May 10, 2010

How do environmental regulations affect investments in biofuel and biofuel R&D?: the case of transgenic trees.

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Paper prepared for presentation at the 14th ICABR Conference
"Bioeconomy Governance: Policy, Environmental and Health Regulation, and Public Investments in Research"
Ravello, Italy, June 16-18, 2010

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Abstract

Genetically engineered or transgenic trees can play a major role in providing the feedstock for an energy sector that relies increasingly on renewable energy. Biomass energy sources such as wood, both in the form of direct combustion and in the production of liquid biofuels for transport, are being viewed as a major energy source of the near future. Worldwide there is a growing emphasis to shift from fossil fuel to renewable energy sources largely in recognition of the GHG emissions associated with fossil fuels.

The potential exists for customizing trees to provide energy, both as a feedstock for liquid biofuels and for direct combustion either as raw wood chips or a wood pellets. However, in the U.S. all transgenic plants, including trees, automatically come under regulation and must be deregulated if they are to be grown in large commercial operations. Although there is a process for deregulating transgenic plants through the US Department of Agriculture – Animal Plant Health Inspection Service (APHIS) and other government agencies, the process has become increasingly slow and cumbersome, particularly for perennial plants including trees. Indeed, it is argued that the obstacles to deregulation have been increasing. This paper looks at that situation and identifies some of the elements that contribute to the slowing of the process. It notes some inherent conflicts and social tradeoffs between a timely deregulation process and concerns about environmental obstacles given current legal decisions.

Paper to be considered for special issue of AgBioForum: **Yes**

Key Words List

Biotech, biofuels, biomass, transgenetic, genetic engineering, trees, regulations, litigation, APHIS

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By Roger A. Sedjo

Genetically engineered or transgenic trees can play a major role in providing the feedstock for an energy sector that relies increasingly on renewable energy. Biomass energy sources such as wood, both in the form of direct combustion and in the production of liquid biofuels for transport, are being viewed as a major energy source of the near future. Worldwide there is a growing emphasis to shift from fossil fuel to renewable energy sources largely in recognition of the GHG emissions associated with fossil fuels.

The potential exists for customizing trees to provide energy, both as a feedstock for liquid biofuels and for direct combustion either as raw wood chips or a wood pellets. Faster biological growth is, of course one desired dimension. In addition, frost resistance trees, which could be grown in areas now too cold for trees of the desired species, might be usefully grown for energy purposes, e.g., eucalyptus in the U.S. South.

However, in the U.S. all transgenic plants, including trees, automatically come under regulation and 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 – Animal Plant Health Inspection Service (APHIS) and other government agencies, the process has become increasingly slow and cumbersome, particularly for perennial plants including trees. Indeed, it is argued that the obstacles to deregulation have been increasing. Strauss et al. 2010 argue that the regulatory restrictions on plants produced using recombinant DNA and asexual gene transfer have increased in recent years. This current paper looks at that situation and identifies some of the elements that contribute to the slowing of the process. It notes some inherent conflicts and social tradeoffs between a timely deregulation process and concerns about environmental obstacles given current legal decisions.

Background

In the U.S. there is also growing emphasis of the substitution of renewable energy sources for traditional fossil fuels. A major renewable resource is biomass, which includes agricultural wastes, grasses and wood. Currently, the Energy Act of 2007 mandates large increases in the substitution of cellulosic biofuel in the form of ethanol for gasoline. Additionally, wood pellet production is growing very rapidly, with large volumes of wood pellets being exported to foreign countries with subsidies for wood energy use, particularly in Europe. Also, many U.S. states have renewable energy standards (RES) that require the substitution of renewables for fossil fuels in electrical power generation. Finally, the recent Biomass Crop Assistance Program (BCAP) provides a subsidy for the use of wood as an energy source in many uses. All of these new wood energy uses promise to dramatically increase demand on the U.S. resource.

A recent study estimated the implications of meeting the mandates of the Energy and Security Act of 2007 by utilizing biomass from the U.S. industrial wood market. It projected a dramatic increase in U.S. wood harvests with log prices rising by about 20% in 2020 above what they were projected to have been otherwise. Such a price rise in the wood resources generated projections that indicated a decrease the competitive position of the traditional U.S. industrial wood processing industry, particularly pulp and wood composites. This finding, furthermore, did not consider the additional impacts on the market of the RES and the new demands being put on the forest by wood pellets.

A potential offset to the increasing demand pressures on US forest resources, which appear to be likely from the increased use of wood renewables, might be found in the development of trees that are genetically engineered to provide wood particularly suitable for energy purposes. One aspect would be rapid biological growth and a short harvest rotation. Eucalypts trees are well suited to this task often showing astonishing growth. This has resulted in their being grown and utilized worldwide for a vary of purposes.

However, eucalypts trees tend to be intolerant to cold weather, which limits their geographic distribution. Research is underway to develop frost resistance eucalypts trees that would be fast growing and resistant to occasional freezes, such as occur in the U.S. South.

The US Regulatory System

A requirement to the development GMO trees with desired characteristics for growth in certain regions and/or traits particularly suitable for energy is found in the regulator system of the U.S. Sedjo (2004) examined the regulatory system as it applied to trees at the end of the 1990s and outlined the process and identified the regulatory hurdles. However, at that time the system had only deregulated one tree, the papaya, and well established precedents had not yet been established. Unfortunately the intervening period has seen only modest clarification with only one tree, the plum, having moved through the process. The transgenic plum tree[1] has been the focus of an active research program to address the plum pox disease by the Agricultural Research Service. The ARS developed a disease resistant plum tree through genetic engineering. APHIS has fully deregulated the transgenic tree as has the FDA and the EPA is in the final stages of the transgenic plum's registration. Thus far only two trees, both largely domesticated orchard trees have accomplished essential deregulation.

The U.S. has adapted existing laws, particularly the Plant Production Act and the Federal Plant Pest Act to create a complex set of rules under the 1986 Coordinated Framework and using the regulatory authority of three agencies the EPA, USDA-APHIS, and the FDA. The EPA is responsible for plant incorporated protectants (PIPs) against plant pests, the FDA for food and drug related issues and APHIS for issues related to

[1] See http://www.ars.usda.gov/is/br/plumpox/

agricultural pests and noxious weeds. Annual and perennial plants including crops and trees are regulated largely by APHIS, except where food, drugs or PIPs are involved. The EPA also has responsibility for broad environmental protection under the National Environmental Protection Act (NEPA).

Recently, some have argued that APHIS has become more stringent in its regulation and regulatory oversight. For example, the researcher's responsibility to "notify" the government of field tests that involve transgenics has been replaced by an advanced permission or "permitting" requirement for all field trials (Jones 2009). This has been due in part of what have been viewed as earlier errors and it has been argued that the permitting process has slowed in the last year or so (Strauss et al. 2010).

Concerns regarding transgenic trees

The regulatory structure suggests, that the primary reason for regulation of transgenics is the concern that there may be health, safety, or environmental risks. The problem areas for trees are largely environmental (e.g., see Mullin and Bertrand 1998). The regulators behave as if the introduction of transgenics may pose new risks of environmental damages. In the United States the existence of concerns about the extent to which transgenics could become weed pests is clearly reflected in the Federal Plant Pest Act. More broadly, there are concerns that damages due to gene flow could occur or that transgenics could in other ways disrupt the environment (DiFazio et al. 1999). Some have likened the introduction of a transgenic into the environment as providing a similar risk to the introduction of an exotic, some of which have become invasive. However, many ecologists have argued that the risks of a transgenic are generally lower and more predictable than for an exotic, since the transgenic has only a few introduced genes and the general expression of these is known. Thus, the gene expression associated with transgenics should be more predictable than with an exotic, in which the full expression of most of the genes is unknown, and any problems arising with a transgenic would be easier to identify and manage. However, an exotic plant can be introduced with greater ease than a transgenic.

In any event, 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. Trees, being perennials, differ from the annual plants common in agriculture because of their long life and delayed flowering. Trees, however, are not the only long-lived perennials considered for genetic engineering. Other long-lived plants include importantly many of the grasses. Indeed, 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. Like 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, since certain tissue cultural approaches may be helpful in 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 orchards 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 et al. 2004), although the extent to which it is fully deregulated remains unclear.[2]

Risk and coverage

There are at least two major issues when determining the nature of regulation. First are the types of plants that are covered. Second is the level of acceptable risk. An issue in the development of the appropriate criteria for determining whether a plant is to be regulated, centers around whether the regulation should apply to the transgenic process itself, or to the attributes of the plant or product such as whether it may generate concerns about

[2] 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 their field trial deployment exaggerated as of our conversation in Hangzhou, China on November 10, 2005.

weediness or other adverse risks.   In some countries, e.g., the U.S., what is regulated is determined by the process, in other countries, e.g., Canada, regulation is determined by the novelty of the plant and its attributes (Pachico 2003).

Some biologists have argued that regulation would better be applied to plants on the basis of the plant attributes, rather than simply on the basis of the process of genetic engineering (e.g., see Strauss et al. 2009). 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 GM plants, whether the modification occurred by traditional breeding or genetic engineering.

The argument of those suggesting novelty as the critical criterion is that the transgenic process itself does need not inherently lead to more risky products. Rather, it is argued, the regulatory process should focus on the changes and the attributes, whether generated by traditional or transgenic approaches, which could provide a social or environmental risk. The risks associated with the attributes of the products ought to be regulated and hence, the products themselves, regardless of the process used in their development.

The practical effect of these different criteria, however, is open to question. The attribute approach, that could result in all modified plants whether the result of traditional breeding or genetic engineering, being eligible for a separate assessment. 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 a more efficient than the current system. In deed, it appears that the de facto Canadian system uses the transgenic process to determine which plants may be novel.

Perennials

Although perennials are covered by the same statutes as annual plants, they create special problems for deregulation. Regulatory agencies have raised special concerns and additional scrutiny for perennial grasses and woody plants of interest for biofuels.

Reasons include concerns over the invasive capabilities over long periods and ability to mate with wild or feral relatives. Also, the incomplete domestication for many forest trees may suggest greater survivability in the wild. These concerns result in 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 their anticipated economic or environmental benefits.

These requirements unquestionably conflict with the realities of practical crop breeding that involve cost control and timely completion of field studies. The effects is to greatly 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 for perennial crop improvement.

The Legal Cases

Regulatory restrictions on organisms produced using recombinant DNA and asexual gene transfer have increased in recent years (Strauss et al. 2010). Two recent federal court decisions in the United States have demonstrated a new stringency by the courts that requires the agencies to be very cautious in their procedures. For both these cases, one involving a herbicide tolerant alfalfa and other involved a transgenic bent grass, the courts ruled that the Environmental Assessment (EA) undertaken were too superficial and that a more detail Environmental Impact Statement (EIS) was required. The justification was found in the National Environment Protection Act (NEPA), which was enacted "to promote efforts which will prevent or eliminate damage to the environment."

In the alfalfa seed decision in the U.S. District Court for the Northern District of California (Case 3:06-cv-01075-CRB Document 83, Filed 02/13/07), the court ruled that APHIS erred in applying an exception and not undertaking an EIS, as sometimes called for by NEPA (Geertson v. USDA 2006). Additionally, the Supreme Court has hear oral arguments involving a federal judge's temporary ban on a breed of pesticide-resistant alfalfa, setting the stage for the court's first-ever ruling on genetically modified crops.

Legal experts do not expect a blockbuster decision on the merits of regulating modified plants such as Monsanto Co.'s Roundup Ready alfalfa, but the case, *Monsanto Co. v. Geertson Seed Farms*, has drawn widespread interest because the justices could issue a ruling that would raise or lower the threshold for challenges under the National Environmental Policy Act. Although the court decisions apply to perennial grasses, the inferences suggest that similar standards will likely apply to trees

An EIS requires a substantial increase in time and costs for APHIS and also imposes large additional costs on the developer. This EIS process allows for opponents to raise hypothetical and conjectural negative environmental impacts for detailed scrutiny. A similar opinion came from the District of Columbia District Court (Civil action 03-00020 [HHK]) regarding the Scott Company's genetically engineered creeping bent grass (ICTA v. USDA/Scotts 2006). Both of these cases involved the introduction of pesticide-resistant genes to grass seed, and the issues appear likely to be applicable to the transfer of certain types of genes to trees. While pesticide-resistant genes in trees are apparently not imminent, the fact that the APHIS procedures were deemed by the courts as "arbitrary" and therefore inadequate necessitates the revision and complication of APHIS deregulatory procedures, at least for certain types of transgenic innovations.

The Issue of transgenic Eucalyptus

Similar difficulties arose in the ongoing case of freeze tolerant transgenic Eucalyptus under development for potential use as a wood source for biomass and biofuel related energy in the US. In addition for freeze-tolerance, the tree is genetically engineered to prevent pollen formation so that fertility is reduced. Finally, some trees included a genetic modification to make the lignin more suitable as a Bioenergy crop.

Two issues arose. The first issue was whether to allow the trees to flower during the process of field testing. The second issue 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, the firm, ArborenGen, first had USFS researchers review the literature. Earlier tests of non frost tolerant Eucalyptus using a process that restricts the plant's ability to produce pollen, were successful. Nevertheless, there was a reluctance to allow similar tests for the transgenic eucalyptus.

Second, although the FS experts concluded that field tests at the scale proposed in the permits are not likely to have any impacts on hydrology, their report raised questions about potential impacts of large scale plantings of Eucalyptus in the U.S. South and suggested a methodology for a large scale trial to measure the impacts. However, the area size of planting is restricted by Biotechnology Regulatory Services (BRS) regulations. Thus, the question raised is not permitted to be addressed by field trails.

These decisions suggest movement toward a Catch 22 situation where large scale trials are viewed as necessary to answer some of the more wide ranging environmental questions, while at the same time it is not clear which agency has to power to authorize large scale trials. Additionally, even if authorized, such trials could become prohibitively expensive with much of the expense is due to the costs of requisite containment as well as the lengthy time period involved.

The Inherent Conflicts: Comparative Costs

The process of deregulation obviously involves costs to the developer over and above the direct costs in developing the transgenic product (Sedjo 2006). However, these costs are socially justified on the basis of concerns over negative effects, largely environmental; affects when talking about forest trees. This is true although concerns about unexpected risks in agriculture, an admittedly less complex area since most crops are annuals, have not materialized so far (Qaim 2010).

Issues such as gene flow concerns vary with the particularly plant but generate concern. Indigenous transgenic trees, such are poplar and pine may have a higher probability of gene flow into the nature forest. This problem is exacerbated by the comparative lack of domestication of these trees thus their being more fit in the wild. By contrast orchard trees, such a papaya and plum, are more highly domesticated and less likely to find a responsive host. An exotic, such as Eucalyptus, is much less likely to fine a receptive host for its genes due to the absence of an indigenous genus.

Given the inherent challenges and unique costs associated with the transgenic technology, especially when working with perennials, the developer must try to select the more efficient pathway. An advantage of genetic engineering is that the time and costs required to make the transformation can be substantially reduced over what might be involved with a traditional breeding approach. However, successfully navigating the regulatory process is not costless. The time and costs that might be saved by using G.E. could be more than lost in moving through the regulatory process.

In many cases the advantage of a transgenic approach is to facilitate a more rapid and low cost transformation of a plant by introducing certain desired traits. However, the deregulation process offsets much and sometimes all of this advantage. The problem is more acute where perennials are involved. For perennials a longer term time perspective must be taken in insure that the field testing experiences reflecting the plants situation of its multi-year time span. Often, perennials are less domesticated raising questions about its potential to successfully escape into the environment one form or another.

However, for some perennials, the use of a traditional breeding approach that avoids the need to navigate through the deregulatory process and avoids the substantial costs incurred in doing so potentially may provide cost and time advantages compared to the transgenic technology. Similarly, with regard to assessing the environmental impacts of perennials over larger areas over time, the higher costs and time involved to achieve deregulation may offset any advantages that the transgenic process may have over traditional breeding.

Summary and Conclusions

The decision of which approach to take to develop a new product – traditional breeding or GE - involves a comparative cost assessment that includes not only the product development costs but also of the costs of deregulation including an assessment of whether deregulation can be achieved. In many cases, traditional breeding may achieve essentially the same result as a GE development approach, but it often takes longer and may be more costly. The widespread use of a GE approach in annual crops attests to the viability of GE when the regulatory process is manageable and predictable. However, with perennials there is greater uncertainly that a particularly produce will be able to navigate the regulatory system successfully.

Finally, it needs to be noted that the traditional and transgenic approaches are not perfect substitutes for one another. Genetic engineering offers possibilities of genetic transfers that are not possible for traditional breeding. In deregulation essentially only one pathway is available within a country. Where the pathway becomes sufficiently stringent and costly, the developer may choose not to make certain investments nor attempt to develop certain types of products. Where foreign markets look promising the developer may chose to relocate his efforts to a country with a more friendly deregulatory system.

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