

Memorandum

To: Forest Health Initiative Regulatory Committee

From: Thomas P. Redick – Global Environmental Ethics Counsel

Date: April 13, 2016

Re: Legal barriers to entry – Nuisance and Regulatory Law and Biotech Trees

This memorandum will discuss in summary form the legal threats that may exist to the release and unconstrained use of the American chestnut with genes altered to resist fungal assaults from the blight that devastated this iconic American tree.

I. Executive Summary

The unrestricted release and use of the American chestnut could stir enough controversy among anti-biotech activists to lead them to file injunctive litigation to stop the launch (release allowing unconstrained use), either through the National Environmental Policy Act (NEPA) (a commonly used tool, with attorneys' fees paid by the government to successful litigants) or the novel common law approach, anticipatory nuisance. Issues relating to major market approval are increasingly becoming the basis for regulatory delays and costly compensatory nuisance litigation. Regulatory rollbacks may be possible for familiar genetic engineering (GE) technologies or for traits using new plant breeding tools, but a new species of tree using GE traits can expect a full regulatory review (and such a full regulatory review might insulate it from NEPA litigation).

II. Analysis & Discussion

A. Injunctions barring release

This section will discuss common law nuisance injunctive relief as well as federal statutory injunctive relief.

1. Anticipatory nuisance injunctions

A genetically engineered (GE) American chestnut could be targeted for anticipatory nuisance by opponents who do not want it released widely or grown in the wild.

The doctrine of anticipatory nuisance has deep roots in the common law, where the law of nuisance and trespass protected property owners from neighboring intrusions. The first environmental impacts to trigger liability were handled through nuisance law throughout the history of the common law. In 1887, the U.S. Supreme Court first recognized a role for anticipatory nuisance as a tool to prevent a public nuisance from emerging. *Mugler v. Kansas* 123 U.S. 623 (1887). 100 years later, the leading book on tort law, Prosser on Torts (5th Ed, 1984) confirmed the existence of this tort, stating that probability (50%+), not mere possibility, of a nuisance could justify granting an injunction. Some states (e.g., AL and GA) have statutes enabling it. Nuisance law has evolved to operate in parallel to federal statutes that govern

adverse impacts of pollution, and where the federal and state statutes fail to offer protection from a nuisance, the common law remedies including an injunction beforehand, and compensation claims after harm occurs.

The state of Illinois has two of the leading anticipatory nuisance cases, involving a chemical facility, *Wilsonville v. SCA Services Inc.*, 426 N.E.2d 824, 842 (Ill. 1981) and concentrated animal feeding operation (CAFO) that had a state permit. *Nickels v Burnett* 798 N.E.2d 817 (Ill. App. 2003). Iowa law was applied by a federal court to enjoin a CAFO in *Rutter v. Carroll Foods*, 50 F. Supp. 2d 876 (N.D. Iowa 1999). An Oklahoma court enjoined a state-approved landfill due to an alleged high probability of contaminated leachate from the landfill to neighboring landowners. *Sharp v. 251st St. Landfill, Inc.* 925 P.2d 546 (Okla. 1996). Many cases are collected from various states over the last 100 years in Margaret Grossman, *Anticipatory Nuisance and the Prevention of Environmental Harm and Economic Loss from GMOs in the United States*, 18 *Journal of Environmental Law and Practice*, 107 (2008) (pdf on file with author).

Where plaintiffs fail to show a serious permanent intrusion and the defendant's proposed activity has significant social benefit, the court may deny an injunction for anticipatory nuisance. *Id.* citing *Duff v. Morgantown Energy Associates*, 421 S.E. 2d 253 (W. Va., 1992); See also, *Burch v. Nedpower Mount Storm, LLC*, 647 S.E. 2d 879 (W.Va. 2007) (i.e. wind power is beneficial, the state-approved and did not enjoin). As a result, the supporters of the restored American chestnut must document the societal benefits that would arise from the planting of a restored American chestnut.

The export market of non-GMO/organic chestnuts and chestnut hardwood might be impacted adversely by the use of a GE American chestnut without complete containment. Public nuisance for disruption of a major export market – *In re Syngenta China Corn* (Viptera) – and private nuisance for pollen drift onto one's farm – *In re Aventis* (Starlink) – have been recognized as viable claims against biotech seed companies selling products that lack required regulatory approval at home or abroad. No court, however, has recognized a duty to protect an organic or non-GMO grower from pollen drift, since they assume a duty to maintain their own containment in exchange for a premium payment.

In the only reported case to date involving anticipatory nuisance and biotech crops, this theory was used against biotech canola in Canada. In *Hoffman & Beaudoin v. Monsanto Canada*, 2005 SKQB 225, appeal dismissed, 2007 SKCA 47, involved biotech canola that was unapproved in the European Union. In dismissing the claim for anticipatory nuisance, Bayer Crop Sciences and Monsanto Canada won an important partial victory early in the litigation. The court rejected the plaintiffs' claims that defendants substantially contributed to a nuisance when they dropped export-oriented identity preservation and failed to safeguard canola exports to the EU with their voluntary identity-preservation program, citing US case law in support.

2. National Environmental Policy Act Injunctions

A series of injunctions vacating USDA approvals starting in 2007 have delayed approval in the US for Roundup Ready (RR) Alfalfa and RR Beets using the injunctive power of the National Environmental Policy Act (NEPA). The basic argument has been that USDA approved the particular biotech crop before sufficient field testing had occurred and all environmental and economic impacts (e.g., to exports, to non-GMO, or organic crops). In a case involving RR bentgrass that had crossbred with wild grasses adjacent to the field trial test fields, the court held that USDA had acted arbitrarily in denying the plaintiff's claim that the GE bentgrass from the Scotts Co. and Monsanto should be listed as a noxious weed under the Plant Protection Act (PPA). As a result, the court found that USDA had violated NEPA by failing to consider whether field trials were exempt from the need for an environmental assessment or environmental impact statement. *International Center for Technology Assessment, et al. v. Johanns*, 473 F. Supp.2d 9 (D. D.C. 2007).

The latest NEPA lawsuit, filed in March 2016 in California federal court, challenges the FDA's approval of Aquabounty GE salmon via an Environmental Assessment (EA), which is a less detailed review than the environmental impact statement (EIS). The advantage that NEPA litigation has over the anticipatory nuisance claim discussed above is that successful NEPA litigants can recover their fees under the Equal Access to Justice Act.

The looming threat of NEPA has induced the USDA to conduct a lengthy EIS for dicamba-resistant corn and soybeans, delaying approval for at least 18 months. This makes a NEPA threat troubling both for the costly litigation and regulatory delays even without litigation.

The upside of having a thorough EIS during approval of the GE American chestnut could be the prevention of potential NEPA claims and might prevent anticipatory nuisance against the developer, if the USDA were found to have adequately considered the risk to exports in its EIS evaluating that regulatory submission.

Given the intent to release the GE American chestnut into the wild, a consultation with the federal Fish and Wildlife Service (USFW) may be worth considering before release of this tree into the wild. It has jurisdiction over wildlife refuges that might be available for a limited initial release of this tree. Janet Carpenter, *Impacts of GE Crops on Biodiversity*, (June 2011) U.S. Fish and Wildlife Service, http://training.fws.gov/resources/course-resources/pesticides/GMOs/impacts_of_ge_crops.pdf.

B. Regulatory Rollback options

NEPA's wings were clipped for transportation-related projects, including biofuels, in the Fixing America's Surface Transportation Act (FAST Act). If the American chestnut were grown for biomass production, it might qualify for this rollback of NEPA liability (shorter time to sue and any litigant has to raise the issues litigated in their regulatory comment). A contained initial launch as part of carbon sequestration/biomass might be the least risky approach to a successful deregulation and widespread use.

Changes in regulations do occur from time to time (e.g., USDA's recent effort to shorten timelines to approval succeeded for many pending traits). The regulatory agencies are currently

considering new approaches to biotech crops, particularly for new plant breeding tools (NPBT). There is a case to be made for reducing regulatory obligations for new but familiar traits in corn, soybeans and other commodity crops that raise similar risk issues. As a new species with long life and broad pollination, however, the GE American chestnut would not appear to be familiar enough to fit into this theory for reduced regulation.

While new legislation does not appear likely, a USDA regulatory overhaul is underway, particularly as to its approach to new plant breeding tools (NPBT). At present, those tools using no viral vectors remain unregulated in US. As is discussed below, however, these crops bred using NPBT may face overseas approvals issues – the Cartagena Protocol on Biosafety has this on its agenda for its upcoming meeting in December, 2016 in Cabo San Lucas. Similar overseas approvals issues might arise with cisgenics (using the same species genetics to improve resistance, etc.). These overseas approval issues might influence USDA policy on NPBT.

Regulatory rollbacks may be possible for familiar GE technology or for traits using new plant breeding tools, but a new species of tree using GE traits can expect a full regulatory review (and such a full regulatory review might insulate it from a NEPA attack).

C. Major Market Approval issues

The new Syngenta case (In re Syngenta China Corn) has a rule that seed companies have a duty to maintain programs keeping crops lacking overseas approval contained via voluntary stewardship for overseas approval/export disruption risks. This case is notable given that 1) U.S. corn growers asked for this trait through their trade association, the National Corn Growers Association, and 2) for the first two years of Viptera sales, the Chinese purchased U.S. corn without complaining of the presence of this widely marketed, uncontained event.

The trials are starting in 2017 and the boundaries of this novel duty to avoid trade disruption will be determined. Syngenta's half-hearted efforts to implement stewardship only served to increase its liability, and prevent its current claim that "we didn't need China approval" to fall flat with the court so far.

D. Off-patent traits and Overseas Approval

A similar threat of trade disruption arises when using newly off-patent biotech traits ("generics"). When approvals expire in major markets (e.g., China, the EU) those off patent crops will require renewal overseas. While the American chestnut might be able to use these tools to good effect, the overseas approval issues require acquisition of data from the original patent holder. A review of the available intellectual property and its patent status (e.g., who owns CRISPR?) would be appropriate as new tools are considered for use in breeding.

III. Conclusion – Take-Away Points

In sum, the proponents of release and use of the American chestnut would be well-advised to consider the following points:

- Given threats of injunction under federal (NEPA) or common "anticipatory nuisance" law, careful consideration of all relevant economic and environmental impacts should

be undertaken (i.e., “stewardship” meeting or exceeding applicable industry standards), preferably during the regulatory approval process.

- An expedited approval process should be a long-term goal for all GE organisms, but a new species of tree using GE traits should expect – indeed, should seek – a full regulatory review since such a review would help to insulate it from a NEPA attack.
- The boundary for biotech company liability is being drawn in the pending Syngenta case, and decisions at trial and on appeal could extend it beyond the “major market approval at launch” standard to “major market approval post-launch” taking the entire chain of commerce or stakeholder concerns into account. Until these concerns are addressed, the proponent must incur the cost of identity-preservation pending such requisite approval.
- For intellectual property, updating any relative freedom-to-operate studies to determine the patent status, including off-patent or research licensing issues, for any relevant gene or process.