Legal Barriers and Potential Benefits of Biotech Trees

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This article will update legal issues and potential benefits arising from innovation in recombinant DNA plant breeding of trees using modern biotechnology ("biotech trees") and the regulatory process at home in the U.S. and abroad.

A. USDA Approvals and Environmentalist Concerns

At the turn of this millennium, Michael Schechtman biotechnology coordinator for the U.S. Department of Agriculture ("USDA") noted that commercial approval of a biotech tree would be considered "in an open and public process" -- USDA would review "environmental, scientific and other issues that need to be carefully considered and addressed before genetically engineered trees are used commercially." Rick Weiss "Biotech Research Branches Out," Washington Post (August 3, 2000) available at http://www.biotech-info.net/branching_out.html. (last visited April 26, 2012). In 2005, USDA's website listed field trials of 63 tree species.

1. Biotech Papayas

The first successful commercial launch of a biotech tree was a food crop in 1998 – the biotech papaya. This virus-resistant papaya's success may have saved an industry but Hawaii lost some exports to certain Asian nations with mandatory GM food labeling laws. About a third of Hawaii's papaya crop is exported to Japan, and somewhere between 5 and 10 percent is exported to Canada; most of the rest goes to U.S. consumers. Under heavy virus pressure, papaya production had dropped by 40%. See *Uphill Struggle for Hawaii's Biotech Papayas*, Cropchoice (Japanese exports alone account for 40% of Hawaii's fresh papaya market) available at www.cropchoice.com/leadstry9a4f.html?recid=95. After illegal transgenic papaya showed up in Japan in January 2002, hopes for exports to that market suffered a setback. Reuters, Japan Steps Up Checks on GM Papaya Imports from U.S., (January 28, 2002), available at http://archives.foodsafety.ksu.edu/agnet/2002/1-2002/agnet_january_28.htm. (last visited April 26, 2012).

In late 2011, Japan approved the import of biotech papaya for food, feed and processing (not for planting). U.S. papaya producers are eager to regain access to this important market, after exports dropped from up to $15 million annually ten years ago, to under $1 million last year. U.S.-GM Papaya Finally Approved for Japanese Market, Australia Agri-food Awareness (2011) http://www.afaa.com.au/news/n_news-2148.asp. (last visited April 26, 2012).

Exporters should note, however, that Japan also notified the World Trade Organization that it is expanding its list of products requiring a GM label to require both products containing papaya (e.g., fruit snacks) and any product made from the papaya (e.g., processed products that contain no protein, like alcoholic beverages). The National Tax Agency (hereinafter referred to as "the NTA") will add "papaya" to the agricultural products subject to mandatory "GM" labeling for liquors made with products from GM crops, despite confirmation of the safety of GM papayas by

Japan's Ministry of Health, Labour and Welfare. US. Department of Agriculture, GAIN Report No. JA1048 (Dec. 19, 2011) http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Japan%20approved%20GM%20papaya_Tokyo_Japan_12-19-2011.pdf. (last visited April 26, 2012). This type of "process-production method" labeling is controversial under international trade law, as the U.S. learned in its recent defeat at the WTO defending a law requiring tuna products to be certified "dolphin safe".

2. 2008 NAS Report

A National Academy of Sciences ("NAS") Board report in 2008 suggested the beginnings of a consensus within the forest science community about studying the impact of GE trees on the environment, suggesting "Ecological risks of perennial species cannot be modeled using annuals like corn or soybeans" and that "The efficacy of biological confinement has not been evaluated in the field over the long term." According to some reports, pollen from some tree species can travel 1,000 kilometers, e.g., from North Carolina to Canada, but at such distances, the potential for physical impact to a related species is infinitesimal.

These concerns regarding confinement can be addressed via the use of "Genetic Use Restriction Technologies" (GURTs). Many trees pollinate more widely than crops like corn and canola and may lead companies to make the first commercialization of GURT technology to make trees sterile so that they cannot commingle their genes with other trees. While the use of GURTs has been controversial enough (anti-biotech activists call this "terminator technology" which prevents saving of seed from year to year) that Monsanto opted not to use this gene in cotton and other crops, despite its obvious use in preventing theft of intellectual property. With biotech trees, however, there may be reason to use these genes – in fact, key innovators like ArborGen, the leading biotech tree company in the U.S., are willing to make use of them. Similarly, in the case of the first genetically engineered animal submitted for U.S. Food and Drug Administration approval, the AquaAdvantage salmon from Aquabounty Farms, methods are used to restrict the fertility of the salmon, thereby minimizing the potential for impact to wild salmon populations.

3. ArborGen's Pending Approval Process – Freeze-Tolerant Eucalyptus

USDA is considering ArborGen's biotech eucalyptus for deregulation, and recently survived a challenge under the National Environmental Policy Act to its Permit allowing planting an estimated 260,000 flowering GE eucalyptus trees across seven southern U.S. states on 330 acres in experimental field trials. Environmentalists are vowing to continue their fight against genetically engineered "frankentrees" Peter Downs, "*Court loss won't stop environmentalists' battle against modified-eucalyptus trees*", The Commercial Appeal, (October 23, 2011) available at http://www.commercialappeal.com/news/2011/oct/23/court-loss-wont-stop-tree-battle/?print=1. (last visited April 26, 2012)

Next step will be USDA approval of an application to commercialize the frost-tolerant trait. This will provide a test case for similar trees working their way into the U.S. market. For example, Arborgen has another trait that would increase Eucalyptus growth rates allowing a

shorter time to harvest -- five years not seven, increasing productivity by up to 30 tons/acre/year. Improving productivity will benefit the pulp and paper producers in Brazil and the United States, including the Brazilian charcoal industry.

Under the Energy Independence and Security Act, the US mandates 36 billion gallons of biofuels to be produced by 2022, with 16 billion gallons coming from cellulosic biofuel by 2022 and 1 billion gallons from biomass-based diesel in 2012. Biomass from GE trees may contribute toward meeting this objective. A September 2011 press release from ArborGen stated that "ArborGen expertise will be critical in meeting one of the IBSS partnership goals of exploring the inherent performance and cost advantages of short rotation woody crops such as eucalyptus, pine and poplar…[and]…optimizing wood characteristics for optimal conversion to advanced 'drop in' biofuels…" The IBSS partnership will be "to help land owners, rural communities and the emerging biofuels industry make decisions that promote sustainable development." Arborgen Website, http://www.arborgen.com/ (last visited April 26, 2012)

4. USDA Support for Biotech Tree Innovation

Other uses of biotechnology may bring back trees from virtual extinction. In 2009, the USDA Forest Service, in cooperation with a power company (Duke Energy) and a foundation (the U.S. Endowment for Forestry and Communities), formed the Forest Health Initiative (FHI). See www.foresthealthinitiative.org (last visited April 26, 2012)). FHI is a "collaborative effort to advance the country's understanding and role of biotechnology to address some of today's most pressing forest health challenges." FHI will employ plant breeding tools of biotechnology to restore this species to wild forests and apply for regulatory approval for field trials to allow flowering of a genetically modified American chestnut to test for environmental impacts. FHI plans to build on the extensive research already accomplished on the American chestnut by the American Chestnut Foundation and others as a model system for how biotechnology can potentially protect trees. This initiative may use biotech tools (e.g., fungal-resistance traits) along with genome-assisted breeding to bring existing resistance genes from related species (e.g., European or Asian chestnut trees) via cross-breeding. The mapping of the Chinese chestnut genome to identify resistant genes will provide USDA with a good idea of the value of breeding resistant trees using genomic information, which may help other hardwoods face disease threats (e.g., elm, oak, hemlock etc.)

The first step will be to safely and effectively develop an American chestnut that resists chestnut blight and root rot. Researchers have biotech versions of the American chestnut in sapling form, too young to determine their viability against the fungus. This could restore the original American chestnut – a fast-growing tree reaching to 100 feet tall – back to its former glory in the forests of the Eastern U.S. Press Release, UGA Researchers Could Help Restore Devastated American Chestnut (2009) available at http://www.acf.org/pdfs/news/2009/7-July/UGA_Researchers_Could_Help_Restore_Devastated_American_Chestnut.pdf. (last visited April 26, 2012). The first field trial of these chestnut trees will reveal "new approaches to enhance the health and vitality of other trees, forests, and forest ecosystems." FHI, *Advancing Forest Health through Biotechnology* (2009), available at www.foresthealthinitative.org/index.html.

These biotech chestnut trees will have to coexist with other chestnut trees (of European or Asian genetics) that are grown in the U.S., some of which are exported to nations like Korea. In the U.S., demand for locally grown chestnuts exceeds limited supply, which is offset by imports. The long-term goal is to develop a thriving domestic chestnut industry using European and Asian chestnut trees and hybrids. Michael A. Gold, Mihaela M. Cernusca, & Larry D. Godsey, *U.S. Chestnut Market Report* (June 2005) http://www.agmrc.org/media/cms/chestnutmarketreport_3FE47A5CA2BFC.pdf. (last visited April 26, 2012). A 2004 survey of U.S. chestnut producers (all using European and Asian chestnuts or hybrids) revealed producers in 15 states (top four are Michigan (21%) Oregon and (16%), CA (12%) and WA 8%). The University of Missouri Center for Agroforestry (UMCA) wants to establish a viable chestnut industry by breeding chestnut cultivars and consumer awareness and demand in a nation long-deprived of adequate domestic supplies of chestnuts. See Hunt K., M. Gold and W. Reid, *Growing Chinese chestnuts in Missouri*, Agroforestry in Action. University of Missouri Center for Agroforestry, (2002) Available at http://www.centerforagroforestry.org/. (last visited April 26, 2012)

The University of Missouri's chestnut-breeding "Horticulture and Agroforestry Research Center" is located in one of the few states – and the only one in the Farm Belt of the Midwest – to have a "Grower District Authorization Act" that enables formation of production zones. This is ideally suited for creating coexistence between any locations. Such districts have proved effective in segregating non-food canola from its food-grade relatives, grown miles away in a segregated district, and in contrast to the non-GMO zones of California and Europe, creating such a district is voluntary.

To promote stewardship and transparency when introducing these trees, the FHI might follow the "Responsible Use Principles" issued by the Institute for Forest Biotechnology. http://www.responsibleuse.org. These principles and practices were developed with input from a broad range of stakeholders in the U.S. and abroad for users of biotech trees that want to follow good stewardship practices.

B. International Issues

The international community may not be as receptive as the US in approving biotech trees, with the possible exception of China and Brazil.

1. Biotech Trees in China

Perhaps the first biotech tree planted in the world was an herbicide-tolerant poplar with the "aroA" gene in 1987 in China. Since commercialization in 2002, over one million biotech poplars have been planted, including some biotech varieties. Some Chinese academics are critical of China's State Forestry Administration because it does not track the precise locations of biotech poplars —it is difficult to distinguish biotech poplar from "non-GM" trees without a costly genetic test. Moreover, nursery salesmen at markets reportedly get higher prices by saying – true or not – that their planting materials are biotech trees. As a result, tracing the locations of biotech poplars will be exceedingly difficult. See Fred Pearce, China's GM trees get lost in

bureaucracy, New Scientist, (2004) available at http://www.newscientist.com/article/dn6402-chinas-gm-trees-get-lost-in-bureaucracy.html. (last visited April 26, 2012)

China has called for about 6 million hectares of tree plantations to reverse decades of deforestation that have left China facing serious droughts, loss of topsoil, and deadly floods. The World Bank has loaned China over $600 million to establish tree plantations. China's use of trees, including some biotech poplars, appears to have helped it manage devastating losses of topsoil to rivers, through riparian planting of fast-growing, pest-resistant biotech poplars. Dietrich Ewald, Jianjun Hu and Minsheng Yang, Transgenic Forest Trees in China in TREE TRANSGENESIS, RECENT DEVELOPMENTS (Matthias Fladung and Dietrich Ewald, Eds.) Springer (2006) (excerpt available at http://www.springerlink.com/content/p3m204142700243w/).(last visited April 26, 2012)

Since 2006, China has also allowed commercial production of virus resistant biotech papaya that a Chinese university developed and grew on approximately 3,500 hectares in 2007. While China has a mandatory GM food labeling law, this does not appear to have deterred producers and end users of the papaya fruit.

2. Brazil

ArborGen is currently carrying out field trials of reduced lignin GM trees in Brazil. The company set up operations in Campinas, Sao Paulo state three years ago. ArborGen started its GM tree trials in Brazil in 2005. This year, ArborGen won approval from Brazil's regulatory authority (CTN-Bio) to carry out a second full-rotation field trial of GM eucalyptus trees.[9] ArborGen is working in partnership with "some of the largest forest product companies in the region," according to RISI. "ArborGen to focus on forest product industry cluster in South America", RISI, (May 2007). GURTs are prohibited in Brazil, but, GE trees could be used for charcoal and bioenergy production in Brazil. Activists hoping to stop GE trees are at work in Brazil as well. See Global Justice Ecology Project, **Analysis of the State of GE Trees and Advanced Bioenergy, (March 22, 2012)** available at http://www.biosafety-info.net/file_dir/11739570714f82b110c9e60.pdf (last visited April 26, 2012)

3. Proposed Biodiversity Convention Moratorium and Proposed Liability Protocol

Non-governmental Organizations ("NGOs") that oppose all biotech organisms signed a statement requesting a moratorium on release of biotech trees (mainly African and European parties) asking the CBD to ban biotech trees at the CBD Meeting of the Parties (MOP 10) and Biosafety Protocol Meeting of the Parties (MOP 8) in Brazil in 2006. Large Alliance of NGOs and Indigenous Peoples Calls for Ban on Genetically Modified Trees for Biofuels, available at http://www.gefreebc.org/gefree_tmpl.php?content=biofuel_alliance. This call for a ban has failed in successive meetings (e.g. at MOP 9 in Bonn, 2008, the attempt to drive a moratorium was not successful but the Biosafety Protocol Parties reiterated the precautionary approach language). Activists cited research in many countries: Australia, Brazil, Canada, Chile, China, Finland, France, Germany, Japan, New Zealand, Portugal, Spain, Sweden, United Kingdom and United States.

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The United States (non-party to the CBD), Argentina and Canada – none of whom have signed the Cartagena Protocol on Biosafety (Biosafety Protocol) regulating transboundary movements of biotech organisms -- all argued that that countries should be able to use their own national regulations to deal with any biosafety or contamination issues relating to biotech organisms, including trees.

While no moratorium biotech tree appears to be forthcoming , the CBD and Biosafety Protocol have reaffirmed the need for a "precautionary approach" to biotech trees. This could lead some nations to deny approval for planting biotech trees, pending unnecessary extensive long-term studies in containment, including greenhouse and confined field trials. This precautionary approach to approval would seek to avoid "possible negative environmental impacts on forest biological diversity" and potential socio-economic impacts on the livelihoods of indigenous and local communities.

Transboundary liability for biotech trees could be compensable under the 2010 Nagoya-Kuala Lumpur Supplementary ("NKLS") Protocol, which will amend the Biosafety Protocol if it enters in force upon full ratification. This NKLS protocol directs the adoption of a process for international rules and procedure in the field of liability and redress. A viable claim must demonstrate that: 1) there has been an adverse effect on conservation or sustainable use of biological diversity or risks to human health; 2) the effect is measurable or observable for the purposes of attribution of impacts; and 3) the adverse effect is significant. Anastasia Telesetsky, *The 2010 Nagoya-Kuala Lumpur Supplementary Protocol: A New Treaty Assigning Transboundary Liability and Redress for Biodiversity Damage Caused by Genetically Modified Organisms* 14 ASIL (January 10, 2011) available at www.asil.org/insights110107.cfm. http://www.biotech-info.net/branching_out.html.

3. Industry Initiatives & Compensation "Compact"

The biotechnology industry is creating a voluntary compensation and arbitration scheme (the "Compact") to address harm to biodiversity caused through the fault of a biotech seed company, subject to the customary defenses in negligence law. This parallel industry "Compact" that would set up an arbitration system to protect biodiversity from potential risks posed by "living modified organisms" (including biotech trees) using the following elements:

- Protection of biological diversity as a "public good" by the State.
- Science-based evidence and decision-making.
- Responsibility channeled to the "operator" who caused the damage.
- Legal "due process" for handling claims for damage to biological diversity.
- Independent unbiased decision-makers (an important aspect of "due process"), who provide practical and fair application.
- Respect for precedent in the country's legal system. Where there is developed law, there is no reason to change basic approaches to liability and redress in relation to this new and relatively safe technology.
- Social responsibility: enabling the use of more sustainable technology that is essential to food and agricultural security while appropriately protecting biological diversity.

This NKLS protocol appears likely to become law in the next few years (the ratification process is on pace to enter into force).

If the NKLS enters into force, the Biosafety Protocol parties would be required to pass implementing laws at the national level. This will be a process unfolding over coming decades, with potentially restrictive laws in some nations that restrict innovation in biotech trees. Combined with the industry Compact (assuming key companies in biotech trees participate). Other industry stewardship mechanisms, including the Responsible Use principles developed by the Institute for Forest Biotechnology, offer a reasonable compromise to the "precautionary approach" that the EU and other nations propose. This stewardship may allow use of these trees to enhance, not degrade, the global environment.

While these legal protections provide more safeguards than past plant-breeding and pest-protection technologies introduced into forestry, there will always be a lingering concern in some environmental groups -- is there enough protection in place? For industry, a counterargument exists – are we regulating so much that we might be keeping safer, more environmentally responsible trees from the market? Only time will tell whether the additional measures of legal protections taken have reached the optimum level of protection.

Conclusion

Biotech trees will find their place in this world, providing fiber, fuel and even sustainable comfort food (e.g., biotech American chestnuts roasting on an open fire). This is an industry to watch, as it evolves toward "responsible use" and takes its place in the pipeline of sustainable biotech products.

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