalfa hay grown in the U.S. is consumed on dairy farms, with approximately 200,000 total acres of organic alfalfa hay harvested annually. JA 118, 243, 347. Alfalfa is essential for dairy operations; it provides the highest quality forage available, rich in protein, fiber, and energy. JA 652, 988. CROPP Cooperative's members alone require 150,000 tons of organic alfalfa each vear to keep their production at current levels. JA 647. While USDA has recently clarified that organic livestock must have a minimum of 120 days per year on pasture, see U.S. Department of Agriculture, National Organic Program; Access to Pasture (Livestock), 75 Fed. Reg. 7154 (February 17, 2010), the loss of a reliable supply of certified organic alfalfa would irreparably cripple the organic dairy industry. Farm management costs would dramatically increase, and the direct financial impact on organic dairy farmers due to lost domestic and international

markets would be in the hundreds of millions of dollars.

A. Gene Spread From Genetically Modified Organisms Has Destroyed Entire Markets For Organic Crops.

History has shown the catastrophic consequences to markets for organic or GE-free crops resulting from the infiltration of GE transgenes. These genes have proven uncontainable time and again, regardless of the preventative actions taken by regulators and farmers. In many cases, the contamination has caused widespread collapse of organic or non-GE markets in the United States and abroad.

Even the risk of contamination of organic alfalfa with RRA will have significant and immediate economic consequences for organic dairy farmers. See JA 243. Testing of alfalfa seed for the presence of the glyphosate-resistant gene costs \$179 to \$259 per sample, and some organic farmers would be forced to spend on the order of \$25,000 annually just to verify that their alfalfa crops were free of GE transgenes. JA 648, 653-54. For companies like CROPP Cooperative, which pool milk supplies, every dairy farmer will have to test alfalfa on a regular basis to assure there is no contamination. Just months ago, in the wake of APHIS' release of its Draft EIS and based on its own comprehensive field testing, a major U.S. seed company noted to its customers that "[i]t is becoming clear that [the RR Alfalfa gene] . . . can easily spread and that we are going to have to take extraordinary measures when producing foundation seed and commercial seed for GMO sensitive markets." Cal/West Seeds, *CW News*, Winter Issue 2010, *available at* http://www.regulations.gov/search/Regs/home.html#docket Detail?R=APHIS-2007-0044 (Docket Item No. APHIS-2007-0044-7617.2).

In 1995, Petitioner's genetically engineered species of glyphosate-resistant canola (Brassica napus), known as GT-73 or Roundup Ready canola, was among several GE canola varieties introduced in Canada following approval by the Canadian Food Inspection Agency. While it was understood by regulators that some gene spread could occur, the speed and extent of out-crossing among and between canola crops far surpassed even the most conservative predictions. See, e.g., JA 859-60. Volunteer canola plants carrying GE traits were found in non-GE fields after only two seasons of commercial cultivation and occurred at distances of 800 meters in 2001 and 2500 meters in 2002. JA 859-60. Field studies conducted after the widespread planting of GE canola showed a remarkably rapid loss of biological purity in conventional B. napus cultivars. One study of pedigreed, non-GE canola found that 32 of 33 samples were in fact contaminated with GE varieties, some samples at levels of 2% or more. JA 872.

The economic consequences of this contamination were swift and severe, for seed sales as well as for Canadian organic and GE-free canola markets. The European market for organic canola from western Canada disappeared virtually overnight when a major seed distributor acknowledged that conventional canola seed had been contaminated by GE canola prior to being sold to several EU countries. Stuart Smyth, et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECHNOLOGY 6 (June 2002). Today, canola crops and oil from Western Canada cannot be marketed as organic or non-GE, and the small but once-burgeoning industry has collapsed. *See id.*; JA 139.

Similarly, the discovery of pervasive contamination of conventional rice by a GE variety known as LL601 caused a billion-dollar decline in European and other international markets for U.S. rice in 2006. See E. Neal Blue, Risky Business: Economic and regulatory impacts from the unintended release of genetically engineered rice varieties into the rice merchandising system of the U.S. (Greenpeace, 2007), available at http://www.greenpeace.org/raw/content/international/ press/reports/risky-business.pdf. The widespread discovery of LL601 in global supplies of rice was described by industry experts at the time as "the most significant event in the history of the U.S. rice industry." Lisa Shumaker, U.S. GMO Rice Caused \$ 1.2 Billion in Damages (Reuters News Service, November 5, 2007). Reflecting the near impossibility of comprehending, much less containing, the impacts of GE gene spread, a comprehensive USDA investigation ultimately failed to find the source of the contamination event. International markets responded rapidly to the news of the contamination; EU nations

ceased imports of U.S. rice, and futures prices for U.S. rice dropped ten percent in two days for a short term loss of \$168,000,000. JA 884.

B. Organic Alfalfa Farmers Will Struggle To Meet USDA Organic Standards And Will Suffer Market Rejection If GE Alfalfa Is Widely Introduced.

Widespread planting of RR alfalfa imposes massive risk and uncertainty on the continued viability of organic dairy farming, due to the link between certified organic alfalfa used as feed by organic dairies. Contrary to Petitioners' assertion that organic alfalfa growers may market their crops as certified organic "regardless of any inadvertent cross-pollination," Pet.Br. 38, contamination of organic alfalfa could lead to the loss of organic certification.

To be marketed or sold as certified organic, alfalfa hay must be grown according to standards established by the USDA's National Organic Program ("NOP") under authority of the Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501 et seq. (2009) ("OFPA"). NOP regulations prohibit certified organic operations from using "excluded methods," which are "methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. . . ." 7 C.F.R. §§ 205.105(e), 205.2. A producer of certified organic alfalfa may not use excluded methods, and under the NOP standards organic

dairies and other livestock facilities must use feed that is completely organic. There is no *de minimis* exception to the 100% organic feed requirement. *Id.* § 205.237(a). The Federal Respondents agree the matter is not so clear as Petitioners have described it. *See* Resp.Br. 27, n.6.

But regardless of the application of the NOP regulations, the values and choices of organic consumers will ultimately drive the market conditions for GEtainted organic alfalfa and dairy products. As APHIS' Draft EIS for RRA explains, "one of the unique attributes of organic foods, and one reason consumer demand for organic foods is increasing, is the intended absence of GE ingredients in the process of producing them." U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement (November 2009) 60 ("Draft EIS"), available at http://www.aphis.usda.gov/ biotechnology/downloads/alfalfa/gealfalfa deis.pdf (emphasis added). Consumers in the U.S. organic market have identified the ability to avoid GE organisms as a leading reason for purchasing certified organic products. See, e.g., JA 447, 705, 731. This consumer sentiment is reflected by the staggering number of public comments – in excess of 200,000 – received by APHIS on the Draft EIS, largely critical of its deregulation proposal. Without consumer confidence, the markets will fail even though the extent or degree of GE contamination may be difficult to ascertain. JA 989-90.

Congress and the USDA have repeatedly sought to establish and protect meaningful organic standards in order to build consumer confidence and facilitate the growth of the market for certified organic products. The very purpose of OFPA is to "facilitate interstate commerce" in organically produced food, in part by establishing a regulatory program to "assure consumers that organically produced products meet a consistent standard[.]" 7 U.S.C. § 6501(2)-(3). Like the NEPA analysis itself, the scope of relief granted for a failure to comply with NEPA in this case ought to be consistent with and advance congressional purpose as established by OFPA. See, e.g., Oregon Natural Desert Ass'n v. Bureau of Land Management, 531 F.3d 1114, 1130 (9th Cir. 2008).

This risk of market rejection is even greater overseas. International markets for alfalfa will be notably more sensitive to the presence of GE transgenes due to their more stringent regulation of GE products and strong consumer demand for GE-free foods. JA 150, 243. Just five countries (Japan, Republic of Korea, Taiwan, Canada, and Mexico) account for 98% of the total metric tons of alfalfa exported. Japan, by far the leading importer of U.S. alfalfa hay, has a zero-tolerance policy for unapproved GE crops. Draft EIS at R-7, R-10, JA 430-35. For these reasons foreign importers of alfalfa hay, in Japan and elsewhere, are known to demand certainty from their American suppliers; in some cases, this demand for

certainty trickles down to U.S. alfalfa farmers who must alone bear the risk of GE contamination. *See, e.g.*, JA 239-44, 409-11, 420-23, 738.

II. THE LOWER COURTS CORRECTLY RECOGNIZED THAT ADDITIONAL RELEASE OF PETITIONER'S GENETICALLY ENGINEERED ALFALFA PRIOR TO FURTHER ENVIRONMENTAL REVIEW WOULD IRREPARABLY HARM THE ABILITY OF ORGANIC FARMERS TO CHOOSE TO MARKET ORGANIC PRODUCTS.

Amici desire to continue to grow, produce, and market organic products without GE organisms. But the unregulated release of RRA would irreparably harm that choice. As this Court stated in the antitrust context, prevention of "free choices between market alternatives is inherently destructive of competitive conditions" and deserving of condemnation "even without proof of its actual market effect." Associated General Contractors of California v. California State Council of Carpenters, 459 U.S. 519, 528 (1983). This same condemnation is deserved in evaluating the equitable factors involved with injunctive relief, where "[f]or those farmers who choose to grow nongenetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop." Pet.App. 44a.

As described earlier, the organic industry is a vibrant, thriving sector of today's agricultural economy,

JA 407, 730-31, 741, 823, 989, whose very existence would suffer from additional unregulated release of RRA prior to further environmental review. The reports of actual instances of RRA contamination, JA 419, 658, 663, 664, 666, 672; the history of organic (and, in some cases, conventional) market collapse following the planting of other GE crops, JA 112, 139; and the growth of contamination over time, JA 131, 693, 694, 696; all demonstrate that such a harm

We first discovered the unintended presence of the Roundup Ready gene in our conventional alfalfa seed in 2005. It was identified in one of our foundation seed production lots grown in California. We tested the foundation seed lot prior to shipping it to a producer who intended to plant it for organic seed production. A representative sample of the seed lot was sent to a qualified lab and tested positive for the CP4EPSPS gene at the .01% level. The sample was tested again and was found positive at the .03%. After discovering that the foundation seed had been contaminated, we initiated tests on certified seed grown at three different field locations in Washington State using the same foundation seed lot. Seed from two of the three locations tested positive at the .01% level. The foundation seed was produced in 2003 in a field located in Solano County California. We didn't discover that it contained the Roundup Ready gene until after it had been used to plant the certified fields. Cal/West Seed had zero access to Roundup Ready seed at that time; therefore we assume the contamination originated from an external source.

JA 672-73.

³ Monsanto's argument that this evidence is "hearsay," Pet.Br. 14, ignores the actual testing that was involved in some of this documentation. For example, Cal/West seeds, a seed grower, in describing a contamination event, stated that

would not be speculative, but instead significant and unremediable through traditional monetary damages. JA 112. Moreover, any new contamination will also damage organic farmers' ability to comply with the OFPA standards in a manner that cannot be repaired through the payment of damages. Injunctive relief was designed to avoid this very type of novel harm. Pet.App. 45a; compare eBay, Inc. v. MercExchange, LLC, 547 U.S. 388, 393 (2006) (criticizing a district court's denial of an injunction on the basis that the district court created too "broad [a] classification" when the district court concluded that a plaintiff's "lack of commercial activity in practicing the patent" suggested that the plaintiff patent holder lacked irreparable harm, instead pointing out that the loss of choice suffered by self-made inventors to license their patents to others might be sufficient for establishing irreparable harm) with Winter v. Natural Resources Defense Council, 129 S. Ct. 365, 376 (2008) (rejecting injunctive relief and pointing out that the activity that plaintiffs had sought to enjoin were training exercises that had been taking place in the same area for the last 40 years); see also California v. American Stores Co., 492 U.S. 1301, 1307 (1989) (finding injunctive relief appropriate given the harm that would result to citizens from a substantial lessening of competition in the relevant market).

Consideration of harm to farmers' choice is consistent with the type of public interest that this Court has considered in the injunction context. In *Winter*, this Court considered the harm faced by the public if

the Navy were enjoined from engaging in its naval training operations. See 129 S. Ct. at 376-77 ("In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the remedy of injunction."); see also id. at 376-80. The harm faced by the public in this case is similarly significant — beyond even the irreparable harm suffered by the plaintiff farmers. If unregulated RRA is released without additional environmental review, not only would the plaintiff farmers be injured, but so would the public by losing its ability to choose to produce, buy, and sell organic products.

This harm to the public interest is cognizable even in the context of a NEPA injunction for two reasons: organic market choice is intertwined with impacts to the physical environment; and the harm to the public is similar to the public interest considerations in other NEPA injunction cases. As explained earlier, the market choices of organic growers, producers, and consumers and the environmental impacts are intertwined and predicated on minimizing underlying harm to the physical environment, due to the decreased off-farm inputs, reduced use of pesticides, and increased biodiversity through organic production management systems. See 7 C.F.R. § 205.2; see also Department of Agriculture, Agricultural Marketing Service, National Organic Program: Access to Pasture, 75 Fed. Reg. 7154, 7181 (February 17, 2010) (establishing stricter roles of pasture in organic livestock, including provisions to "protect[] natural

wetlands and riparian areas," that as a whole are "intended to satisfy consumer expectations that ruminant livestock animals graze on pastures during the grazing season"). Simply put, members of the organic community participate in the organic market in order to reduce their impacts on the environment. Thus the harm to market choice faced by the public falls well within the "effects" considered under NEPA, which "includes ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative." 40 C.F.R. § 1508.8 (defining the language of "effects" under NEPA). Moreover, the harm to market choices is one faced not only by the plaintiffs, but by all growers, producers, and consumers of organic products, and therefore part of necessary consideration of the public interest involved in assessing the propriety of any injunctive relief. See Winter, 129 S. Ct. at 380.

Indeed, the harm that the public faces here goes to the core of this country's respected values. The availability of market choice has always been one of the key freedoms respected by this Court. See, e.g., FTC v. Ticor Title Insurance Company, 504 U.S. 621, 632 (1992) ("The preservation of the free market and of a system of free enterprise without price fixing or cartels is essential to economic freedom."). Moreover, "the heart of our national economic policy long has been faith in the value of competition." Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951). The unregulated

release of RRA without additional environmental review would harm such competition - not through anticompetitive practices found illegal by this Court⁴ - but through the physical destruction of the competitive products through contamination. The evidence presented to the district court states that one of the main reasons that individuals choose to be organic producers is because they desire to avoid genetically engineered crops, see, e.g., JA 648, and that the unregulated release of RRA would result in loss of farmers' chosen livelihood of organic farming, see, e.g., JA 649. Evidence in the record also attested to the difficulty of organic seed farmers selling contaminated seeds, JA 254, 549; the difficulty of farmers and producers in finding noncontaminated seeds, see, e.g., JA 745-46, and organic feed, see, e.g., JA 647-48; as well as the unavailability of measures for prevention of GE contamination, see, e.g., JA 664, 693, 695. Finally, the record shows how contamination by RRA would devastate the reliance of organic consumers on organic certification because

⁴ Although at issue here is the physical destruction of competitive products – such as organic alfalfa and dairy products sustained by organic alfalfa – relevant to the public interest, rather than other aspects of anticompetitive practices also relevant to the public interest, these other anticompetitive concerns with Monsanto can also be seen in the U.S. Department of Justice's current antitrust investigation of Monsanto's seed pricing systems. *See, e.g.*, William Neuman, *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. TIMES B1 (March 12, 2010), available at http://www.nytimes.com/2010/03/12/business/12seed. html.

many of these consumers purchase organic products in order to avoid genetically engineered ingredients. See, e.g., JA 649, 745, 824; see also Consumer Reports National Research Center, Organic Food Poll, at 3 (February 8, 2010), available at http://greenerchoices.org/pdf/OrganicFood%20Poll_Public%20Release_Feb%2 02010.pdf (stating that a "majority of respondents expressed some level of concern with contamination of organic food crops by genetic engineering"). All of this demonstrates the harm to economic choice faced by growers, producers, and consumers of organic products.

Petitioner attempts to downplay this harm by describing it as merely an economic loss, Pet.Br. at 38, rather than the type of harm considered in evaluating the appropriateness of injunctive relief. But no amount of money damages can compensate for this loss of choice for the general public. Cf. Am. Trucking Ass'n v. City of Los Angeles, 559 F.3d 1046, 1059 (9th Cir. 2009) (pointing out that economic loss so severe as to lead to the "loss of one's business" can constitute irreparable harm, even though irreparable harm is usually not demonstrated by economic loss alone). As this Court stated in Business Electronics Corp. v. Sharp Electronics, "The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain – quality, service, safety, and durability – and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers." 485 U.S. 717, 757 (1988) (quoting National Society of Professional Engineers v. United States, 435

U.S. 679, 695 (1978)). Depriving consumers of the ability to choose between GE and non-GE alfalfa will permanently alter the market's structure, and prevent a full and fair competition between GE and non-GE alfalfa in the marketplace. This artificial inhibition of competition will permanently disrupt the market's natural evolution in ways that are impossible to fully predict. See generally Summit Health, Ltd. v. Pinhas, 500 U.S. 322, 331 n.11 ("The federal power to protect the free market may be exercised to punish conduct which threatens to impair competition even when no actual harm results") (quoting favorably United States v. Staszcuk, 517 F.2d 53, 60, n.17 (7th Cir. 1975).

Finally, Petitioner's suggestion that non-RRA is merely another "varietal" whose "purity" can be maintained "through well-established stewardship techniques," Pet.Br. 1-2, is similarly misleading. First, evidence on the record demonstrates the current difficulties of preventing GE contamination that go well beyond varietal contamination, see, e.g., JA 664, 693, 695. Next, the price premium commanded in the market place by organic products, JA 823 — considered to be GMO-free by consumers — indicates that consumers consider non-RRA to be a distinct product market from RRA varietals, which do not command a similar price premium.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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