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Transgenic Trees for Biomass: The Effects of Regulatory Restrictions and Court Decisions on the Pace of Commercialization

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Resources for the Future

Wood has great potential as a bioenergy source, both as a feedstock for liquid biofuels for the transport sector and also as biomass, a direct source of energy that can be used to produce electric power. Trees, however, are generally slow growing, and some species that do grow quickly are not widely adapted, hence the interest in genetically engineered (GE) trees. In many cases, traditional breeding may achieve comparable results, and the developer must assess which is more efficient and less costly—pursuing a traditional approach or achieving deregulation of a GE product. The traditional and transgenic approaches are not perfect substitutes, however: genetic engineering can effect transformations not possible through traditional breeding. This article examines the regulatory process and the effects on development and commercialization of regulatory restrictions and recent court decisions. It discusses recent US legal cases, which—although not directly involving transgenic trees—have implications for tree deregulation and the pace of commercialization.

Key words: bioenergy, eucalyptus, genetic engineering, litigation, regulation, renewable energy, transgenic trees.

Introduction[1]

Worldwide, there is a growing desire to shift from fossil fuel to renewable energy sources. An important reason for this is the concern about emissions of greenhouse gases—believed to be associated with global warming—released though the use of fossil fuels, as well as broader energy security issues. Biomass, which includes agricultural wastes, grasses, and wood, is a major renewable resource. Both in the form of direct combustion and in the production of liquid biofuels for transport, biomass is seen as a major energy source for the near future. Rapid-growing genetically engineered (GE)—or transgenic—trees can play a major role in providing the feedstock for an energy sector that relies increasingly on renewable energy.

The potential exists to provide energy—as feedstock both for liquid biofuels and for direct combustion either as raw wood chips or as wood pellets—through customized trees. One obvious goal of genetic engineering is faster growth of the biological feedstock. Another desirable customization might be to develop trees that can withstand harsh environmental conditions, such as cold winters. For example, one of the world's fastest-growing hardwood trees, the eucalyptus, cannot tolerate frost. However, it might be feasible to grow freeze-tolerant transgenic eucalyptus trees in many locations, including the southern United States.

However, the United States regulates all transgenic plants, including trees. These trees must be deregulated if they are to be grown in large commercial operations (Sedjo, 2004). Although there is a process for deregulating transgenic plants through the US Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS) and other government agencies, the process has become slower and more cumbersome, particularly for perennial plants such as trees. For example, Strauss et al. (2010) report that the regulatory restrictions on plants produced using recombinant DNA and asexual gene transfer have increased in recent years. In this article, I examine the deregulation process, discuss some relevant legal cases, and identify some of the elements that may have contributed to the slowing of the process. I note some inherent conflicts and social tradeoffs between a timely deregulation process, investments in improved transgenic products, and concerns about environmental obstacles.

Background

The United States is among the nations looking for ways to substitute renewable energy sources—including biomass—for traditional fossil fuels. For example, the Energy Independence and Security Act of 2007 (Public Law 110-140) mandates large increases in the produc-

1. *This article is the outgrowth of an earlier paper by Strauss et al. (2010). However, the author is solely responsible for the opinions expressed and any errors in this article.*

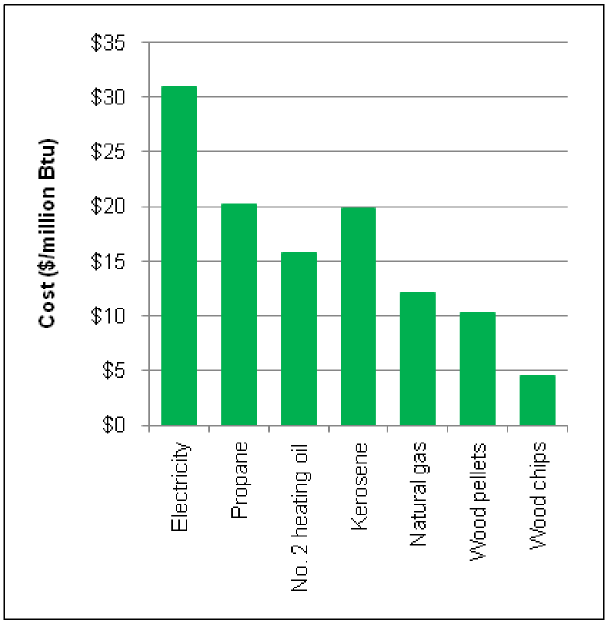

Figure 1. Residential fuel costs for various fuels.
Source: Bergman and Zerbe (2008).

tion of biofuels, which are liquid transport fuels usually in the form of ethanol; today in the United States ethanol is predominantly made from corn. The act mandates that a significant volume of the ethanol be cellulosic, produced from materials such as wood, grasses, and non-edible plant material.

Additionally, other wood energy uses are also expanding. Furthermore, many US states have renewable energy standards (RES) that require the substitution of renewables for fossil fuels in electrical power generation. Wood is likely to be prominently used in these cases. Also, the wood-pellet industry is growing very rapidly. Pelletized wood is a highly efficient wood fuel made from sawdust that has been shredded and tightly compacted. The United States exports large volumes of wood pellets to foreign countries, particularly European countries that subsidize the use of wood energy. Finally, the recent Biomass Crop Assistance Program offered by the USDA provides a subsidy to those who use wood as an energy source for many purposes (Sedjo, 2010). All of the new wood energy uses promise to increase demand for these US resources dramatically.

A recent study (Sedjo & Sohngen, 2010) estimates the implications of meeting the mandates of the Energy Independence and Security Act of 2007 by using biomass from the US industrial wood market. It projected a dramatic increase in US wood harvests, with log prices rising in 2020 by about 20% above what they were projected to have been otherwise. This price increase would lead to a decrease in the competitive position of the traditional US industrial wood-processing industry, particularly pulp and wood composites. This finding, furthermore, does not consider the additional impacts on the market of RES and potential stress on the forests by the demand for wood pellets.

One way to offset the increasing pressures on US forest resources may be to use GE to develop trees that are particularly suitable for energy purposes. Such trees would have to grow fast so that they could be harvested in short rotations. Eucalyptus trees are especially well suited to this task and are capable of astonishing growth in some locations. As a result, they are grown and used worldwide for a variety of purposes. However, eucalyptus trees are intolerant to cold weather, which limits their geographic distribution. Research is underway to develop fast-growing freeze-resistant trees that can survive occasional freezes, thereby making them suitable in a large number of additional regions, including the southern United States. A critical question is whether a suitable transgenic eucalyptus, if developed, would be able to be deregulated and so available to be used extensively in the United States.

Table 1. GHG emissions by commodity.

Cropping system	Net GHG emissions
Corn and soybean	40%
Reed canary grass	85%
Switch grass	115%
Hybrid poplar	115%

Source: Colorado State University (2007)

Biofuels

Wood has great potential as a bioenergy source, both as a feedstock for liquid biofuels for the transport sector and also as biomass, a direct source of energy that can be used to produce electric power. Figure 1 provides a comparison of the relative costs of various fuels, both fossil and biofuels, in which the costs of biofuels compare favorably with the other energy sources. The data suggest that the wood biofuel energy can be costs competitive in many circumstances.

Table 1 provides estimates of the life-cycle greenhouse gas (GHG) emissions of various cropping systems. Note that trees planted on bare ground, along with switchgrass, promote the largest net reduction of GHG emissions. The trees are able to achieve more than 100% reduction in net carbon emission over the energy generation equivalent amount of gasoline. This is accomplished since, in addition to the biofuel substituting for the fossil fuel and thereby offsetting the carbon that would have been released, a new carbon sink is established in the form of the new forest.

The US Regulatory System

In its current state, the US regulatory system (USDA APHIS, 2009) has made it difficult to develop GE forest trees. Sedjo (2004) outlined the regulatory system as it applied to trees, the process, and identified the regulatory hurdles. However, at that time the system had deregulated only one species of tree, the papaya, which meant there were no established precedents. Since that time only one other tree species—the plum tree—has moved through the process. The transgenic plum tree[2] has been the focus of an active research program to address the plum pox disease by the Agricultural Research Service. They developed a disease-resistant plum tree through genetic engineering. APHIS has fully deregulated the transgenic plum, and the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) are in the final stages of registering the transgenic plum. Thus, in more than a decade only two tree species have been deregulated—both are domesticated orchard trees (Sedjo, 2006).

The United States has adapted existing laws to create a complex set of rules under the 1986 Coordinated Framework for Biotechnology, using the regulatory authorities of three agencies: EPA, USDA APHIS, and FDA. The EPA regulates plant-incorporated protectants (PIPs), which include pesticides produced by plants and the genetic material needed by the plant to manufacture the substances. The FDA oversees GE food and drugs, and APHIS is responsible for any GE organism or product that may pose a risk to an agricultural plant. Annual and perennial plants, including crops and trees, are regulated largely by APHIS, except where food, drugs, or PIPs are involved. The EPA also is responsible for broad environmental protection under the National Environmental Protection Act (NEPA; Public Law 91-190, with several amendments).

Under the 2000 Plant Protection Act, APHIS acquired expanded authority over noxious weeds and is responsible for consideration of direct or indirect injury or damage. Recently, some have reported that APHIS has become more stringent in its regulation and regulatory oversight. For example, APHIS is now proposing to end the system of notifying the government when field tests begin for transgenic organisms and require that the testers obtain permission before they can begin a field test (Jones, 2009). Strauss et al. (2010) note that although the rule has not formally changed, APHIS has implemented a de facto change in response to earlier errors in the application of the rules.

Concerns Regarding Transgenic Trees

The regulatory structure suggests that the primary reason to regulate transgenics is the concern that there may be health, safety, or environmental risks. However, the widespread use of a GE approach in annual crops attests to the viability of GE when the regulatory process is manageable and predictable (Qaim, 2010). There is greater uncertainty, however, that a perennial product will be able to navigate the regulatory system successfully. For trees, the problem areas are largely environmental (e.g., Mullin & Bertrand, 1998). There are concerns that gene flow could cause harm or that transgenics might disrupt the environment in various ways (DiFazio, Leonardi, Cheng, & Strass, 1999). Some have likened the introduction of a transgenic organism into the environment to the introduction of an exotic species, some of which have become invasive. However, many ecologists have argued that the risks from a transgenic plant are generally lower and more predictable than for an exotic one. Exotic plants can be introduced easily and have many unrecognized genes, and it is difficult to predict how they will affect their new habitat. Transgenic plants, on the other hand, are introduced in a controlled fashion. They have only a few introduced genes, and scientists understand how these genes behave. Thus, it has been argued that it would be easier to identify and manage any problems that arose in connection with a transgenic plant (Handcock & Kokanson, 2004).

The primary concern with transgenic trees continues to be environmental risks, and that remains the focus of their regulation. Indeed, the regulatory hurdles become more formidable with trees. Unlike the annual plants common in agriculture, trees are perennials and experience delayed flowering. Trees, however, are not the only long-lived perennials considered for genetic engineering. Many grasses are also long-lived perennials. In fact, in this decade, transgenic grasses have preceded trees in testing the regulatory process. Grasses have also been subjected to more stringent standards, particularly by the courts. As with trees, delayed flowering in grasses generally makes the examination of the impacts of the introduced genes over generations more difficult. However, impact assessment is not impossible, because certain tissue culture approaches may be helpful in

2. *See http://www.ars.usda.gov/is/br/plumpox/.*

reducing the intergenerational delays. Nevertheless, regulatory complexities, including the long and costly time periods involved to assess impacts, are likely to persist.

Thus far, as noted, only two orchard trees have been deregulated or are about to be deregulated in the United States. In China, by contrast, a transgenic poplar has been reported as having been commercialized (Xu, Bennett, Tao, & Xu, 2004), although the extent to which it is fully deregulated remains unclear.[3]

Risk and Coverage

There are at least two major issues when determining the nature of regulation: the types of plants that are covered and the level of acceptable risk. One issue when determining whether a plant is to be regulated is whether the regulation should apply to the transgenic process itself or to the attributes of the transgenic plant or product, such as whether it may become invasive or pose other risks. In some countries, such as the United States, it is the transgenic process that determines what is regulated. Other countries, such as Canada, base their regulatory decisions on the attributes of the plant (Pachico, 2003).

Some biologists have argued that it would be better to base regulation on the plant attributes rather than simply on the process of genetic engineering (see Strauss, Tan, Boerjan, & Sedjo, 2009). When considering plant attributes, the decision would be based on the novelty of the plant independent of the process used in its development. This criterion would be applied, in principle, to all novel plants, including GE plants, whether the modification occurred by traditional breeding or genetic engineering.

Those who suggest novelty as the critical criterion argue that the transgenic process itself does not inherently lead to more risky products. Rather, they say, the regulatory process should focus on the changes and the attributes that could pose a social or environmental risk, whether generated by traditional or transgenic means. It is the risks associated with the attributes of the products and, hence, the products themselves that should be regulated, regardless of the process used to develop them.

The practical effect of these different criteria, however, is open to question. An unintended result of the attribute approach might be that all modified plants, whether the result of traditional breeding or genetic engineering, would be subject to the same assessment process now reserved for transgenic plants. The preliminary process to determine whether regulation was required for each modified plant could be hugely cumbersome. It is not clear that this would be more efficient than the current system. Indeed, despite the attribute approach described in Canadian law, de facto Canada appears to use the transgenic process as an important determinant of which plants may be novel.

Transgenic Perennials

Although perennials are covered by the same statutes as annual plants, they create special problems for deregulation. Perennial grasses and woody plants of interest for biofuels have already come under scrutiny by regulatory agencies because of their potential to become invasive over long periods and the possibility that they would mate with wild (feral) relatives. Trees may be subject to even closer review because they are not completely domesticated, which suggests that transgenic trees may have a greater capacity to survive in the wild. These concerns may form a rational basis for regulations that require stringent containment through all phases of research and development regardless of the source of the gene, the novelty of the trait, or the anticipated economic or environmental benefits of the transgenic plant.

These requirements unquestionably conflict with the realities of practical crop breeding that involve cost control and timely completion of field studies. The effect is to confound the researcher's ability to undertake meaningful agronomic and environmental studies, and thus hamper—and in most cases preclude—the use of recombinant DNA breeding methods to improve perennial crops.

The Legal Cases

Although there has been no recent notable litigation involving trees, there have been at least two important litigations around grasses. As noted, grasses—like trees—are perennials, and the multiple-year issues are similar. Thus, it might be expected that the application of the regulations, too, is likely to be similar.

Regulatory restrictions on organisms produced using recombinant DNA and asexual gene transfer are said to have increased in recent years (Strauss et al., 2010). Two recent federal court decisions in the United States have evidenced a new stringency that requires the agencies to be very cautious in their procedures. Both of

3. *Ms. Li Shuxin, of the Department of Policy and Law, State Forest Administration, advised the author that transgenic trees had not yet been commercialized, and the extent of its field trial deployment had been exaggerated (personal communication in Hangzhou, China, on November 10, 2005).*

these cases involved the introduction of herbicide-resistant genes to grass seed—alfalfa and bent grass—and fell under the NEPA, a law that was passed "to promote efforts which will prevent or eliminate damage to the environment." In the regulatory process, APHIS relied upon environmental assessments rather than the more detailed environmental impact statement (EIS) process that NEPA sometimes requires. Conducting an EIS is much more costly and time consuming for both the regulating agency and the developer than the environmental assessment process. The EIS process allows opponents to raise hypothetical and conjectural negative environmental impacts for detailed scrutiny.

In the alfalfa seed decision in the US District Court for the Northern District of California, the court ruled that APHIS erred in applying an exception and not undertaking an EIS (*Geertson v. USDA*, 2006). The court placed a temporary ban on genetically-modified alfalfa. A similar opinion came from the District of Columbia District Court regarding the Scott Company's GE creeping bent grass (*ICTA et al. v. USDA/Scotts*, 2006).

Upon appeal, however, the US Supreme Court later heard oral arguments involving the federal judge's earlier temporary ban on a breed of herbicide-resistant alfalfa. In June 2010, the Court reversed the lower court's injunction against transgenic alfalfa, ruling that the trial court should not have entered an injunction to remedy a NEPA violation without holding an evidentiary hearing to resolve factual issues (McEowen, 2010). In addition, the court ruled that a less drastic remedy than a nationwide injunction against planting was available. The bent grass follow-up is still in progress.

The Issue of Transgenic Eucalyptus

Issues such as gene flow vary with the particular plant but generate concern among some environmentalists. Because they are not fully domesticated and thus can readily cross-pollinate with wild relatives, indigenous transgenic trees—such as poplar and pine—may have a higher probability of gene flow into the natural forest. By contrast, orchard trees—such as papaya and plum—are more highly domesticated and less likely to find a responsive host. An exotic—such as eucalyptus—is unlikely to find a receptive host for its genes in places such as the southern United States because of the absence of an indigenous genus.

Also, we may already have seen the results of the earlier court rulings. The two initial legal cases involving grasses may have been translated into increased scrutiny of transgenic trees. However, the very recent Supreme Court ruling may ultimately moderate some aspects of that scrutiny. An example is the experience of a US bioengineering firm, ArborGen. The firm has been working to develop a freeze-tolerant transgenic eucalyptus tree, whose wood could be used as feedstock for biomass and biofuel energy in the southern United States. To determine whether lowered lignin content would make these trees more suitable as bioenergy feedstock, a subset of the trees received a genetic alteration that impeded lignin formation. Researchers made other genetic modifications as well, e.g., by altering a gene that controls pollen formation, they reduced fertility. The targets of ArborGen's tree improvement program are summarized in Figure 2.

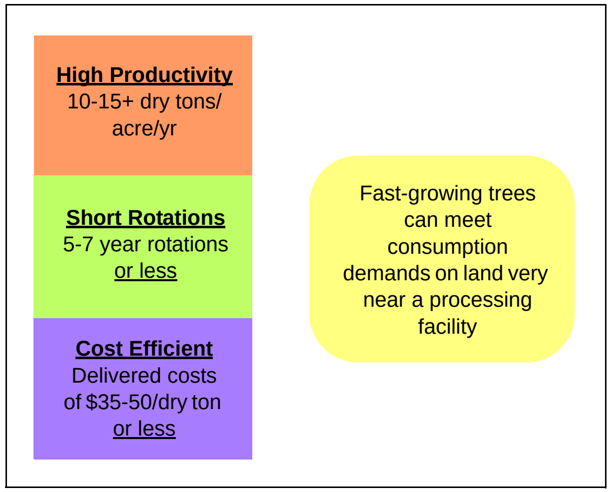

Figure 2. ArborGen targets.
Source: Provided by Barbara Wells (personal communication, 2009) of ArborGen.

Two issues related to deregulation arose in ArborGen's testing. The first issue was whether to allow the trees to flower during the process of field testing. The second issue is related to the size of the trial and its effect on local hydrology. To obtain a permit for field trials for a transgenic freeze-tolerant eucalyptus, ArborGen first had researchers from the US Forest Service review the literature. Earlier tests of frost-intolerant eucalyptus, using a process that restricts the plant's ability to produce pollen, were successful. Nevertheless, the regulators initially were reluctant to allow similar tests for the transgenic eucalyptus.

Second, although the US Forest Service experts concluded that field tests at the scale proposed in the permits were not likely to have any impacts on hydrology, their report raised questions about potential impacts of large-scale plantings of eucalyptus in the southern

United States and suggested a methodology for a large-scale trial to measure the impacts. The Biotechnology Regulatory Services (BRS), which is a part of APHIS, restricts the size of planting areas. Initially, the BRS argued that its regulations did not permit field trials on the scale proposed, setting up a Catch-22 situation: large-scale trials would be viewed as necessary to answer some of the more wide-ranging environmental questions, yet the agency would not have the power to authorize large-scale trials. However, after receiving public comments and in light of the Supreme Court's decision, the agency recently authorized a significantly larger field trial to allow the questions to be more adequately addressed.[4]

The Inherent Conflicts and the Pace of Commercialization

Given the inherent challenges and unique costs associated with the transgenic technology, especially when working with perennials, the developer must try to select an efficient pathway to commercialization. Genetic engineering often makes it possible to transform an organism much more quickly and less expensively than is possible using traditional breeding approaches. However, these savings in time and money might well be more than offset while moving through the deregulatory process. The problem, as demonstrated above, of regulatory cost and duration is substantially more acute where perennials are involved. Transgenic perennials must be field-tested for longer than a year to ensure that the testing reflects the behavior of the plants over a multiyear time span and to evaluate their potential to escape into the environment and interbreed with related natural plants.

For these reasons, it may be less costly and time consuming to employ a traditional breeding approach to modify some perennials than to try to accomplish the same end using transgenic technology. Although from a technical standpoint it may be possible to accomplish the desired changes more quickly using genetic engineering, the added costs and time needed to assess the long-term environmental impacts of engineered perennials over large areas may offset any advantages that the transgenic process has over traditional breeding.

4. *http://www.environmentalleader.com/2010/06/10/arborgen-approved-to-test-gm-trees/*

Summary and Conclusions

Biomass energy is a renewable energy that has substantial potential to substitute for fossil fuels both as a liquid biofuel and also as biomass energy. Wood could play a very important role as bioenergy. Using transgenic approaches could increase the growth rates of biomass (generally) and trees (specifically) thereby providing additional efficiencies to biomass energy.

However, transgenic trees are required to be legally deregulated. The process of deregulation involves costs to the developer both in the direct costs of development and also in costs necessary to achieve deregulation and commercialization. Many of these costs are socially justified because of concerns over the possible negative effects—largely environmental—of GE forest trees. However, these costs may also include substantial litigation costs. Examples have been discussed related to the litigation experiences in cases involving the perennial grasses. The difficulties associated with undertaking the requisite field tests for tree deregulation are cited. Where alternatives are available, traditional breeding approaches could avoid the costs involved with deregulation of GE products. Although some evidence indicates that deregulation standards as applied are becoming more stringent, the recent Supreme Court decision has perhaps signaled a step back toward an easing in the regulatory process. Also, the subsequent accommodation of the regulators to the field testing required for knowledge and for deregulation for eucalyptus suggests some regulatory easing.

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