Legal Backgrounder

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ENGINEERING LEGAL RISK MANAGEMENT INTO AGRICULTURAL BIOTECHNOLOGY

by

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Agricultural biotechnology's first "mass tort" has worked its way through various courts through multiple class actions and individual claims that growers and consumers filed against Aventis Crop Sciences, Inc. (and its successor-in-interest, Starlink Logistics, Inc.). Starlink™ corn was genetically engineered to resist pests and herbicide, but its legal protectors did not engineer sufficient protection from class action attorneys. While Starlink™ corn, like all biotech crops produced in the U.S., was subject to extensive federal regulation and voluntary industry-wide monitoring for any risk of human injury (risk management far beyond the level of care given to other plant breeding methods), Starlink™ corn nevertheless caused a billion dollar loss almost entirely from claims for economic loss.

The recall of Starlink™ corn led to a surprisingly broad reading of nuisance law by a U.S. District Court in July 2002, recognizing a claim for a nationwide economic "public nuisance," which in turn led to a $110 million court-approved class action settlement for corn growers around the U.S. The first part of this LEGAL BACKGROUNDER will discuss the novel precedent created by this District Court and suggest that improved containment ("stewardship" or "identity preservation") will be required to protect grain prices from future compensable economic impacts. The second part will discuss "anticipatory nuisance" as a tool for imposing improved stewardship on a careless biotech company.

Starlink™ Corn's Seminal "Public Nuisance" Decision. It is nearly three years since Starlink™ corn was first discovered in taco shells in the fall of 2000 by activists armed with genetic tests ("PCR" tests) that detected the unique genetic sequence of Starlink™ corn. The economic impacts are still rippling through the corn belt from this corn, which could resist both insects and herbicide but could not legally be commingled with food. After this problematic protein was found in various foods, an EPA Advisory Panel recommended a near-zero tolerance for it. The EPA overruled the request that Aventis made for a reasonable tolerance for Starlink™ corn. A massive recall of food and grain ensued.

Given the massive economic impact of the EPA-mandated recall of Starlink™ and given the problematic stewardship of Aventis and its agents, Starlink™ corn will yield a harvest of legal precedents. The most troubling precedent is the decision allowing nationwide "public nuisance" class actions compensating growers for economic impacts. In denying Aventis' motion to dismiss various claims in *In re Starlink Corn Products Liability Litigation*, 212 F. Supp. 2d 828 (N.D. Ill., 2002), Judge Moran allowed

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plaintiffs to allege that Starlink™ corn could be a nationwide "public nuisance." While public nuisances are usually subject to *injunctions* to stop the harm, each of these individual class action plaintiffs was paid *compensatory damages* for alleged nationwide impacts to corn prices. Within months of this ruling, the plaintiffs (nearly all corn growers nationwide) settled for up to $110 million, with notice given to thousands of corn growers who lost money due to depressed corn prices.

This seminal "public nuisance" precedent could define the future marketplace for *all* crops produced using recombinant DNA ("biotech crops") that lack regulatory approval in any significant marketplace, including biotech crops lacking approval in overseas markets (which may impose unreasonably low tolerances for varieties of biotech crops lacking regulatory approval). In an age when readily foreseeable economic loss could increasingly be caused by overseas trade barriers to unapproved biotech crops,[1] the *Starlink* precedent could exert a profound chill on innovation in agricultural biotechnology. Class actions seeking compensatory damages for economic loss could become common place. The EPA's near-zero tolerance stance in the Starlink™ corn recall, combined with the *Starlink* decision allowing nationwide "public nuisance" class actions, could break fertile new ground for future nuisance lawsuits.

Before the *Starlink* decision, lawyers representing biotech industry clients contended that this "public nuisance" claim was unprecedented, since it sought compensation for interference with corn markets. Starlink™ corn, like other "unapproved-overseas" varieties of biotech corn[2] lacked regulatory approval in major export markets ("unapproved-overseas" varieties of biotech crops). If "unapproved overseas" biotech crops commingle through negligent stewardship, they may cause economic loss that is compensable in the post-Starlink™ era. Recognizing a claim for public nuisance in the case of Starlink™ could readily lead to public nuisance claims against biotech crops lacking regulatory approval overseas. In both cases, the commingling of the biotech crop causes economic loss after careless handling leads to foreseeable, readily prevented commingling with crops bound for export markets.

After the *Starlink* decision, Sheila Birnbaum, the attorney defending Aventis, correctly identified these compensatory "public nuisance" claims as being based upon "very novel tort theories." Andrew Harris, *Danger Uncertain, But Suits Multiply,* NAT'L LAW J., Sept. 9, 2002. The court treated channels of grain commerce as if commingling grain had blocked a public thoroughfare. Since grain flowed from various tributaries (farms, elevators, etc.) and grain shipments were blocked at overseas ports due to commingling of Starlink™ corn, like a river of grain that is blocked by a negligent act, the court apparently saw ample room in vague nuisance precedent to apply public nuisance law to this commingling incident.

Starlink™ corn's legal impact may be fleeting – this precedent arose from a motion to dismiss public nuisance claims. This motion was denied by a federal district court in a case that settled shortly thereafter. No appeal was taken to establish this as precedent at the level of a federal Circuit Court of Appeals, so it remains merely persuasive, not dispositive, District Court precedent.

Fortunately, however, *Starlink*'s legal precedent in public nuisance provides responsible biotech companies and growers associations with a solid legal foundation for insisting upon strict identity preservation for varieties lacking overseas approval. For the next few years, agricultural biotechnology companies will have to perfect the uncertain art of containing unapproved biotech crops in closed-loop production systems. For the biotech industry to play its inevitable, necessary role in agricultural production (including production of industrial or pharmaceutical compounds), the threat posed by class actions seeking compensation for economic impacts must be neutralized. If U.S. agricultural biotechnology industry can contain each problematic "unapproved" variety, it will prevent the recurrence of this troublesome legal novelty. If class action settlements for other biotech crops begin to be reported, however, investors will flee life sciences companies.

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[1]In addition to the European Union, which has held U.S. corn since 1997 due to commingling of certain unapproved biotech varieties, there is a new international treaty, the Cartagena Protocol on Biosafety, which could raise new trade barriers as nations struggle to comply with its terms, and grain exporters take steps to avoid having ships turned away due to the presence of traces of unapproved biotech crops. See, Convention on Biological Diversity Website, text of Cartagena Protocol on Biosafety, http://www.biodiv.org/biosafety/protocol.asp.

[2]For purposes of this paper, an "unapproved" variety of biotech crop will refer to one that lacks approval to be imported as grain (not necessarily planted as seed, but solely for processed food or feed) into any major overseas markets, (e.g., Europe, Japan, etc.).

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The Liberty Link Soybean – Stopping the $10 Billion Debacle. While the *Starlink* decision is a novel extension of nuisance doctrine, this extension was not entirely unpredictable. For years, creative plaintiffs' attorneys have been bringing public nuisance actions against guns, lead paint and other products. Aventis was specifically warned, in 1998, of the threat that nuisance law posed. The American Soybean Association (ASA), representatives of American soybean growers (growers who have rapidly adopted biotech crops) told Aventis of the potential for nuisance law to expand to capture the economically cataclysmic commingling of varieties of biotech crops that lack approval for export to the European Union. Since unapproved-in-EU soybeans cannot commingle without causing massive disruptions in grain shipments to major export markets, logic dictated that a compensable economic "nuisance" could result. To avoid an economic cataclysm, ASA persuaded Aventis to refrain from marketing Starlink™'s sister seed, Liberty Link™ Soybean, and Aventis avoided creating an economic public nuisance. After months of negotiations, Aventis abandoned its plans to commercialize the soybean; even today it still awaits approval by the EU. Aventis did so despite having secured full "food and feed" approval in the U.S. and having invested significant resources.[3]

As a result of this joint effort by Aventis and ASA in 1998, U.S. soybean exports were spared the broad ban that stopped U.S. corn exports to the E.U. from 1997 to the present. In contrast to soybeans, the U.S. corn industry only exports about 20% of the U.S. crop, and it only sustained approximately $200 million per year in lost exports. In contrast, the export market for soybeans is over 50% of its soybean harvest. U.S. soybean exports to the E.U. are ten times the size of corn, with several billion dollars of soybeans shipped annually to Europe alone. Given the subsequent decision in *Starlink*, ASA arguably helped Aventis avoid as much as $10 billion in potential liability for nuisance class actions.

ASA used an updated approach to contain the 1999 launch of the high-oleic soybean sold by Dupont, which was grown under careful containment with the assistance of ASA (in defining the necessary level of care, and persuading the EU authorities that this level of care was adequate). ASA used the threat of a "friendly" public nuisance action, informing Dupont that soybean growers were prepared to enjoin a cataclysm in soybean export markets. In estimating nuisance liability risks for Aventis and Dupont, however, ASA actually underestimated the scope of the *Starlink* case's application of nuisance law. The *Starlink* decision by Judge Moran extended nuisance law to cover grain that was never actually commingled with Starlink™ (i.e., growers far removed from the actual commingling of Starlink™ still suffered compensable economic loss). The court allowed a nationwide class to recover for impacts to grain prices, which was truly a novel and unpredicted event in the history of laws regulating agricultural biotechnology.

In contrast to "private" nuisance law, which would require physical interference with an individual grower's property, the "public" nuisance claim in *In re Starlink* did not limit relief to growers directly affected by pollen drift or post-harvest commingling of Starlink™ corn. These growers alleged that they had sustained "special harm" distinguishing them from the public at large (just as fishermen sometimes lose their livelihood from pollution to a river that kills the fish that they would have caught). Given its expansive view of recoverable "special harm" in a public nuisance action, the *Starlink* decision may hand this public nuisance power, which is usually wielded by state attorneys general, to class action counsel representing a few named plaintiffs on behalf of thousands of U.S. citizens. As a result, given subsequent events arising from the Starlink™ recall, ASA's cautious approach has been validated by the *Starlink* decision. The ASA's stewardship plan could be used to prevent another massive (e.g., over $100 million) class action settlement.

Anticipatory Nuisance and Stewardship Standards. To protect the entire chain of export commerce from future economic debacles like the one Starlink™ corn caused in export markets, the chain of commerce in U.S. export grain commodities — growers, grain shippers, agribusiness, etc. — may need to invoke the little-used doctrine of "anticipatory" public nuisance against substantial threats to export markets. Given ASA's track record of successful negotiations without litigation, it is clear that an informed and credible threat

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[3]The CEO of ASA, Steven Censky, outlined ASA's approach at the 1999 Biotechnology Roundtable on "Liability and Labeling" hosted by the American Bar Association's Committee on Agricultural Management for its Section on Environment, Energy and Resources. *See* Stephen Censky, *Improving Communication from Seed Production through Retail,* Summary at http://www.cast-science.org/cast/biotech/0002abab.htm. Monsanto provided a road-map at the same meeting for continuous improvement in stewardship. Counsel for Aventis was also in attendance. Neutral legal forums, such as the American Bar Association's Committee on Agricultural Management, can provide a resource for creating risk management tools to protect the entire agricultural biotechnology industry, and the chain of commerce that it serves, from the mistakes of any link in the chain of "identity-preserved" commerce.

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of an injunction to restrain an impending public nuisance is a valuable tool that can help biotech crops continue on the path to becoming the dominant model for grain production. There is ample authority under "federal common law" for seeking an injunction under long-standing "anticipatory nuisance" doctrine.[4] This can be applied where there are transboundary threats to the economic interests of an adjacent state.

At present, however, most of the actions involving "anticipatory nuisance" involve proposed "concentrated animal feeding operations" (CAFOs") under state law. In *Nickels v. Burnett,* 2003 Ill. App. LEXIS 1278, No. 02-MR-175 (Ill. App. October 20, 2003), the court affirmed an anticipatory nuisance injunction against a proposed CAFO, holding that "It is well settled that a plaintiff may seek to enjoin an activity that may lead to substantial future harm." (Citing *Village of Wilsonville v. SCA Services, Inc.,* 86 Ill. 2d 1, 25 (1981)). The court found that plaintiffs presented extensive evidence of the potential harms to human health and land values (i.e., economic loss) from operation of the hog facility, should it be allowed to begin to operate. Since the harms described were "substantially certain" to occur, injunctive relief was available.[5] As a result, for any future threat of economic loss from a biotech crop that reaches the billion-dollar mark, there should be grounds for injunctive relief.

In contrast to the ASA's friendly "customer audit" of stewardship, which holds the nuisance injunction in abeyance pending negotiation and pre-filing mediation, the *Starlink* litigation and these "anticipatory nuisance" lawsuits are costly and contentious. The agricultural biotechnology industry in the United States (its primary home worldwide, at present) could be devastated by litigation if it does not implement adequate measures for "containment" of biotech crops that are not approved for export. With sound stewardship, the U.S. life sciences industry can contain the Starlink™ precedent to its unique fact pattern.

Biotech companies can work closely with growers associations armed with a crop-specific "standard of care" that the EU and other wary overseas markets can accept. A heightened level of industry-wide stewardship could be established immediately with standard stewardship clauses incorporated in agreements signed by growers. The contracts could be enforced by the threat of contractually stipulated injunctive relief against those who fail to comply with stewardship standards. This industry-wide mandatory stewardship program would also "isolate" the public nuisance precedent established in the Starlink™ cases, by preventing another set of "bad facts" from reaching appellate courts and making "bad law" for biotech companies.

Conclusion. The *Starlink* decision created novel tort precedent which should be contained by coordinated biotech industry efforts to ensure that no new bad facts arise to make more bad law. Fortunately, the Starlink™ corn debacle also provides the key to negotiating solutions to future threats posed by biotech crops, using the threat of injunctive relief to persuade a biotech company to undertake enhanced stewardship. A coordinated strategy between growers and biotech companies is needed to prevent both: (1) economically cataclysmic impacts and (2) devastating legal precedents that could cede control of our biotech industry's future to plaintiff's class action attorneys.

The *Starlink* court's treatment of the entire marketplace as a public thoroughfare, creating a public nuisance that can be compensated through payment of damages, is a truly novel and innovation-threatening extension of nuisance doctrine. Starlink™ corn clearly disrupted this public "thoroughfare" in the global grain marketplace, causing a public nuisance that caused damages to individual growers through a decline in the price of corn. The economic threat posed by biotech crops to the marketplace, however, is vastly outweighed by the threat to the agricultural biotechnology industry from this novel legal development. In other words, the economic impact upon the U.S. economy and the world from the threatened loss of future innovation in agricultural biotechnology is a cataclysm well worth avoiding, through careful legal planning and cooperation.

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[4]*See*, *e.g.*, *Missouri v. Illinois*, 180 U.S. 208; 21 S. Ct. 331; 45 L. Ed. 497; 1901 U.S. LEXIS 1298 (1901); Charles J. Doane, *Comment: Beyond Fear: Articulating a Modern Doctrine in Anticipatory Nuisance for Enjoining Improbable Threats of Catastrophic Harm*, 17 B.C. ENVTL. AFF. L. REV. 441 (Winter, 1990).

[5]*See* 17 B.C. ENVTL. L. REV. 441 (cases summarized through 1990); *Cf.*, *Rutter v. Carroll's Foods of the Midwest, Inc*., 50 F. Supp. 2d 876 (1999) (motion to dismiss claim for anticipatory nuisance denied; anticipatory injunctive relief claims were allowed against pork feeding/finishing operation).

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