

LIABILITY FOR GENETICALLY MODIFIED FOOD

ARE GMOs A TORT WAITING TO HAPPEN?



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When there is a gap between technology and the law, who will be the potential victims, and how will they be compensated for their loss? Most importantly, can we resolve these critical questions in ways that will provide incentives to avoid accidents and injuries in the future?

In the area of genetically modified organisms (GMOs), the patent rights of biotech companies have long been established under US law and beyond, reaching into international markets through treaties. However, with ownership comes great responsibility—and potential liability. This article will approach the subject of these legal liability risks broadly, briefly touching upon patent infringement. It will then expand into other novel forms of tort liability such as contamination cases and potentially product liability for injury to persons as well as property in the future.

Where We Are Now

Genetically modified (GM) plants are engineered by inserting the DNA of an unrelated species into the target plant at the cellular level, generating the desired trait throughout the plant and its crop for consumption. The most common form of GM traits are plants manipulated to withstand a weed-killing pesticide, Roundup, sold by Monsanto along with the pesticide-resistant plants, and crops inserted with the soil bacterium *Bacillus thuringiensis* (Bt) to induce a toxicity against certain insects. These GM crops—corn, soy, canola, cotton, sugar beets, potatoes, rice, tomatoes, and numerous other varieties—have become so widespread in the United States that they now comprise

almost all of the plantings and the vast majority of component products in the US market.¹

The US statutory system predates the invention of GMOs and fails to recognize any risks inherent in the technology, whereas the European Community (EC) has developed regulations specifically in response to this novel technology. In contrast to the U.S. laissez-faire legal treatment, which encourages their adoption and does not require mandatory labeling of GM ingredients, the international community has reacted with caution and a strict regulatory regime that only allows these GM products if they are shown to be safe, labeled, and monitored. This divergence in approach has caused problems for international trade in effectively narrowing the market for US agricultural products, which are not segregated and cannot be shown to be free of GMOs.²

Meanwhile, patents for genetically altered products have proliferated in the United States, with ownership concentrated in a small number of companies. One survey revealed that 71 percent of all agribiotechnology patents are owned by the top five companies in the field: Pharmacia (now owned by Pfizer, Inc.) (21%, 287 patents), DuPont (20%, 279 patents), Syngenta (13%, 173 patents), Dow (11%, 157 patents), and Aventis (6%, 77 patents). More than 90 percent of the genetically modified seeds in the world today are sold either by Monsanto or by licensees of Monsanto genes.³ As the number continues to grow exponentially, Monsanto currently holds 5,355 GMO patents, far more than any other biotech company.⁴

Patent Infringement Cases

Along with the multitude of GM patents have followed patent infringement cases initiated by the biotech companies. Monsanto vigorously enforces its intellectual property rights, aggressively pursuing farmers with seed contracts and lawsuits against those whose fields contain any of their GM crops even for the cross-pollination or seed drift into their fields, succeeding for patent infringement because the law does not

require intent to plant the patented GM seed. Monsanto has filed 136 lawsuits against American farmers, involving 400 farmers and 53 small businesses or farm companies and resulting in 70 judgments awarded to Monsanto against farmers totaling \$23,345,821.⁵ With an annual budget of \$10 million dollars and a staff of 75 devoted to investigating and prosecuting farmers, Monsanto also has the means and motive to intimidate farmers into compliance.⁶

The patentability of genetic modifications has been upheld in the seminal cases of *Diamond v. Chakrabarty*, in which the Supreme Court famously declared that patentable subject matter included “anything under the sun that is touched by man”;⁷ and *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, which extended this principle explicitly to include GM plants and seeds.⁸ Most recently, patent infringement has been found in the secondary market against an Indiana farmer who purchased and planted commodity seeds, generally used as animal feed, that contained Monsanto’s patented GM soybean seeds. In *Monsanto v. Bowman*, these second-generation seeds, which were not subject to a licensing agreement from this derivative purchaser, were still afforded protection under patent law according to both the District Court and the Court of Appeals for the Federal Circuit.⁹ In rejecting the application of the doctrine of patent exhaustion for self-replicating technologies, the lower courts extended the monopoly-like hold of Monsanto to the future market; this novel case is currently on appeal to the US Supreme Court.¹⁰

However, there are some signs that non-GM farmers might be proactively going on the offensive rather than waiting to be the targets of these lawsuits. In *Organic Seed Growers & Trade Association v. Monsanto Co.*, the organics industry sued Monsanto, pre-emptively challenging the validity of its patents as harmful rather than useful and claiming future damages to organic plants from GM contamination.¹¹ Although this lawsuit was dismissed by the District Court for lack of standing, the

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WHO WILL BEAR THE RISK OF THE SIGNIFICANT POTENTIAL HARM FROM GMOs?

case was not evaluated on the merits and is currently on appeal.¹² Regardless of whether this innovative argument will be able to turn back the clock on the proliferation of patents for genetically engineered plants, the lawsuit documents many of the hazards and represents a new offensive against Monsanto's aggressive enforcement tactics. By shifting the presumptions and putting Monsanto on the defensive, this case may further have the effect of potentially changing the tide in this area.

The logical gap between ownership and liability has long been evident in the pollen-drift cases, where the biotech company has notoriously prevailed despite the fact the farmers not only lacked intent to use the GM seed but might even have suffered economic loss from the contamination, particularly if the farm was organic.¹³ Clearly Monsanto has already established its dominance in ownership, but with that ownership must come responsibility—and liability. The biotech industry claims that, after more than 15 years of GM crop use, there are no well-documented food-safety problems and no threat to biodiversity. However, these claims are contradicted by reported incidents of superweeds and contamination.¹⁴ Moreover, in the absence of long-term studies, with postulated risks to human health and the environment, the potential impacts are as of yet unknown. With the biotech companies' well-established ownership, the

consequences could be new forms of liability.

Tort Liability for Contamination

Farmers who plant GM crops may be liable under tort-based theories when genetic drift or outcrossing occurs, and the seeds spread to the fields of other farmers who had no desire to plant GM crops and now face problems of contamination.¹⁵ In addition, the seed manufacturers may be directly liable for harm in potential lawsuits by non-GM farmers and even consumers. This tort-based liability could include claims for contamination on behalf of farmers whose fields have been tainted with unwanted GMOs due to outcrossing, migration, and commingling of seeds. The damages may be high both on the individual farmers' level for injury to their crops, especially if the plaintiff farmers face potential loss of organic certification, and on the market level for loss of a domestic or international export market.

In lawsuits for contamination from cross-pollination, one can easily envision liability through common law torts such as private and public nuisance, trespass, negligence, and strict liability. Precedents are currently developing, as demonstrated in the following case examples.

ProdiGene

In an incident in 2002, an experimental corn engineered by ProdiGene to produce pharmaceuticals began sprouting in soybean fields designated for human and animal consumption near the company's Nebraska and Iowa sites. The US Department of Agriculture (USDA) seized 500,000 bushels of tainted soybeans and charged ProdiGene nearly \$3 million in fines and disposal costs.¹⁶ In addition to pollen drift, the contamination was caused by the commingling of plants from improper handling. As a result, the Animal and Plant Health Inspection Service (APHIS) proposed tightening guidelines for field testing plant-made pharmaceuticals (PMPs)

to mandate that no food crops could be grown in the same field in the following planting season and that experimental PMPs be grown further away from conventional crops, as well as the use of segregated equipment and cleaning protocols.¹⁷ However, these proposed regulations were never implemented.¹⁸

Fortunately in this scenario the contaminated product had not reached the market, but in future incidents the farmers and suppliers were not so lucky—resulting in private lawsuits and liability for the seed manufacturers.

StarLink Corn

In another incident of contamination, StarLink corn, which had been genetically engineered with a Cry9C protein to protect crops against certain insects but was not approved for human food due to concerns it would cause allergic reactions, accidentally entered the food supply and was discovered in taco shells and corn chips, among other products. As a result, 300 corn products were recalled and a testing/screening program was implemented, but the impact on international trade devastated the US corn industry as Japanese imports of corn dropped substantially; the Japanese government now mandates segregation of the export channels as well as a zero-tolerance policy.

Consumers and farmers filed class action lawsuits against the biotech manufacturer, Aventis, under several theories of liability, including negligence, strict liability, and nuisance.¹⁹ In addition to bearing the cost of recalling the product and destroying the remaining seed inventory as well as detecting and eliminating any residual StarLink in the US corn supply for eight years, Aventis ultimately settled class actions with consumers who allegedly suffered allergic reactions (despite the fact that no such reactions were proven) for \$9 million; and it settled with corn growers who allegedly suffered depressed corn prices as a result for another \$110 million. Most significantly, the StarLink cases confirmed that "negligence, negligence *per se*, strict liability in tort, trespass, private nuisance, public nuisance, and others are all theories under

which the company which markets a product might be liable for damage that would result.”²⁰

Moreover, the foundation was established for a new concept of economic loss—that the contamination of the crop caused a depressing effect on the prices of an entire crop market, and every farmer who sold any corn that year was in fact damaged because of depressed prices—a notion that could also apply when a genetically engineered crop is fully approved in the United States but is not approved in major export markets. This economic loss doctrine is now being successfully applied in the LibertyLink rice litigation.

LibertyLink Rice

In 2006, LibertyLink rice (LL 601), a variety of genetically modified rice genetically modified to withstand higher doses of the Liberty weed killer glufosinate that was in an experimental trial phase and not approved for human consumption, somehow entered the commercial rice supply in all five of the Southern states that grow long-grain rice (Arkansas, Texas, Louisiana, Mississippi, and Missouri) and infiltrated food products. As a result, Japan and the European Union (EU) placed strict limits on US rice imports, with European nations requiring extensive testing to show lack of contamination and Japan banning American rice altogether. US rice prices dropped dramatically; within four days of the USDA announcement in August, a decline in rice futures reportedly had cost US growers about \$150 million, and by September, rice prices had declined 10 percent. The USDA hastily approved the LibertyLink rice for human use retroactively based on its similarity to previously approved varieties, a move which further exacerbated the loss of international markets.²¹

A class-action lawsuit was filed on May 17, 2007, by rice farmers in Arkansas, Missouri, Mississippi, Louisiana, and Texas against Bayer CropScience, alleging its genetically modified rice contaminated the crop and caused severe economic loss.²² The rice

producers asserted public nuisance, private nuisance, negligence *per se* (based on violations of federal and state statutory law), negligence, strict liability for ultrahazardous activities, and strict product liability. After a series of multimillion dollar jury verdicts, in July 2011 the biotech company settled with 11,000 farmers for \$750 million.²³

In this case, the plaintiff farmers did not need to prove contamination of their own fields, but rather, their economic loss from the drop in the international markets for long-grain rice due to the contamination of the national commercial rice crop based on their individual market share. It is also significant to note that there are no claims in the rice litigation that LibertyLink harmed or risked human health. If such claims are filed in the future on behalf of consumers for these or other genetically modified crops, one can only imagine the magnitude of the liability that would be faced by the biotech companies and possibly the farmers who planted these crops.

In viewing pollen drift as an incident of contamination rather than patent infringement, and allowing a lawsuit by the farmers whose fields have been infiltrated, the legal consequences will be more consistent with a sensible public policy. Shifting legal liability onto the companies in the best position in terms of knowledge and control will provide the economic incentive for them to take adequate measures to prevent such pollen drift in the future.

Potential Liability for Injury to Persons As Well As Property

Already allergens have arisen as a concern associated with GMOs, as illustrated by the GM soybean that Pioneer Hi-Bred engineered with a Brazil nut gene to improve its protein content. The altered soybean provoked severe allergic attacks in eight individuals sensitive to Brazil nuts but not soybeans.²⁴ Fortunately, it occurred to someone in advance that this type of nut could be a serious allergen, and there happened to be serum samples from persons allergic to the donor species available for testing, so the testing was done premarket,

and the company withdrew the product. However, this case illustrates the dangers of the absence of labeling, because without a label alerting consumers that a soybean could contain genes from a highly allergic nut, even individuals aware of their severe allergies would have no warning. In this instance, due to a unique set of circumstances, the product was halted before it came to market; if not, potential injuries and liabilities would have been the most likely outcomes.²⁵ In addition, in view of the novelty of the technology and the absence of long-term studies, toxicity, unintended effects, and potential harm await to be discovered in the future.²⁶

Seed manufacturers and GM farmers may face liability to consumers, environmental organizations, trade associations, and the government for harm to human health and the environment. Consumer claims for injuries may also arise in the future from the failure to warn of the presence of genetically engineered components. Liability would most appropriately be based on a torts theory where manufacturers would be held strictly liable for the injuries caused by their unreasonably dangerous products, including harm to the environment, human health, and economic loss due to loss of international markets. Finding biotech companies liable for the results of their genetic engineering would comport with public policy because it would shift liability to those best able to control the product, ensure its safety, conduct rigorous testing, and disseminate critical information such as the size of buffer zones needed around GM plants. By holding biotech companies accountable for any injuries that flow as a consequence, strict liability would thus provide proper incentives to prevent the harm from occurring in the future.

The most difficult hurdle for potential plaintiffs in cases involving environmental and human injury will be proving causation, but (as with the tobacco industry model) when a scientific breakthrough in this area occurs through studies and unfortunately an incident or health crisis, liability and change will follow.

It should be noted that assumption of risk could not be used as a defense to a product liability claim by the biotech industry unless the products were clearly labeled as genetically modified and the public warned of any potential hazards. The consumer must be aware of whether a product contains GM ingredients, along with the potential risks, and voluntarily assume these risks through their purchases and intentional ingestion of these foods. Of course, a labeling and informational campaign approach would only enable the assumption of risk defense to be raised; a jury would still have to be satisfied that these risks were affirmatively undertaken by the consumer. Moreover, a manufacturer's responsibility to the public and greater ability to minimize these risks should ultimately be given more weight in the equation to assess liability. Nonetheless, there may be reduced costs in the form of a significantly diminished risk of liability from lawsuits, at least with respect to potential claims for injuries that may occur due to a failure to warn. Because such labeling and warnings are not currently required under federal law, voluntary labeling and information dissemination would be a wise approach for biotech.

In view of substantial potential liability, it would be in the best interests of the biotech industry to self-regulate proactively before state and federal regulators step in along with attorneys through the private tort system. As injuries and damages prove to be no longer theoretical but prohibitively expensive, the industry should come to realize that safety is good business.

A Glimpse Into the Future

Who will bear the risk of the significant potential harm from GMOs? While in the short run it is the consumers who are unknowingly ingesting these substances due to the scientific uncertainty that in the United States has given the government the regulatory leeway to allow these substances into the food supply without mandatory labeling and monitoring, ultimately it will be the farmers who plant the GM crops and the biotech companies who

have developed and propagated their invention. From a risk assessment perspective, biotech companies should have cause for concern. So too should farmers, who must be made aware of and carefully consider these legal liability risks in making their decisions on whether to plant GM crops and whether, indeed, they will in the long run be as profitable as the biotech companies would lead them to believe. In leaving these decisions to the farmers and companies through regulatory inaction and a lack of statutory rigor, perhaps US policy makers have after all unwittingly set the stage for a tort waiting to happen. ♦

Endnotes

1. Recent statistics indicate that GM crops comprised 93% of soybeans, 86% of corn, and 93% of cotton planted in 2010; and GM canola, squash, papaya, alfalfa, and sugar beet were widely planted. USDA ECONOMIC RESEARCH SERVICE, GENETICALLY ENGINEERED (GE) CORN VARIETIES BY STATE AND UNITED STATES, 2000-2011, available at <http://www.ers.usda.gov/Data/BiotechCrops/all-tables.xls>; ISAAA BRIEF 41-2009: EXECUTIVE SUMMARY, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, <http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp> (last visited June 16, 2012) (documenting rise in GM plantings in the first 14 years, from 1996 to 2009). The Grocery Manufacturer's Association reported in 2005 that 75% of all processed foods in the United States contain a GM ingredient, including almost every product with a corn or soy ingredient and some containing canola or cottonseed oil. See Americans Clueless About Gene-Altered Foods (Mar. 23, 2005), <http://www.msnbc.msn.com/id/7277844/> (statement of Stephanie Childs, Grocery Manufacturers of America). Projecting from the exponentially higher plantings since then, that figure should be substantially higher today.

2. See Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring With Positive Implications for International Trade*, 40 INT'L LAW. 95 (2006) (analyzing the differing regulatory approaches of the United States and the EU as a reflection of the cultural views of risk and scientific uncertainty with an impact on international

trade).

3. See Debra M. Strauss, *The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology*, 45 STAN. J. INT'L L. 287, 289-90 (2009) (analyzing the intellectual property treatment of genetically engineered seeds, contrasting U.S. patent law with international treaties, and proposing a model that would promote constructive innovation for the public benefit by encouraging "socially responsible technology") [hereinafter Strauss, *International Intellectual Property Rights*].

4. U.S. Patent Office Database, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnethtml%2FPTO%2Fsearch-adv.htm&r=0&f=S&dl=50&d=PTXT&RS=AN%2Fmonsanto&Refine=Refine+Search&Refine=Refine+Search&Query=AN%2Fmonsanto> (last visited June 15, 2012).

5. Center for Food Safety, *Monsanto v. U.S. Farmers Report* (2010 update), available at <http://www.centerforfoodsafety.org/wp-content/uploads/2012/03/Monsanto-v-US-Farmer-2010-Update-v.-2.pdf>.

6. Center for Food Safety, *Monsanto vs. U.S. Farmers Report* Monsanto vs. US Farmers (2005), available at <http://www.centerforfoodsafety.org/pubs/CFSMonsantovsFarmerReport1.13.05.pdf>.

7. *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980) (upholding patents issued for bacteria genetically engineered to break down crude oil spills).

8. *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001) (confirming the patentability of hybrid corn seed and newly developed plant breeds). Subsequent decisions upheld the patentability of animals, even mammals. See, e.g., *Transgenic Non-Human Mammal*, U.S. Patent No. 4,736,866 col.9 l.35 (filed June 22, 1984) (issued Apr. 12, 1988) ("a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal . . .").

9. *Monsanto Co. v. Bowman*, 686 F. Supp. 2d 834 (S.D. Ind. 2009), *aff'd*, 657 F.3d 1341, 1345-46 (Fed. Cir. 2011).

10. See *Bowman v. Monsanto Co.*, No. 11-796 (Apr. 2, 2012), pending petition, <http://www.scotusblog.com/case-files/bowman-v-monsanto-co/>. The Supreme Court has asked the Solicitor General to submit a brief expressing the government's views in this case, a

development that statistically increases the odds of the Supreme Court accepting the petition for certiorari.

11. Organic Seed Growers and Trade Association et al. v. Monsanto Co., No. 11-CV-2163-NRB (S.D.N.Y. filed Mar. 29, 2011).

12. See *Farmers Determined to Defend Right to Grow Food—File Appeal in OSGATA v. Monsanto*, ORGANIC SEED GROWERS & TRADE ASS'N (Mar. 28, 2012), <http://www.osgata.org/farmers-determined-to-defend-right-to-grow-food-file-appeal-in-osgata-vs-monsanto>; see also Debra M. Strauss, *The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply*, 48 IDAHO L. REV. 267 (2012) (further discussing this lawsuit, its significance, and subsequent developments).

13. See Strauss, *International Intellectual Property Rights*, *supra* note 3, at 298. The case of Percy Schmeiser, a Canadian farmer aggressively pursued by Monsanto for patent infringement despite his lack of intention and the fact that his own long-developed crop of corn was mutated by the Monsanto seed, is one of many dramatic examples. *Id.* at 295-97; *Monsanto Canada, Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (Can.). Perhaps the inequity of resources has prevented farmers from pursuing their legal rights in this area.

14. William Neuman & Andrew Pollock, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, available at http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?ref=food_prices (Roundup-resistant weeds like horseweed and giant ragweed are forcing farmers to spray fields with more toxic herbicides and to use more expensive techniques previously abandoned—more labor-intensive methods like pulling weeds and regular plowing.). The National Research Council has also issued its own warning about the emergence of resistant weeds and other risks as limiting the potential benefits of GM crops. NATIONAL RESEARCH COUNCIL, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES 2 (Apr. 13, 2010), available at <http://www.nationalacademies.org/includes/genengcrops.pdf>.

15. See Debra M. Strauss, *We Reap What We Sow: The Legal Liability Risks of Genetically Modified Food*, 16 J. LEGAL STUD. BUS. 149, 155-68 (2010) (discussing theories of legal liability and lawsuits arising from incidents of contamination from GMOs, and concluding

that the interests of seed companies, farmers, and consumers will converge in this area to mandate greater certainty and safety) [hereinafter Strauss, *Legal Liability Risks*].

16. Arlene Weintraub, *What's So Scary About Rice? Biotech Crops Can Make Drugs—But They Must Be Kept Out of the Food Chain*, BUS. WK., Aug. 1, 2005, at 58; see also The Pew Initiative on Food and Biotechnology, *Pharming Reaps Regulatory Changes*, May 15, 2003, available at <http://lists.iatp.org/listarchive/archive.cfm?id=74423> (finding that seeds inadvertently left behind in former test sites mingled with soybeans that were harvested and stored before the situation was discovered). Two months earlier, Prodigene had to destroy 155 acres of corn in Iowa due to contamination suspected from the windblown pollen of its drug-producing plants. See Karen Perry Stillerman, *Pharmaceutical Food Crops in a Field Near You*, Union of Concerned Scientists, http://www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_genetic_engineering/pcc-article.html.

17. See John S. Harbison, *The War on GMOs: A Report from the Front*, National AgLaw Center, Aug. 2004, at 2-3, http://www.nationalaglawcenter.org/assets/articles/harbison_gmos.pdf; Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11337-01 (proposed Mar. 10, 2003) (to be codified at 7 C.F.R. Part 340); Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed. Reg. 3271-01 (proposed Jan. 23, 2004) (to be codified at 7 C.F.R. Part 340).

18. See, e.g., USDA, Introduction of Genetically Engineered Organisms, Draft Programmatic Environmental Impact Statement—July 2007, http://www.aphis.usda.gov/brs/pdf/complete_eis.pdf (study by APHIS proposing further changes to these regulations).

19. *In re StarLink Corn Products Liability Litigation*, 212 F. Supp. 2d 828, 833 (N.D. Ill. 2002).

20. Donald Uchtmann, *Liability Issues: Lessons from StarLink*, 10 RICH. J.L. & TECH. 23 (2004). Ironically, Aventis later sold its crop science unit to Bayer CropScience, which subsequently became responsible for LibertyLink rice.

21. Rick Weiss, *Gene-altered Profit-killer: A*

Slight Taint of Biotech Rice Puts Farmers' Overseas Sales in Peril, WASH. POST, Sept. 21, 2006, at D01.

22. *In re Genetically Modified Rice Litigation*, 06-md-1811, U.S. District Court, Eastern District of Missouri.

23. See Strauss, *Legal Liability Risks*, *supra* note 15, at 156-60 (extensively analyzing the massive LibertyLink rice litigation and predicting its ultimate settlement); Andrew Harris & David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, BLOOMBERG (July 2, 2011), <http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html>.

24. Julie A. Nordlee et al., *Identification of a Brazil Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688 (1996).

25. Food allergies are a growing concern in the United States: "As many as 15 million people have food allergies," including an estimated 9 million, or 4% of adults and nearly 6 million or 8% of children, with young children affected the most. The Food Allergy & Anaphylaxis Network, "Food Allergy Facts and Statistics for the U.S.," <http://www.foodallergy.org/files/FoodAllergyFactsandStatistics.pdf>. Because the typical focus is on "food with genes transferred from the 8 to 10 most commonly allergenic foods, public-interest groups have cautioned that existing rules inadequately protect people against lesser-known transgenic allergens to which they might be sensitive." Marion Nestle, *Allergies to Transgenic Foods: Questions of Policy*, 334 NEW ENG. J. MED. 726 (1996).

26. See Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 167 (2006) (discussing the health and environmental risks of genetically modified food) (citing NATIONAL RESEARCH COUNCIL, REPORT IN BRIEF, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (July 2004), http://www.nap.edu/html/ge_foods/ge-foodsreportbrief.pdf).

