

PANEL REMARKS ON LIABILITY

LIABILITY ISSUES: LESSONS FROM STARLINK

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{1} Good afternoon ladies and gentlemen. I have an enormous opportunity and challenge. Here I am, the final speaker, on this final panel, on this beautiful Friday afternoon, on this beautiful campus. Stay “tuned” for just a few more minutes to hear my remarks regarding liability issues and then we will adjourn to the great outdoors.

{2} Drew Kershen’s earlier presentation reminded me that issues related to genetically modified foods are issues that can generate great passion. More generally, I have seen many different perspectives presented today by different speakers. Each speaker has made a unique and valuable contribution to this program and has helped all of us understand biotechnology in a more complete way. I hope I can follow suit.

{3} Let me turn to the topic of civil liability issues related to agricultural biotechnology. I will examine civil liability in the context of the StarLink incident, an incident that has been alluded to on several occasions earlier today. To refresh your memories, StarLink was an incident in which a particular genetically engineered corn variety – StarLink™ – was approved by the EPA for animal feed use only. This “split” approval (approval for feed but not food use) occurred in 1999, but the larger planting of StarLink seed was in year 2000. The discovery of trace amounts of StarLink corn in taco shells and other foods confirmed that StarLink had inadvertently moved from feed channels into food channels, even though it was not yet approved for food use. Thus, any food containing StarLink was, in fact, “adulterated” as the term is defined in the Federal Food, Drug, and Cosmetic Act. Foods containing StarLink were recalled from grocery store shelves. StarLink seed was also taken off the market. The whole incident raised issues of who is liable for what.¹

I. The StarLink incident teaches us that the costs of civil liability can be very high.

{4} When we look at the StarLink incident, we can make one general point: if, in spite of a rigorous regulatory system, something does go wrong with a biotech product – perhaps people experience an allergic reaction or, as in the StarLink case, perhaps some people experience economic damage – then the costs of civil liability can be incredibly high.

{5} For example, Aventis, the company that “owned” StarLink, first incurred significant costs in purging StarLink from food and export channels. Millions of dollars were expended by Aventis in an effort to get this product back into “feed only” uses after it moved inadvertently into food and export channels. And this cost was only the beginning.

{6} There also was a settlement of consumer class action lawsuits where consumers alleged that they



suffered allergic reactions. The cost of that settlement was about nine million dollars, a second cost arising because Aventis made the mistake of allowing this product to move into food channels where it was not yet approved.² Interestingly, the nine million dollar cost of settling this consumer Class Action lawsuit occurred without any conclusive evidence that any allergic reactions to StarLink's novel protein had, in fact, taken place. We still haven't established whether StarLink's Cry9C protein is or is not an allergen. It has never been proven not to be an allergen because that is a very, very difficult thing to prove.

{7} But the Starlink-related liability doesn't end there. As we speak, farmers across the corn belt are deciding whether they should opt out of another Class Action lawsuit, this one brought by non-StarLink corn producers. Farmers must make a decision by March 21, 2003 – within a week – about whether to opt out. Each farmer that remains in the class will submit a claim for his or her respective share of a \$110 million proposed settlement of this Class Action lawsuit.³ By the way, that's not "big bucks" for individual corn producers. I worked through some numbers. It's about a dollar or two an acre for every acre of non-Star Link corn harvested for grain in the year 2000.

{8} But liability may not end there, either. What settlements will be made with food retailers regarding food recalls? What settlements will be made with other companies for rejected food shipments? Any such settlements are unlikely to be very public. But undoubtedly the food recalls create liability issues as well.

{9} My first general point is this. The StarLink incident teaches us that if a company makes a mistake in commercializing a transgenic crop, the cost of civil liability for food biotechnology can be very high. In the case of StarLink, it included the costs of destroying the remaining seed inventory, locating and removing from the U.S. corn supply StarLink corn and corn commingled with StarLink, settling with consumers who allegedly suffered allergic reactions (although no such reactions were proven), settling a class action lawsuit by corn growers who allegedly suffered depressed corn prices as a result of the mistake, and probably settling other claims for damages arising from food recalls and rejected food shipments.

II. The StarLink incident illustrates that many legal theories may support liability claims.

{10} My second point is that there are, in fact, many legal theories that potentially support liability claims if there is, in fact, damage resulting from genetically engineered products. For example, if we look at the Non-StarLink Farmers Class Action lawsuit, on July 11, 2002, Judge Moran ruled upon a Motion to Dismiss.⁴ In that Motion we see that negligence, negligence *per se*, strict liability in tort, trespass, private nuisance, public nuisances, and others are all theories under which the company which markets a product might be liable for damage that would result. There is no shortage of potential theories.

{11} Most importantly, Judge Moran dealt with the economic loss doctrine.⁵ This is a doctrine that arguably could limit the responsibility of Aventis or Aventis' successors for the economic damage that resulted. This is the very kind of damage that the non-StarLink farmers were alleging, namely that the whole StarLink incident caused plaintiffs' crop to become contaminated and caused a depressing effect on corn prices, and every corn farmer who sold any corn that year was in fact damaged because of depressed prices. The economic loss doctrine might well preclude such recovery, but in his analysis of briefs on that issue, Judge Moran concluded that the economic loss doctrine, in the setting of StarLink, does not necessarily bar the Plaintiffs' claims, and there should be an opportunity to offer proof on

various issues, including whether plaintiffs suffered direct harm, if the case proceeds to trial.

III. StarLink has sensitized the agriculture/food biotech chain to issues of liability.

{12} Liability risks are clearly an important part of any decision by a biotech company to commercialize a transgenic product. Thus, the liability regime is a complement to our regulatory system. It is not just regulatory approval or lack of approval that will determine whether a product can go to market. Separate and apart from the regulatory approval of the product, there will be an assessment by the company of any civil liability risk, and the company will weigh the potential profits of marketing that product against that liability risk. The liability risk is a significant influence on the decision to commercialize a product and helps assure us that only safe products come to market.

IV. Should a special liability regime be created for biotechnology?

{13} One of the policy questions surrounding biotechnology is whether claims for damages allegedly arising from the use of biotechnology products should be determined under existing principles of liability, or whether an alternative liability regime should be created. In 1994, Dan Burk and Barbara Boczar outlined one proposal for a comprehensive biotechnology products liability scheme.⁶ Under their proposal a special, no-fault liability scheme would apply to all products (a) produced through specified biotechnology techniques and (b) approved for use by a regulatory agency. Also, compensation would be limited to the costs of medical care, death benefits, lost earnings, and pain and suffering (there would be caps on pain and suffering awards and no punitive damages would be allowed).

{14} As a practical matter, no such alternative biotechnology liability scheme has been adopted for the United States to date. For now, the U.S. appears to be content with biotech-related liability issues being resolved within the general tort liability scheme, based on theories previously noted.

V. Special liability issues where products are unapproved in major export markets.

{15} The EPA has stated that it will not grant any more “split” approvals like we saw in the StarLink case where the genetically engineered corn was approved for feed but not food uses. However, we do have an analogous situation when some products are fully approved in the United States, but are not approved overseas. What if farmers grow these products on a large scale in the United States and these crops “spillover” into export channels, e.g., shipments to the European Union where many biotech crops are not yet approved because of the *de facto* moratorium on new approvals? In such a situation there is the potential for the export shipments to be either substantially discounted or even rejected and we have potential for economic loss.

{16} Some of what we’ve learned in the StarLink liability litigation is probably applicable to this situation. And it’s especially relevant since there is a new product coming out on the market this spring – a corn variety known as YieldGuard Rootworm™ – that has been genetically engineered to protect it from corn rootworm, a terribly devastating pest which has adapted so that our normal corn/soybean rotation doesn’t disrupt its life cycle anymore.⁷ Corn farmers are now using substantial amounts of pesticides to control this pest, since they can no longer control it with crop rotations. Suffice it to say, YieldGuard Rootworm™ is expected to be a popular product with farmers. It’s going to be grown in areas like my home state, Illinois, which also produces a lot of the grain for export because of our proximity to the river transportation system.



{17} There is a great deal of concern among farmers. Their concern is not about the safety of the product in a health sense, nor are farmers concerned about potential damages to the environment (farmers believe it is going to be very positive in that regard; it will replace pesticides that are viewed as being more problematic). Their concern is about the potential negative impact of genetically engineered rootworm resistant corn on their export markets.

VI. Summary

{18} We've learned much about liability from the StarLink incident:

- The cost of civil liability for food biotech can be very high if a company makes a mistake in bringing a biotech product to market.
- There are numerous legal theories that may support liability claims in the right set of circumstances (and there is no apparent movement to create a special "no-fault" liability system for the products of biotechnology).
- The potential for liability is incorporated into a company decision to move forward in marketing a product; thus the liability regime complements the biotech regulatory regime in helping to assure that products coming to market are safe.
- The potential for commingling and the resulting "economic loss" that arose from EPA's "split" approval of StarLink is also present when a genetically engineered crop is fully approved in the U.S. but is not approved in major export markets.

{19} In addition, there are many liability-related issues to be resolved in the future. For example, throughout the food chain, who has what responsibility to prevent the inadvertent mixing of approved-and unapproved-for-export grain? Who has what responsibility to test, and with what protocols? Who can be indemnified through contract language, and when do these liability-shifting contracts violate public policy? Could the potential release of a fully approved variety in the United States be enjoined through court action because the release in the U.S. of an "unapproved-in-export markets" variety might constitute a public nuisance. This issue has been discussed in the past with the result that a biotech company chose to voluntarily withhold its product from market until additional overseas approvals could be forthcoming.⁸

{20} The liability issues related to agricultural biotechnology are intriguing. They are exciting for the Plaintiff's bar, for the Defendant's bar, for policymakers, for consumers, and for all of us.

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¹ See D. L. Uchtmann, *StarLink™ -- A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. LAW, 159, 174-202 (2002).

² Jill Carroll, *Judge Will Approve Settlement on Use of StarLink Corn*, WALL ST. J., Mar. 7, 2002, at A4.

³ See *In re StarLink Corn Products Liability Litigation*, 152 F. Supp. 2d 1378 (J.P.M.L. 2001)

⁴ *In re StarLink Corn Products Liability Litigation*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

⁵ *Id.* at 838.

⁶ See Dan L. Burk & Barbara A. Boczar, *Biotechnology and Tort Liability, A Strategic Industry at Risk*, 55 U. PITT L. REV. 791, 794 (1994). The authors argue that the traditional tort liability system doesn't serve the public interest well because many issues will require expert scientific testimony and such issues tend to bring out the worst in the American tort liability system. The authors also argue that, absent a special liability system, the costs of liability will make the biotech industry uncompetitive internationally. *Id.* at 794.

⁷ The trade name for the product is YieldGard Rootworm™. See EPA, Fact Sheet (EPA Publication Number: 730-F-03-01) for *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn (March 6, 2003), available at http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_006484.htm (last visited Jan. 7, 2004).

⁸ Thomas P. Redick, *Biopharming, Biosafety, and Billion Dollar Debacles: Preventing Liability for Biotech Crops*, 8 DRAKE J. AGRIC. LAW 115, 136-37 (2003).

