on its authority to control plant pests, and so the USDA has regulated crops on the basis of the way plant-pest-based tools are used to make them. It is a bizarre approach, given the low pest risk from the tools. But it had some merit when it was first developed because foreign genes were often inserted into the plant genome by a bacterium that can be lethal to some plants. Once in place, the expression of the foreign gene was guided by a series of genetic elements pulled from plant viruses.

To get around this, researchers at Scotts made GM grass without using plant pests. It took more work, but the company reasoned that the streamlined regulation — as well as possible greater consumer acceptance and relief from the patent stranglehold on more traditional genetic-engineering methods — would make it worthwhile. So they mined the wealth of plant genomic data now available, snipped a herbicide-resistance gene from the model plant *Arabidopsis thaliana*, sewed it to genetic elements pulled from maize (corn) and rice to drive the gene's expression, and used a gene gun to blast it into the Kentucky bluegrass genome.

This technique is not the only GM method likely to fall outside USDA regulations. Plant biologists have made tremendous strides since the current rules were cobbled together in 1986, advancing both our fundamental understanding of plant genetics and the technical know-how in manipulating gene expression. Genetic changes can now be made at specific sites in the genome, and foreign genes can even be expressed in plant cells without integrating them into the genome at all. And gene expression can be regulated using RNA molecules — including, in some cases, ones made by the plant in response to attack by a pathogen.

Many of these advances are still years from commercialization. But regulators must prepare the ground. Monsanto GM soya beans, which use RNA interference to modulate the expression of endogenous genes, are already awaiting a decision from the USDA.

The USDA and others need to reconsider how they define and control GM species. If a crop developer uses genetic engineering to delete a discrete segment of a plant genome, how much regulation does that require? Would those same guidelines be appropriate for a crop that expresses half-a-dozen foreign herbicide- and insect-resistance genes, engineered without the use of plant pests? Such questions are particularly important where — as in the United States — GM regulation rests not on the final product of genetic engineering, but on the methods used in the process.

The European Commission is tackling the issue, and has commissioned a study into how new plant techniques fall under the rubric of the European Union definition of GM crops. Similarly, the USDA's Advisory Committee on Biotechnology and 21st Century Agriculture has raised the problem as a point of concern. But the USDA's proposed changes to its GM regulatory powers, released in draft form in 2008, failed to address challenges posed by new technologies.

***"In the United States, genetic-modification regulation rests not on the final product but on the methods used."***

The USDA's Kentucky bluegrass ruling comes at a crucial time for agricultural biotechnology. Some estimate that the world must increase the rate of growth in agricultural productivity by 25% per year to meet growing worldwide demand for food and biofuels. Many argue that advances in agricultural biotechnology, some of which may come from GM crops, will be needed to meet this demand. Industry, particularly smaller companies, needs to know how these crops will be regulated before they will invest to develop new techniques.

The new breed of GM crops could help gain wider acceptance for the technology, by settling long-standing unease about the use of foreign genes and the inability to target such genes to a specific location in the genome. But it is doubtful that dubious consumers are ready for GM crops to escape regulation altogether. ■

# With strings

*Researchers should shrug off their fears and welcome the concept of venture philanthropy.*

When the Maryland-based Cystic Fibrosis Foundation invested in Californian biotechnology company Aurora Biosciences in 2000, it launched a revolution. Before then, it was taboo for a biomedical charity to take a stake in a commercial firm; instead, foundations usually sent their money to academic labs. Those days are over — now is the era of 'venture philanthropy'.

Under this model, continued investment in research can depend on projects reaching predetermined milestones and deadlines. And, as we report on page 275, charities have started to take an interest in controlling the intellectual property that results from such projects. That idea makes some uneasy, but the benefits extend beyond royalties: clauses in intellectual-property agreements can be used to protect a philanthropic investment as well. One risk of working with industry, for example, is that a promising drug can be shelved if the company that owns the patent rights pulls the plug on efforts to develop it as a therapy. To protect against this, much research funded by philanthropies is now subject to interruption licences, which allow charities to regain — and relicense — intellectual-property rights if a project ceases.

Then there is the 'research-only' clause, which promotes continued scientific progress in a field by encouraging companies to allow academic labs to study patented technology. However, patents remain an important currency in business. The best way to develop a new drug is probably for charitable investors to take a guiding, but not overly controlling, hand in intellectual property. If a charity demands high royalties, industrial partners — beholden to the financial demands of their investors — may shy away from the project. And if a charity calls for co-ownership of the intellectual property with a company or university, potential partners might hesitate to license the resulting patents.

University researchers can also benefit from paying closer attention to intellectual property. In some ways, the concept runs counter to the intellectual freedom prized in academia. But the venture-philanthropy approach could be a useful model, especially as the search for funds and the push towards translational research nudge more academic labs into partnerships with industry. Collaborations between academia and pharmaceutical companies are already using research agreements that grant researchers rights similar to those in interruption licences (see *Nature* **474,** 433–434; 2011).

Many academics reject the notion of patents altogether, preferring their research to remain openly accessible. In some cases, this approach has worked. The Alzheimer's Disease Neuroimaging Initiative, a US-based public–private partnership, has unquestionably accelerated the search for new diagnostic tools without patenting its results. The Michael J. Fox Foundation has also taken this approach in its Progression Markers Initiative to find biomarkers of Parkinson's disease.

Industry has seen the value of such projects, and is pushing for more of them. But the approach works best when laying important, early-stage scientific groundwork. Eschewing patents can stifle the development of downstream projects by discouraging private-sector investment.

Yet that does not mean that academics — or charities — should capitulate completely to industry's demands. Indeed, both should expect some push-back from industry at the negotiating table on even minor control measures such as interruption licences. But to take a stronger line on the ownership of intellectual property will ultimately help all those involved in health-care research to turn ideas into therapies. ■

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