In the United States Court of Appeals for the Federal Circuit

MONSANTO COMPANY,

Plaintiff/Appellee,

v.

MITCHELL SCRUGGS, EDDIE SCRUGGS, SCRUGGS FARM & SUPPLIES, LLC; SCRUGGS FARM JOINT VENTURE; HES FARMS, INC.; MES FARMS, INC.; and MHS FARMS, INC.,

Defendants/Appellants.

Appeals from the United States District Court for the Northern District of Mississippi, Case No. 00-cv-161, Judge W. Allen Pepper, Jr.

BRIEF OF AMICUS CURIAE CENTER FOR FOOD SAFETY

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Center for Food Safety (CFS) is located at 660 Pennsylvania Ave., S.E., Suite 302, Washington, DC 20003. CFS is a tax-exempt, non-profit, membership organization incorporated in the District of Columbia. Since the organization's founding in 1997, the activities of CFS have addressed the environmental, economic, ethical, human health and social concerns raised by the development and commercialization of agricultural and food processing technologies, including genetic engineering.

CFS seeks to protect human health and the environment by ensuring that products of genetic engineering are thoroughly safety tested prior to any marketing and that foods created through genetic engineering, if on the market, are appropriately labeled. CFS also seeks to encourage full public participation in defining the policy issues presented by genetically engineered crops and to provide consumers with a means of identifying genetically engineered foods that are on the market.

CFS also plays a major role in the public interests community's advocacy concerning the breadth and expansion of patent rights over agricultural biodiversity. As part of this effort, CFS attorneys provided legal consulting in the case J.E.M. Ag Supply, Inc. Farm Advantage, et al. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001), that was heard by the U.S. Supreme Court in the October 2001 term. In that case the Court was faced with the straightforward issue of whether the United States Patent & Trademark Office (U.S. PTO) had illegally extended "utility" patent protection rights, under §101 of the U.S. Patent Act, 35 U.S.C. §101, to sexually reproducing plants. CFS attorneys were directly involved in the case and filed an *amici curiae* brief in June 2001 on behalf of the National Farmers Union and the American Corn Growers Association.

Additionally, on January 13, 2005, the Center for Food Safety released an extensive review of Monsanto's use and abuse of U.S. patent law to control the usage of staple crop seeds by U.S. farmers. CFS launched its investigation to determine the extent to which American farmers have been impacted by litigation arising from the use of patented genetically engineered crops. The report, entitled *Monsanto vs. U.S. Farmers*, details the results of this research, discusses the ramifications for the future of farming in the U.S., and outlines policy options for ending the persecution of America's farmers. See Center for Food Safety, *Monsanto vs. U.S. Farmers*, Jan. 2005, available at http://www.centerforfoodsafety.org/Monsantovsusfarmersreport.cfm (last visited May 3, 2005). This work has made CFS a leading public interest organization providing technical assistance to attorneys, farmers and farm organizations defending against patent infringement suits brought by genetically engineered seed producers such as Monsanto.

CFS has also been involved in numerous other cases challenging the expansion

and breadth of intellectual property rights over agricultural life forms. CFS has a genuine and substantial interest in the outcome of this case. CFS believes that the decision of the Federal Circuit in this matter will have far reaching implications concerning the expansion of intellectual property rights, the legal precedents establishing liability over genetically engineered crops.

Patenting is the principle tool used by corporations such as Monsanto to concentrate their power over agricultural and natural resources. It is also the basis for the profitability of genetically engineered foods. Upholding the lower court's decision would further promote expansion of Monsanto's patent power and would grant it more of an ability to garner control over agricultural resources and farmers.

Accordingly, CFS seeks to assist the Court in deciding questions relating to CFS' expertise in agricultural, environmental and intellectual property issues.

ARGUMENT

I. Introduction

In a recent decision, a federal district court described the tactics used by plaintiff Monsanto against farmers when it seeks recovery for alleged infringement of their intellectual property rights. The court aptly depicted plaintiff Monsanto's behavior:

In order to protect it patents, Monsanto sent "agents" into the farming community to ensure that farmers were not purchasing Roundup Ready seed, harvesting it, saving seed from the crop and then planting second generation Roundup Ready seed the next season. Under the patents, farmers were obligated to purchase new Roundup Ready seed each year and were prohibited from saving second generation seed. This changed the way farmers had done business as traditionally they saved seed, cleaned it and replanted it the following year. The scorched-earth policies used by Monsanto in enforcing the single-use restriction against farmers in some instances altered the customary neighborly relationships for which farmers are known. Instead of helping each other with barnraisings and equipment sharing, those caught saving seed, a practice that is hundreds of years old, were turned into "spies" against their neighbors, replacing the atmosphere of cooperation with one of distrust and suspicion.

<u>Stratemeyer v. Monsanto</u>, Docket No. 02-CV-505 (S.D. Ill. March 28, 2005) at 3-4 (footnote omitted)(noting that the court's strong language describing Monsanto's tactics was warranted). The case at hand involves another instance of the plaintiff's "scorched earth" tactics and represents an opportunity for the Court to deny Monsanto further monopoly power to use in its attempts to erode the country's farming culture.

Amicus Center for Food Safety (CFS) is well versed in the tactics of Monsanto. Over the course of a year and a half, CFS performed an in-depth analysis of the impacts to American farmers arising from Monsanto's use of patent rights associated with genetically engineered seeds and crops. <u>See</u> CFS, *Monsanto vs. U.S. Farmers* (2005). After extensive research and numerous interviews with farmers and attorneys, CFS' findings concerning Monsanto are consistent with those described by the court in <u>Stratemever</u>. Monsanto has used heavy-handed investigations and ruthless prosecutions that have fundamentally changed the way many American farmers farm. The result has been nothing less than an assault on the foundations of farming practices and traditions that have endured for centuries in this country and millennia around the world, including one of the oldest, the right to save and replant crop seed.

Monsanto's position as a leader in the field of agricultural biotechnology and its success in contractually binding farmers to its genetically engineered seeds result from its concerted effort to control patents on genetic engineering technology, seed germplasm, and a farmer's use of its engineered seed. Monsanto begins the process of seizing control of farmers' practices by getting them to sign the company's technology agreement upon purchasing patented seeds. This agreement allows Monsanto to conduct property investigations, exposes the farmer to huge financial liability, binds the farmer to Monsanto's oversight for multiple years, and includes a variety of other conditions that have effectively defined what rights a farmer does and does not have in planting, harvesting, and selling genetically engineered seed.

In general, Monsanto's efforts to prosecute farmers can be divided into three stages: investigations of farmers, out-of-court settlements, and litigation against farmers Monsanto believes are in breach of contract or engaged in patent infringement. Monsanto itself admits to aggressively investigating farmers it suspects of transgressions, and evidence suggests the numbers reach into the thousands. According to farmers interviewed by CFS, these thousands of investigations frequently lead to the second stage: Monsanto pressuring the farmer to settle out of court for an undisclosed sum and other terms agreed to in confidential settlements.

The case before the Court exposes that many of Monsanto's efforts to coerce settlements on alleged "infringers" of their intellectually property have suffered from a fatal flaw. As discussed below, the patents under which defendants have been sued do not actually claim patent rights over the seeds and plants that American farmers are alleged to have used in contravention of Monsanto's intellectual property. As a result, this case is about more than just than the defendants' behavior, it affects farmers across the country.

Unfortunately, the defendants in this action are really one more statistic. As this Court is well aware, Monsanto has already led many farmers into the courtroom. Based upon CFS research, the four patents at issue in this case, and particularly the Patent No. 5,352,605 ('605 patent), are used by Monsanto to prosecute farmers in virtually every case that it brings across the country. The consequences from the defendant's misuse of the '605 and other patents as a weapon against farmers are significant. As the CFS report shows:

- As of March 2005, Monsanto has filed 90 lawsuits against American farmers for alleged patent infringement; <u>See</u> CFS, *Monsanto vs. U.S. Farmers* (2005) at 4.
- The lawsuits involve 147 farmers and 39 small businesses or farm companies, and have been directed at farmers residing in half of the

states in the U.S.; Id.

- The largest recorded judgment made thus far in favor of Monsanto as a result of a farmer lawsuit is \$3,052,800.00; Id. at 5.
- Total recorded judgments granted to Monsanto for lawsuits amount to \$15,253,602.82; and Id. at 34.
- Farmers have paid a mean of \$412,259.54 for cases with recorded judgments. Id.

Startling though these numbers are, they do not begin to tell the whole story.

Many farmers have to pay additional court and attorney fees and are sometimes even

forced to pay the costs Monsanto incurs while investigating them.

No farmer is safe from the long reach of Monsanto. Farmers have been sued

after their field was contaminated by pollen or seed from someone else's genetically

engineered crop¹; when genetically engineered seed from a previous year's crop has

¹ In a concurring opinion in <u>SmithKline Beecham Corp. v. Apotex Corp.</u>, 365 F.3d 1306, 1331 (Fed. Cir. 2004), the court suggested that the biological spread of a patented plant on to the fields of a non-adopting farmer could not possibly be intended to be consistent with the purposes of the Patent Act and lead to the situation in which the contaminated farmer would be consider to be infringing the patent. Judge Gajarsa stated:

This crystalline compound raises a question similar to one that might arise when considering the invention of a fertile plant or a genetically engineered organism, capable of reproduction, released into the wild. Consider, for example, what might happen if the wind blew fertile, genetically modified blue corn protected by a patent, from the field of a single farmer into neighboring cornfields. The harvest from those fields would soon contain at least some patented blue corn mixed in with the traditional public domain yellow corn--thereby infringing the patent. The wind would continue to blow, and the patented crops would spread throughout the continent, thereby turning most (if not all) North American corn farmers into unintentional, yet inevitable, infringers. The implication--that the

sprouted, or "volunteered," in fields planted with non-genetically engineered varieties the following year; and when, as in this case, they never signed Monsanto's technology agreement but still planted Monsanto's seed. In all of these instances, Monsanto takes advantage of the fact that patent infringement is a strict liability offense. <u>See Jurgens v. CBK, Ltd.</u>, 80 F.3d 1566, 1570, n.2 (Fed. Cir. 1996) (stating that patent infringement is a "strict liability offense" in which "a court must award 'damages adequate to compensate the infringement,' regardless of the intent, culpability or motivation of the infringer."). It does not appear that Monsanto cares whether the use was unwitting, the patents allegedly infringed actually claim the seed or plant, or if a technology use agreement was ever signed.

Ultimately, the case before the Court represents Monsanto's further attempt to create absolute control over the American farmer. It also represents the first opportunity for this Court to examine Monsanto's abusive and illegal tactics with the benefit of a complete record of experts and their reports. <u>Compare Monsanto v.</u> <u>McFarling</u> (McFarling II), 363 F.3d 1336 (Fed. Cir. 2004); <u>Monsanto v. Ralph</u>, 382 F.3d 1374 (Fed. Cir. 2004). This Court should not sanction Monsanto's coercion of farmers across the country based upon a misrepresentation of the scope of the '605

patent owner would be entitled to collect royalties from every farmer whose cornfields contained even a few patented blue stalks--cannot possibly be correct.

patent claims. Such a disproportionate determination would be counter to law and, as described below, should be voided for policy reasons.

II. Farmers Do Not Infringe the Monsanto Patents.

Patent infringement occurs where a party "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). The first step in determining whether infringement has occurred is called claim construction to determine "the meaning and scope of the patent claims asserted to be infringed." <u>Markman v. Westview</u> <u>Instruments, Inc.</u>, 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Claim construction is an issue of law that the appellate court reviews *de novo*. <u>See Cybor</u> <u>Corp. v. FAS Techs., Inc.</u>, 138 F.3d 1448, 1456 (Fed. Cir. 1998)(en banc).

Before the Court are four patents at issue: Patent No. 5,352,605 ('605 patent), Patent No. 5,322,938 ('938 patent), Patent No. 5,164,316 ('316 patent), and Patent No. 5,196,525 ('525 patent). Collectively, the '938 patent, '316 patent and '525 patents are referred to as the McPherson patents. The lower court ruling found that the '605 patent's independent claims were directed to a chimeric gene which is expressed in plant cells incorporating a promoter element, one of two specified promoters, and a heterologous sequence. <u>Monsanto v. Scruggs</u>, 342 F.Supp.2d 584, 591 (N.D. Miss. 2004). The other '605 claims narrow the focus and claim a chimeric gene and plants cells expressing the chimeric gene. <u>Id</u>. at 591-592. The lower court also found that the McPherson patents claims are essentially identical and claim a chimeric transcriptional initiation region containing the enhancer sequence for the 35S promoter, a specified DNA construct for the CaMV 35S promoter, a specified DNA construct containing an enhancer for the 35S promoter, and a plant cell containing the 35S enhancer sequence for the 35S promoter. <u>Id.</u>, at 592.

However, after making these claim construction findings the lower court failed to explain further the boundaries by which the language of these claims are limited. <u>See Markman</u> 52 F.3d at 980 (holding that the claim language delimits the right of the patent holder to exclude). In is imperative that the Court now fill in this gap.

<u>A. Limited Scope of Monsanto's Patent Claims.</u>

Claim construction begins with intrinsic evidence in the record. <u>Vitronics</u> <u>Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996). In undertaking claim construction, patent claim terms are to be given "their ordinary and accustomed meaning as understood by one of ordinary skill in the art." <u>Bell Atl. Network Servs.</u> <u>v. Covad Communications Group</u>, 262 F.3d 1258, 1267 (Fed. Cir. 2001). There is a heavy presumption that a claim term carries its ordinary and customary meaning. <u>CCS</u> <u>Fitness, Inc v. Brunswick Corp.</u>, 288 F.3d 1359, 1366. (Fed. Cir. 2002).

The question before this court is whether the ordinary and accustomed

meaning of the claim terms of the '605 and McPherson patents are understood to encompass the seeds and plants used by farmers across the country. Under the accepted cannons of claim construction these patents do not cover such products. The ordinary and accustomed meaning of the term "plant cell" used in the patents clearly does not include a claim to the seed or plant. Past construction of the word "cell" used broadly on patent claims without any modifier, such as plant used here, has focused solely on the breadth of the term being applied to either eukaryotic or prokaryotic cells. <u>See Sibia Neorusciences, Inc., v. Cadus Pharm. Corp.</u>, 225 F.3d 1349 (Fed. Cir. 2000). Moreover, the ordinary meaning of the word cell is:

The smallest structural unit of living matter capable of functioning autonomously. The basic unit of any living organism. It is a small, watery, compartment filled with chemicals and a complete copy of the organism's genome. <u>www.genomicglossaries.com/content/cell_bio.asp</u> (last visited Apr.26, 2005).

<u>See also</u>, Nill, *Glossary of Biotechnology Terms*, 3rd ed., 2002 (defining "cell" as "the fundamental self-contained unit of life."). Likewise, the ordinary meaning of "gene" is "a natural unit of hereditary material, which is the physical basis for the transmission of the characteristics of living organisms from one generation to another." <u>Id.</u> And the ordinary meaning of a "promoter" is "the region on DNA to which RNA polymerase binds and initiates transcription (of RNA)." <u>Id.; See also</u> <u>McFarling II</u>, 363 F.3d at 1339 ("a promoter sequence is a DNA sequence located in proximity to the DNA sequence that encodes a protein and that, in part, tells the

cellular machinery how much of the protein to make."). The plain meaning of the terms used in the '605 and McPherson patents clearly do not encompass the term seed or plant. A plant is "an organism usu. containing chlorophyll to synthesize food and lacking the power of voluntary movement." Oxford Desk Dictionary, Amer. Ed., 1995. Similarly, a "seed" is "a part of a plant capable of developing into another such Indeed, the distinction between patent claims that cover seeds and plant." Id. plants compared to claims over chimeric genes and plant cells is explicitly recognized in plaintiff's original Complaint.² Monsanto explicitly states in its Compliant that its Patent No. 5,633,435 ('435 patent), no longer at issue in this case, "specifically covers the second generation plants and seeds produced from Roundup Ready® seeds." Pl.'s Compl., ¶ 18. No such similar assertions are made for the '605 patent. Compare, Id. at ¶¶ 24-28. In McFarling II, the court clearly pointed out the differences between the '435 patent claims and those of the '605 patent. The Court describes various '435 claims as being directed to "seed of a glyphosate-tolerant plant" and a "transgenic soybean plant" but states the '605 patent claims "DNA sequences and plant cells containing a promoter." McFarling II, at 1339. Cf. Monsanto v. Roman, 2004 U.S. Dist. LEXIS 10724, *16 (N.D. Tex. 2004)(relying upon existrinic evidence such as

² The complaint used by Monsanto in this case is virtually identical to the complaint it has used in all of its action against U.S. farmers.

Monsanto affidavit that suggests that the '605 patent claims seed).³

Such a distinction in claim terms and scope is also apparent in other Monsanto patents that have a familal relationship to the patents at hand - including patents claiming soybeans and other plants designed to claim plants and seeds created to be tolerant to glyphosate through use of the EPSPS enzyme. The claims in these patents exemplify the limited scope of Monsanto's claims under the '605 and McPherson patents. For example, Monsanto Patent No. 6,803,501 describing a method for making plants tolerant to glyphosate using the EPSPS enzyme that is implicated in the patents at issue here makes specific claims to both the glyphosate tolerant plant (claim 10) and the transgenic seed of the glyphosate tolerant plant (claim 12).

Another similar example arises in the claims of the familal Patent No. 6,884,927 for soybean cultivar 0506249 assigned to Monsanto. The patent includes claims for the transgenic versions of the cultivar that is herbicide resistant. First, claims 1, 6 and 18 specifically use the claim term "seed." Second, dependent claims 2, 6, 11, 12, 14, 15, 17, and 20 claim various versions of the soybean plant derived, using the term "plant," through the use of specifically claimed methods. The use of these terms should not be overlooked by the Court in revisiting the issue of claim

³ The district court's reliance on extrisinic evidence in <u>Roman</u> is plain error. Extrinsic evidence, such as Monsanto expert opinion, cannot be used to vary the plain language of the patent document. <u>See Omega Engineering, Inc. v. Raytek Corp.</u>, 334 F.3d 1314, 1332 (Fed. Cir. 2003).

construction.

Accordingly, in this case the scope of the Monsanto's patents claims under the '605 and McPherson patents should be narrowed so as to not include the "seed" and the "plant" and constructed to claim "chimeric genes" and "plant cells."

<u>B. American Farmers Do Not Plant Chimeric Genes, Promoters or Plant</u> <u>Cells.</u>

Upon addressing the scope of the plaintiff's patent claims, the second step in infringement analysis is the comparison of the properly construed claims to the accused products or process. <u>CCS Fitness, Inc.</u>, 288 F.3d at 1365. On summary judgment the Court should review the lower court's findings concerning infringement *de novo*. <u>Cole v. Kimberley-Clark Corp.</u>, 102 F.3d 524 (Fed Cir. 1996).

A close comparison of the patent claims at issue and the defendant's actions reveal no infringement. Monsanto's claims are premised upon farmers infringing, for example, the '605 patents "by planting unlicensed, brown bagged Round Ready® seed." Pl.'s Compl., ¶ 28. These causes of action suffer from two fatal flaws. First, the '605 and McPherson patents do not claim "seed" or the process of planting "seed." If the patents do not claim "seed" then his use of "seed" is not infringement.

Second, farmers do not plant "plant cells" or "chimeric genes." The distinction between planting of a seed or plant compared to the genes and cells claimed in Monsanto's patents is readily apparent. A gene or cell may not be patented unless it can, through technological means, be isolated from the organism in which it naturally occurs, such as a seed or plant. A chimeric plant gene is one that has been artificially created, typically using multiple sources of plant, viral and bacterial DNA. It is not a self-sustaining life form. <u>See e.g.</u> Gold, E. Richard, *Patents in Genes*, prepared for the Canadian Advisory Committee Project Steering Committee on Intellectual Property and Patenting of Higher Life Forms (Ottawa: Canadian Biotechnology Advisory Committee 2000) at 2-4.

When Monsanto's chimeric genes are inserted into a soybean plant cell, it becomes one of approximately 63,000 genes that comprise the genome⁴ of that plant.⁵ The genetically engineered genes and cells at issue contribute nothing to the germination, growth, maturation, or seed production of the plant into which they may be or become incorporated. Their only utility is to convey glyphosate resistance to a such plant if and when that plant is sprayed with the glyphosate herbicide.

Indeed, it is plant breeding and selection by generations of farmers which has over time contributed to the value of agricultural plants such as soybeans. In North America, the genome of many other agricultural plants are also the product of decades of public investment in plant selection and breeding. As described by one

⁴ The genome of an agricultural plant, such as soybean, represents the full set of the genetic information for that organism.

⁵ Tian, et al., "Characterization of soybean genomic features by analysis of its expressed sequence tags." *Theor. Appl. Genet.* (2004) 108:903-913.

knowledgeable commentator:

The plant genome is a unique entity to the law. It has contained within it the complete set of instructions to reproduce itself with only elemental raw materials as inputs. To date, man has been unable to construct any mechanical or biological device which simulates the ability of the plant genome to both reproduce itself and carry all the information necessary to generate a useful product. Even in the case of plants, the best that man can do is to insert a miniscule part into a very large entity.

Busch, N., "Jack and the Beanstalk: Property Rights in Genetically Modified Plants" 3 *Minn. Intell. Prop. Rev* 1, 136 (2002).

Moreover, a comparison of claims to those of familal Patent No. 6,884,927 is also instructive in comparing the use of the terms "cell" in the patents at issue. For example, claim 2 of this patent claims a soybean plant "produced by growing the seed of claim 1." This suggests that seed is needed to grow the claim in the field. This differs from other claims in the patent that a "tissue culture" can be produced from "cells" and that the "tissue culture" can later be regenerated into a plant in a laboratory setting (Claims 2 and 6). Taken together, these claims suggest that the "plant cell" claims in the '605 and McPherson patents can be differentiated from the 6,884,927 patent and that the customary terms of these patents' claim do not include in scope the seeds or plants as they are grown on the farm or used by defendant and other farmers.

In an effort to avoid the inadequacies in its patent claims Monsanto's bottom line defense has been, "we have a patent; therefore, we can do as we please." On June 28, 2001, the Court of Appeals for the District of Columbia effectively dispatched such an approach of broadly expanding the scope of patent claims. The court stated:

Microsoft argues that the license restrictions are legally justified because, in imposing them, Microsoft is simply "exercising its rights as the holder of valid copyrights." . . . Microsoft's primary copyright argument borders on the frivolous. The company claims an absolute and unfettered right to use its intellectual property as it wishes: "[I]f intellectual property rights have been lawfully acquired," it says, then "their subsequent exercise cannot give rise to antitrust liability." That is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability." <u>United</u> <u>States v. Microsoft Corp.</u>, 253 F.3d 34, 63 (D.C.Cir. 2001).

In using the '605 patent and McPherson patents to sue farmers Monsanto simply cannot resist pressing its patents far beyond the limited monopoly conferred by the claims its has put before the U.S. PTO. Simply put, when it comes to the American farmer Monsanto cannot resist using its patents as baseball bats. <u>See Id.</u> The Court should not condone such action.

III. Extension of Monsanto's Narrow Patent Claims to Seeds and Plants Will Have Significant Impacts on Farmers and Consumers.

The extension of Monsanto's patents claims under the '605 and the McPherson patents to cover seeds and plants will extend Monsanto's inequitable control over farmers across the country. Should the patents at issue be allowed to serve as the basis for infringement the Court will have further eroded farmer's traditional right to save seed, resulting in increased seed prices. It will also have embraced legal reasoning that allows seed companies to dictate the legal rights of farmers through an broad expansion of patent rights over products not claimed in patents. Furthermore, the expansion of Monsanto's limited patent claims from cells and genes to cover all the products into which they become incorporated would set a dangerous precedent for the expansion of patent rights related to future technologies.

A. Impacts on Seed Saving

At present, farmers generally have three options for acquiring seeds: (1) to obtain quality seed each season from public institutes, seed companies or dealers; (2) to save part of their own harvest as seed; and (3) to trade part of their harvest for seed from grain dealers. Should the court uphold Monsanto's claims as extending to seeds and plants, farmers will continue to lose this historical right. Indeed, the Court will have recognized that the result of a few new laboratory experiments on chimeric genes and plant cells, and not the centuries of plant breeding by farmers, can grant Monsanto a wide swath of control over the soybean market.

1. Patents have taken away a centuries-old traditional right to save seed.

Plant varieties are distinct from other patentable materials because they reproduce. Moreover, as noted *supra*, Monsanto has never started from scratch. Most plant breeders build upon the accumulated innovation of farmers and plant breeders from centuries ago. Farmers played a major role in expanding the germplasm base of modern agriculture through experimentation and creation of thousands of new plant varieties. These varieties built American agriculture and helped to prevent genetic erosion. Crucial to this history was the ability to save seed and the exchange of this seed among farmers and breeders, which ensured that a diverse genetic pool was available for all to improve. If Monsanto's patent claims are extended to plants and seeds this critical legacy will be further eroded.

2. Seed saving controls prices

Prices for seed have risen dramatically since 1985 and the extension of utility patents to sexually reproducing plants have undoubtedly contributed to this increase.⁶ Prior to the U.S. PTO's extension of utility patent protection, companies had access to new cultivars and could produce and market a new variety as long as they could cover their cost of production and marketing. Because a company was often using freely accessible germplasm in developing new cultivars, the cost of developing a new variety was much lower. Additionally, the mere act of performing plant research did not render a plant breeder vulnerable to a patent infringement suit. However, utility patents provide companies with greater control over the price and output of their products. Patents and "technology user fees" restrict access to new cultivars by

⁶ For example, the cost of corn seed has increased from \$18.48 dollars per planted acre in 1985 to \$30.29 dollars per planted acre in 1999. USDA, Economic Research Service, <u>Corn costs and returns data</u>, available *at* http://www.ers.usda.gov/Data/CostsAndReturns/car/Corn3.htm (last updated Mar. 27, 2001). Similarly, the cost of soybean seed has increased from \$12.92 dollars per planted acre in 1985 to \$19.25 dollars per planted acre in 1999. USDA, Economic Research Service, <u>Soybean costs and returns data</u>, available *at*

htpp://www.ers.usda.gov/Data/CostsAndReturns/car/Soybean3.htm.(last updated Mar. 27, 2001).

giving the producer sole right to produce, market or license their sale. Since the company developing a new cultivar has an absolute monopoly on that cultivar, the price will not be driven down by competition from new cultivars derived from the patented variety or by farmers saving seeds. Thus, the company can charge the maximum price governed only by the value the new plant variety represents to the buyer.

Seed saving acts as a check on seed prices as efforts by seed companies to raise prices are likely to be met by an increase in saved seed. This was a particularly viable option for farmers in many seed species such as cotton and soybeans. Such action often produced a braking effect on prices for fresh seeds. Additionally, the access to germplasm allowed when patent rights are not overextended helps reduce the cost of plant breeding and creation of new varieties. These lower research and development costs are reflected in the market by lower seed prices. These key economic considerations were recognized by Congress throughout its deliberations and past actions preventing the utility patenting of sexually reproducing plants. Therefore, the Court should not be allowed to fundamentally alter the dynamics of the seed market through an arbitrary and capricious expansion of patent claims on plant cells and chimeric genes to extend to seed or the entire plant..

B. Impacts on Future Technologies Including Nanotechnology.

The extension of Monsanto's claims under the '605 and McPherson patents to

cover seeds and plants would also result in a significant undermining of the integrity of the patent system, especially with the expanded use of biotechnology and other emerging technologies including nanotechnology. Extending Monsanto's patents for a gene or cell to a seed or plant would, in essence, mean that a gene patent "follows" the patented gene wherever it may go. The United States and much of the world is extensively using biotechnology in the engineering of microbes plants, animals and even humans. Should this Court rule that a gene patent includes under its scope all organisms into which such a gene becomes part, this would mean that any organism, including potentially humans, and the subsequent generations of that organism would be included in the patent's scope though not included in the claims or written description of the patent. Since genes often jump from one organism to another this would mean that the patent would also "jump" with the gene travel from one type of organism to another making the eventual scope of a gene patent unpredictable and unknowable without sophisticated genetic testing of any organism. This in and of itself would appear to invalidate the gene patent on a number of grounds including vagueness and inadequate description. Moreover, as discussed, *supra*, this problem of uncontrolled genetic "pollution" in agricultural biotechnology could lead to the chaotic result that millions of farmers whose crops have been polluted with such a patented gene would become unintentional infringers of such a gene patent that has been extended to include the organisms into which it travels.

This confusion and legal mischief is not limited to the arena of biotechnology.

Nanotechnology is among the fastest growing emerging technologies in industrial production today. Nanotechnology involves the manipulation of matter at the atomic and molecular level by using particles in the length of approximately 1 to 100 nanometers.⁷ The use of nano particles is being applied to a numerous areas from medicine to cosmetics to agriculture.⁸ Analogous to the extension of the scope of a gene patent to all organisms into which it travels would be a finding that a patent on a nano particle would follow such a particle into all the products or life forms into which it would become part.⁹ Given the size and ubiquitous nature of such nano particles they could make their way into a vast array of products and organisms again leading to a massive and uncontrolled expansion of the patent on such a particle. Industrial and agricultural producers simply could not know without expensive and sophisticated scientific testing whether their products would be unintentionally infringing on a patent of such a nano particle.

Accordingly, the Court should not set a precedent by which patent claims over specific pieces of genetic material grant automatic control over the entire organism in which it is incorporated.

⁷ National Nanotechnology Initiative, "What is Nanotechnology," available at <u>http://www.nano.gov/html/facts/whatIsNano.html</u> (last visited May 5, 2005).

⁸ <u>See</u> The Royal Society & the Royal Academy of Engineering, "Nanoscience and nanotechnologies: Opportunities and Uncertainties," July 29, 2004, available at <u>http://www.nanotec.org.uk/finalReport.htm</u> (last visited May 5, 2005)

⁹ <u>See e.g.</u> Patent No. 6,888,665 (claiming a nano circuit consisting of two nano particles).

CONCLUSION

The Court should not sanction turning the American farmer into a "poster child" for patent infringement. Continued expansion of Monsanto's patents above and beyond the scope of their claims will makers farmers little more than corporate "serfs" renting the limited available germplasm from a handful of companies. It would also establish a precedent that could significantly undermine the coherence and integrity of U.S. patent law as new areas of technology emerge. For the reasons set forth above and those presented in the Appellants' Brief, the *amicus curiae* urges the Court to reverse the decision of the United States District Court for the Northern District of Mississippi.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

THIS IS TO CERTIFY that on May 9, 2005, I, the undersigned, Joseph Mendelson III,

attorney for amicus Center for Food Safety served a true, correct and exact copy of the Center for Food Safety's Brief Amicus Curiae in the case of <u>Monsanto v. Mitchell Scruggs, et al</u>, Nos. 04-1532, 05-1120/1121 (Fed. Cir.), upon counsel for all parties, via United States Mail, First Class, postage prepaid, addressed as follows:

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