No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to The United States Court of Appeals For the Ninth Circuit

BRIEF OF AMERICAN FARM BUREAU FEDERATION, BIOTECHNOLOGY INDUSTRY ORGANIZATION, AMERICAN SEED TRADE ASSOCIATION AND NATIONAL CORN GROWERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICI CURIAE*[1]

The American Farm Bureau Federation ("Farm Bureau") is a general farm organization representing over 6.2 million member families. Farm Bureau was established in 1919 to protect, promote and represent the business, economic, social and educational interests of American farmers and ranchers. Farm Bureau policy, which is developed through a member-controlled, grassroots process, supports the use of agricultural biotechnology, as well as conventional and organic farming.

The Biotechnology Industry Organization ("BIO"), created in 1993, is the world's largest biotechnology trade association. Its mission is to champion biotechnology on behalf of its 1,200 members—a wide range of entities that are involved in the research and development of numerous innovative biotechnologies. Through its Food and Agriculture Section, BIO has taken the lead in promoting the safety and benefits of genetically-engineered crops developed through agricultural biotechnology. BIO advocates for scientific regulatory approaches for these crops both domestically and abroad, while also supporting the concurrent cultivation of conventional and organic crops.

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[1] Pursuant to Supreme Court Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

Founded in 1883, the American Seed Trade Association ("ASTA") is a voluntary, nonprofit national trade association representing approximately 740 members involved in seed production and distribution, plant breeding, and related industries in North America. ASTA's mission is to enhance the development and movement of quality seed worldwide. Many ASTA members are research-intensive companies engaged in the discovery, development, and marketing of enhanced seed—*i.e.*, seed that has been modified to express certain beneficial or desirable traits.

Founded in 1957, the National Corn Growers Association ("NCGA") represents approximately 35,000 dues-paying corn growers and the interests of more than 300,000 farmers who contribute through corn checkoff programs in their states. NCGA and its 48 affiliated state associations and checkoff organizations work together to help protect and advance corn growers' interests.

Farm Bureau, BIO, ASTA and NCGA support the continued application of advances in agricultural biotechnology like the Roundup Ready alfalfa seed at issue in the present case. Sustained progress in this field requires a firm commitment to science-based regulations and policies. When dealing with products like genetically-engineered crops that have undergone extensive field testing, decisions must be based on evidence, not anecdotes and speculation. Unfortunately, the lower courts in this instance decided to enjoin the use of Roundup Ready alfalfa without fulfilling their legal obligation to evaluate the relevant data.

SUMMARY OF ARGUMENT

The injunction in this case is a watershed event for American agriculture in general, and more specifically for agricultural biotechnology. Agricultural biotechnology is already adopted widely in the U.S. for a number of key crops—including corn, cotton, papaya, sugar beets and soy—

using a robust and established regulatory process. This Court's review is warranted not only because the courts below abandoned the well-established principle that evidence of likely irreparable harm is a prerequisite to issuance of an injunction, but also because ignoring the lack of such evidence raises especially important questions in the context of efforts by innovators to bring the benefits of genetically-engineered crops to market.

Roundup Ready alfalfa, like all genetically-engineered crops, is the product of extensive research and testing that take place over the course of many years. But the research and testing that go into developing these crops are just the beginning. Before a new genetically engineered crop is commercialized in the United States, it is subject to an extensive, science-based regulatory review and authorization process that will include up to three separate federal agencies—for food and feed crops, the U.S. Food and Drug Administration ("FDA"); in some other cases, the U.S. Environmental Protection Agency ("EPA"); and, most relevant in the circumstances of this case, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS" or the "Agency").

The federal regulatory system ensures the safety of genetically-engineered crops, opening the door to the incredible public benefits that those crops offer. For farmers, genetically-engineered crops mean lower input costs and higher yields, which translate into improved incomes. The same higher crop yields benefit consumers all over the world, where agricultural biotechnology offers hope for meeting the planet's rapidly growing demands for food, feed, fuel and fiber. Between 1996 and 2007, this additional production has contributed enough kilocalories of energy to feed about 402

million people for a year.[2] Genetically-engineered crops also allow farmers to control harmful weeds and pests using fewer, more environmentally friendly farming practices. Glyphosate, the herbicide used by Roundup Ready alfalfa farmers, is less toxic than common aspirin, and it quickly decomposes in the soil so that it has no residual activity or long-lasting environmental effects.[3] These and other biotechnologies make sustainable agriculture feasible in more places around the world.

In spite of these current and future benefits, and despite the fact that genetically-engineered crops are already safely consumed by millions of people around the globe, public understanding of agricultural biotechnology remains modest. U.S. Department of Agriculture statistics show, however, that the overwhelming majority of soybeans, cotton, and corn in the United States are biotech varieties. These crops are a firmly established part of the agricultural industry with broad applications offering widespread benefits. The district court in this case, instead of fashioning an injunction based on the evidence before it, declined to conduct an evidentiary hearing and applied a legal standard that effectively presumed the existence of irreparable harm. The court of appeals, in a two-to-one vote, sanctioned the lower court's approach. Without this Court's review, the present case could begin a wave of anti-biotechnology injunctions with the potential to generate uncertainty not only in the agricultural biotechnology indus-

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[2] Graham Brookes, Peter Barfoot, *Focus on income, well-being and food security, Biotech crops: evidence, outcomes and impacts 1996-2007*, PG Economics, Ltd, October 2009, available at http://www.pgeconomics.co.uk/pdf/focusonincomeeffects2009.pdf

[3] Glyphosate Pesticide Information Profile, Extension Toxicology Network, Cornell University, Cooperative Extension, available at http://pmep.cce.cornell.edu/profiles/extoxnet/dienochlor-glyphosate/glyphosate-ext.html.

try, but also throughout American agriculture and in the global food market.

ARGUMENT

I. Scientifically-Regulated Agricultural Biotechnology Is Safe And Beneficial.

The first commercial plantings of genetically-engineered crops occurred in 1996. By 2008, 13 million farmers planted more than 309 million acres in 25 different countries. *See* Clive James, *Global Status of Commercialized Biotech/GM Crops: 2008* (Feb. 2009).[4] The development and delivery of benefits from agricultural biotechnology into the commercial marketplace have been incredible, with the U.S. Department of Agriculture indicating that 91% of soybeans, 88% of cotton, and 85% of corn in the United States are biotech varieties. Two factors explain this rapid adoption of agricultural biotechnology. First, the United States has led the way in establishing a science-based regulatory process that allows innovators to bring safe, new products to market. Second, genetically-engineered crops work. They work to increase incomes for farmers, they work to provide more and better food for consumers and they work to lessen the impact of agriculture on the environment. In short, agricultural biotechnology currently provides significant benefits to many commodity crops, while also helping to offer solutions to help feed, fuel and heal the world in the future.

A. Genetically-engineered crops are subject to science-based federal regulation.

Since 1986, the federal government has regulated agricultural biotechnology crops under a "Coordinated Framework for Regulation of Biotechnology." *See* 51 Fed. Reg. 23302 (June 26, 1986). Three different agencies—APHIS,

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[4] *See* http://croplife.intraspin.com/Biotech/papers/ID_372_james .pdf.

EPA and FDA—share responsibility for regulatory review of genetically engineered plants. APHIS, the agency involved in the present lawsuit, regulates plant products of biotechnology as potential plant pests until, based on a review of an extensive scientific database, including the results of APHIS-regulated field trials, the Agency makes a determination that the genetically engineered plant does not pose a plant risk. FDA thoroughly reviews the safety profile of genetically engineered food crops and enforces rigorous safety standards for food and feed derived from these crops. Some types of genetically engineered plants have been developed to produce their own pesticides. EPA registers the sale and distribution of these plant incorporated protectants. Under this system, each agency regulates products to the extent they fall within the sphere of that agency's authority. Consequently, multiple agencies may regulate different aspects of the same crop.

This coordinated federal effort makes genetically-engineered crops among the most thoroughly tested and stringently regulated in history. The regulatory system is science-based, meaning that agency decisions depend on the results of controlled testing of these products. As a result, the agricultural biotechnology products that have been commercialized under the U.S. regulatory system have been shown to be as safe for producers, consumers and the environment as their conventional counterparts.

B. Genetically-engineered crops create important benefits for producers, consumers and the environment.

Beyond this demonstration of safety, genetically-engineered crops improve the circumstances of farmers, consumers and the environment. The advantages of Roundup Ready alfalfa illustrate these wide-ranging benefits. Alfalfa is a 22-million acre per year crop in the United States. Nearly all of this alfalfa is harvested for animal feed. Unlike con-

ventional alfalfa, Roundup Ready alfalfa is genetically engineered to survive the application of glyphosate, the active ingredient in the herbicide commercially known as Roundup. So a farmer who plants Roundup Ready alfalfa can use glyphosate to control weeds, in lieu of a more expensive combination of other herbicides. By producing more alfalfa while spending less on chemicals for weed control, the Roundup Ready alfalfa farmer can realize greater profits. Not surprisingly, alfalfa farmers were rapidly adopting the Roundup Ready variety when the district court issued its injunction in this case.

Livestock farmers—the primary purchasers of alfalfa hay—also benefit from the adoption of genetically-engineered Roundup Ready alfalfa. The presence of weeds reduces the nutritional value of alfalfa hay. When farmers plant Roundup Ready alfalfa, it increases both the quantity and quality of alfalfa hay available for purchase. In other words, Roundup Ready alfalfa allows the production of more hay with fewer weeds—exactly what alfalfa hay consumers want.

In addition to the benefits enjoyed by farmers and consumers, genetically-engineered crops like Roundup Ready alfalfa can help provide significant benefits for the environment. As already mentioned, farmers who plant Roundup Ready alfalfa can control weeds with glyphosate, as opposed to a variety of other herbicides. These alternatives to glyphosate may have greater impacts on the environment.

The multiple benefits of Roundup Ready alfalfa are just a few examples of agricultural biotechnology's potential to help feed the world. A 2004 study by the National Center for Food and Agricultural Policy showed that genetically-engineered crops increased yields by more than 5 billion pounds annually, and farm incomes by $2 billion. Sujatha Sankula, Edward Blumenthal, *Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2003 – An Update*

of Eleven Case Studies at 92 (Oct. 2004).[5] Globally, pesticide applications fell 6 percent between 1996 and 2004, due in part to the development of pest-resistant biotechnology in plants. Graham Brookes, Peter Barfoot, *GM Crops: The Global Economic and Environmental Impact — The First Nine Years 1996-2004* at 193, PG Economics, Ltd., AgBioForum 8 (2005).[6] Herbicide-resistant crops have both reduced the application of weed-controlling chemicals and facilitated the increased adoption of "no-till" farming methods that improve soil health and reduce erosion.

Astounding as these advances are, they amount to no more than a glimpse of what is possible. Agricultural biotechnology offers the world a way to help feed its population through safe, sustainable farming techniques that could raise the standard of living in rural communities throughout the world. This technology, and the crops derived from this technology, provide solutions to help feed, fuel and heal the world.

II. The Lower Courts' Approval Of An Injunction Without Scientific Evidence Of Harm Threatens The Agricultural Biotechnology Industry.

The legal principles governing the issuance of injunctive relief require courts to consider the relevant evidence of harm. *See Winter v. Natural Res. Def. Council*, 129 S.Ct. 365, 374-75 (2008). In the case of genetically-engineered crops like Roundup Ready alfalfa, that means a consideration of scientific evidence regarding the likelihood that the crop will cause the irreparable injury necessary to justify the "extraordinary remedy" of an injunction (*id.* at 376-77). The lower courts' failure to address the readily-available scientific evidence in this case is indicative of a larger problem en-

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[5] *See* http://www.ncfap.org/documents/2004finalreport.pdf.

[6] *See* http://www.pgeconomics.co.uk/pdf/v8n23a15-brookes.pdf.

demic to judicial handling of biotechnology: Products are so thoroughly studied and tested before being commercialized that courts must deal with substantial scientific evidence when considering possible injunctive relief. The lower courts' mishandling of that problem demands this Court's immediate review.

A. Scientific evidence is the only meaningful way to determine the likelihood of irreparable harm from a genetically-engineered crop.

This Court repeatedly has held that injunctive relief requires proof that the plaintiff is likely to suffer irreparable harm in the absence of an injunction, that such harm outweighs any harm the requested injunction is likely to cause, and that the injunction would be in the public interest. *See eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). The question here is how this standard should be applied in a case where plaintiffs seek to enjoin the use of agricultural biotechnology.

The district court had before it substantial scientific evidence addressing the likelihood that the continued use of Roundup Ready alfalfa would ***not*** irreparably harm the plaintiffs. Even if it were assumed true that normal levels of crop-to-crop pollen flow could cause irreparable harm—a conclusion not supported by science—a number of field studies have measured the gene flow between Roundup Ready alfalfa and conventional alfalfa using various "isolation distances" between plantings.[7] These studies, which were conducted under worst-case scenario conditions that allowed for more gene flow than would occur in the real world, demon-

[7] To maintain the status quo while it conducted the environmental review ordered by the district court, APHIS proposed certain "stewardship measures," including minimum isolation distances between plantings, that were designed to prevent Roundup Ready alfalfa from coming into contact with conventional and organic alfalfa.

strate that the risk of cross-pollination feared by the plaintiffs is negligible. *See, e.g.*, Pet. App. 228a-29a. In particular, the studies showed that gene flow was less than 0.1% for alfalfa being grown for seed, and approximately 2.5 in a million (0.00025%) for alfalfa being grown for hay. *See, e.g.*, Pet. App. 168a-83a, 280a-81a. The studies presented to the district court also ruled out any realistic possibility that glyphosate-resistant weeds would develop during the period of the injunction.

The district court did not evaluate the scientific evidence it received within the framework of this Court's standard for issuance of injunctive relief. Faced with scientific studies directly relevant to the likelihood of irreparable harm, and evidentiary challenges to the plaintiffs' anecdotal claims of injury, the district court refused to conduct an evidentiary hearing. According to the Court of Appeals, this decision to eschew a hearing was an effort "to avoid the catch-22 situation" in which the district court would "perform the same type of extensive inquiry into environmental effects" that it had ordered APHIS to perform. Pet. App. 18a. In fact, the review of potentially significant environmental impacts required by the National Environmental Policy Act ("NEPA") is readily segregable from the question of likely irreparable harm necessitating immediate injunctive relief. Significant environmental impacts under NEPA do not necessarily qualify as "irreparable harm," and can often be completely mitigated in the normal course. The harm needed to invoke a court's injunctive powers, on the other hand, must be irremediable apart from an injunction. By blurring the line between these two distinct inquiries, the district court effectively enjoined the use of Roundup Ready alfalfa without appropriately considering the scientific evidence. As discussed, that evidence demonstrates the extreme improbability and practical impossibility of any measurable impact—let alone irreparable harm—occurring in the absence of an injunction.

The district court's refusal to hold an evidentiary hearing—endorsed over a dissenting opinion by the court of appeals—is precisely the wrong way to approach a question involving the potential impacts of genetically engineered crops. The potential for the incidence of the impacts alleged by the plaintiffs is scientifically measurable. The science submitted to the district court proved that the likelihood of harm under APHIS's proposed conditions was remote. Anecdotal accounts of "contamination" and hypothetical doomsday forecasts have no place in the injunction calculus when appropriately controlled scientific studies can provide data that allows for confident prediction. Ignoring this data is tantamount to an improper presumption of irreparable harm. *See Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 544-45 (1987). Worse, it allows mere speculation to trump carefully conducted scientific testing. The upshot is an injunction that flies in the face of this Court's rule requiring proof of likely irreparable harm (*see Winter*, 129 S. Ct. at 375), disrupting unnecessarily and generating uncertainty throughout the agricultural biotechnology industry.

B. Organic, conventional and Roundup Ready alfalfa farmers can and should coexist.

In addition to ignoring the scientific evidence regarding the effects of genetically-engineered crops, the lower courts' rulings in this case imagine a tension that need not exist between those farmers who employ agricultural biotechnology and those who do not. Both courts discounted APHIS's ability to enforce its proposed "stewardship requirements" for Roundup Ready alfalfa, without considering at all the ability of farmers to voluntarily comply with these protective measures. The "either-or" mentality reflected in the lower courts' opinions is another product of poor information, or a poor assessment of the available information, related to agricultural biotechnology and the farmers who employ it.

The coexistence of crops that should not be commingled is not a novel concept. Field corn and popcorn, for example, are grown in the same geographic regions, even though each variety has unique genetic traits that would harm the other's economic value if gene flow were to occur. Field corn and popcorn farmers accordingly employ management techniques that have long allowed them to peacefully coexist. The same sorts of techniques, including the types of stewardship requirements proposed by APHIS in this case, have also allowed conventional, organic and genetically-engineered crops to coexist. Studies confirm that such coexistence need not cause economic or commercial hardship for farmers. *See, e.g.*, Graham Brookes, Peter Barfoot, *Co-Existence in North American agriculture: can GM crops be grown with conventional and organic crops?* (June 2004).[8]

Farm Bureau, BIO, ASTA and NCGA—organizations whose rank-and-file members are intensely interested in the issue—strongly support the coexistence of conventional, organic and genetically-engineered crops. By questioning the effectiveness of management practices, and APHIS's ability to enforce them, the lower courts in this case are unjustifiably casting doubt on the basic concept of coexistence. The courts' skepticism apparently arose not from any evidence that APHIS's proposed stewardship measures would prove ineffective, but from an unwarranted apprehension that agricultural biotechnology cannot coexist with conventional or organic farming methods. A decision stemming from this kind of unsupported assumption does not and cannot satisfy the well-established standards for issuing an injunction.

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[8]*See* http://croplife.intraspin.com/Biotech/papers/152Coexistence report-NAmericafinalJune2004.pdf.

C. The injunction issued in this case could mark a departure from scientific review of agricultural biotechnology.

Experience has shown that in spite of its numerous, proven benefits and track record for safety, agricultural biotechnology is not well understood by the public at large. In Europe, the frightening concept of the inappropriately named "Frankenfood" continues to color public opinion even though the organization that did the most to promote the term stopped using it years ago. *See* Paul Voosen, *Ghost of 'Frankenfood' Haunts Europe*, Greenwire (Oct. 21, 2009).[9] This has helped lead to a majority of survey respondents in Europe remaining opposed to agricultural biotechnology. *See id.* Six European countries have effectively banned genetically-engineered crops. *See id.* Despite consistent findings of safety from a variety of European scientific bodies, the European Union has not approved a genetically-engineered crop for growing since 1998.

By approving an injunction without considering the relevant scientific evidence, the lower courts in this case may be setting agricultural biotechnology in the United States on a similar path. Already, another judge in the Northern District of California has ruled that APHIS's environmental review of genetically-engineered sugar beets is insufficient. *See Center for Food Safety v. Vilsack*, No. 08-cv-00484, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009). That court now faces the same sort of injunction decision that is the subject of the present petition. The prime difference is that 95% of sugar beet farmers have already switched to the genetically-engineered variety, which was commercialized four years ago. An injunction like the one issued against the use of Roundup Ready alfalfa accordingly would cause a massive

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[9] *See* http://www.nytimes.com/gwire/2009/10/21/21greenwire-ghost-of-frankenfood-haunts-europe-55309.html

disruption for the overwhelming majority of sugar beet farmers, sugar processors and the communities in which they reside.

The ripple effect of the injunction in this case could spread far beyond genetically-engineered sugar beets. APHIS already has deregulated several other genetically-engineered crops, including varieties of corn, cotton, papaya, sugar beets and soy. But dozens of other products are currently going through the regulatory field testing process. Decisions like the injunction against Roundup Ready alfalfa dramatically increase the degree of uncertainty surrounding the availability of these genetically-engineered crops. Seed producers will be delayed in seeing financial break-even on their products that have been reviewed by federal agencies and determined to be safe. Farmers who spent large amounts of time and money preparing to grow Roundup Ready alfalfa now have no idea when they might see a return on their investment. Sugar beet farmers are standing on the same precipice, not knowing whether they will face an injunction that could prevent them from even planting, much less selling their crops.

The ongoing experience in Europe—more than a decade with little progress for genetically-engineered crops—shows that for an industry as young as agricultural biotechnology, the potential for setbacks is real. The United States has put in place a regulatory regime that has been effectively testing and approving genetically-engineered crops, allowing farmers and consumers in this country to reap the amazing benefits that those crops offer. Now the U.S. legal system has thrown sand in the gears, rejecting scientific evidence and creating industry-wide uncertainty. Especially in the context of a science-based industry like agricultural biotechnology, this refusal to consider objective data represents an important and deeply troubling departure from the established frame-

work for issuing injunctive relief that necessitates this Court's review.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted.

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