treated. The UK's Human Genetics Commission released a report saying that doctors and researchers in UK institutions widely ignore genetic test patents. "The public sector health service does not respect this type of intellectual property and France is the same," says Berwyn Clarke, chief scientific and development officer at Cambridge, UK–based Lab21. "The rest of Europe is much more respectful."

At around $3,000, cost is another sticking point. "Myriad has generated a lot of anger and frustration among clinicians and molecular geneticists in the UK health services," Kent adds. Much of the technology used by Myriad was well understood by many scientists, he argues. "They didn't add much value." And this led to the opprobrium from the community.

But Chahine points out that making US Food and Drug Administration–approved tests is expensive, difficult and time consuming, and the very laboratories complaining about Myriad would never take the steps necessary to do that. Certainly, he argues, certain patients can't afford the test, which is unfortunate. "But some people can't afford an MRI [magnetic resonance imaging scan]," he says. "Advanced medical care is expensive."

Chahine's point underscores an interesting dichotomy in how patients value tests that predict cancer risk as opposed to therapeutics to treat disease. Although it could be argued that tests to define treatment are much more valuable as a whole, people don't seem to see it that way. That sentiment, not the validity of gene patents, may be the biggest obstacle for gene-based diagnostic test developers.

Both Myriad and the plaintiffs now have multiple legal avenues open to them. "Most people believe that regardless of what they do next, the case will end up at the Supreme Court," says Anthony Michael, an associate at Paul Hastings in New York.

Malorye Allison *Acton, Massachusetts*

IN their words

"Everybody talks about [their] pyramid of R&D projects. We've got a pyramid, too, it's just upside down."

Biogen Idec (Cambridge, Massachusetts) CEO George Scangos describes the company pipeline after killing 17 drugs in early stages of development. (*Fierce Biotech*, 29 July 2011)

"Julia Gillard [Australia's Prime Minister] isn't standing up to foreign GM countries to protect our daily bread, so Greenpeace has to."

Campaigner Laura Kelly explains why Greenpeace destroyed an experimental plot of wheat, transgenic for an RNA interference construct that suppresses expression of a starch enzyme to alter carbohydrate composition, that was being cultivated in Canberra. (*ABC Canberra News*, 14 July 2011)

GM grass eludes outmoded USDA oversight

In July, the US Department of Agriculture (USDA) said an herbicide-tolerant variety of lawn grass fell outside its regulatory authority. The case represents the first time a large company has purposely and successfully taken advantage of a critical weakness in the regulation of genetically modified (GM) plants. Although the grass maker, Scotts Miracle-Gro of Marysville, Ohio, has no intention of commercializing the product, the route to market for its GM Kentucky bluegrass is now the same as any variety produced by conventional methods, which are not required to follow the agency's approval route—a process that typically requires years of expensive field trials and environmental testing. "The bluegrass decision is a major landmark, as it sets a huge loophole to circumvent [USDA] regulations," says Alan McHughen, a biotechnologist at University of California, Riverside. The regulatory gap has been known to the industry for years and "now Scotts has shown it can be done," he says. As Scotts blazes a regulatory trail, other companies, particularly small developers, may be encouraged to follow.

In the past, GM plants have been captured within USDA's regulatory domain because they were made using "plant pests," such as viruses and bacteria. *Agrobacterium tumefaciens*, a bacterium listed on USDA's plant pest list, is one of the most common delivery systems for shuttling foreign genes into plant genomes. Cauliflower mosaic virus, also on the plant pest list, is a popular tool among crop developers for its promoter, 35S, which is used to constitutively activate the transcription of transgenes.

Scotts, however, used neither of these, nor any other plant pests in creating GM Kentucky bluegrass. Instead of using *Agrobacterium* to deliver the genes, the company used a gene gun, which blasts DNA into plant cells on pellets made of gold. The gene for herbicide resistance, *EPSPS* (5-enolpyruvylshikimate-3-phosphate synthase), came from thale cress (*Arabidopsis thaliana*) and other genetic elements came from corn and rice. None of these technologies is new, but combining them with the intent of bypassing federal oversight exposes the shortcomings of regulations that researchers say should have been overhauled years ago. "The regulations are outmoded," says Carol Mallory-Smith, a weed scientist at Oregon State University in Corvallis. "Technology has changed and they haven't."

Scotts decided to circumvent the regulations after litigation stalled USDA approval of herbicide-tolerant creeping bentgrass, another GM product in the lawn-care company's pipeline. "Deregulation wasn't working for us," says Richard Shank, senior vice president of regulatory and government affairs at Scotts. "We had other grasses in our research greenhouse so we decided to give it a shot."

Scotts chose herbicide-tolerant Kentucky bluegrass for the simplicity of both the genetic materials used to create it and the patents associated with it. But the company will not commercialize this particular variety, Shank says. Arguing it past USDA was largely an exercise—a way to set a precedent for other varieties of

Bill Grove/istockphoto

The USDA has determined it will not regulate Scott's herbicide-tolerant lawn grass, exposing a loophole.

GM grass the company is developing. These new grasses are "several years" away from commercialization and the company plans to work closely with USDA, Shank says.

Now that Scotts has shown it can be done, other plant developers may be tempted to test USDA's authority over their products. "I'm sure companies are salivating over this," says McHughen. On a semantic technicality, regulatory costs "go from $50 million to zero," he says. This avenue may be the most attractive to smaller companies and developers of specialty crops, for whom regulatory compliance can be a great anxiety. "The most limiting factor in getting smaller developers engaged is the regulatory costs," says Kellye Eversole, executive director of the Specialty Crop Regulatory Assistance, a nonprofit that helps crop developers meet US regulatory requirements.

But not all plant developers would gain from skirting USDA regulations. Food crops are subject to oversight by the US Food and Drug Administration (FDA), and products intended for export markets must go through the approval processes of recipient countries. The data collected for these review processes often include the same data collected for USDA, says Adrianne Massey, a managing director at the Biotechnology Industry Organization in Washington, DC. Developers of these plants would "essentially gain nothing" by circumventing USDA, she says.

Seed producers will also have to weigh regulatory cost savings against the time and money it would take to find the right genes and tools to substitute for plant pests. Elizabeth Hood, founder of Infinite Enzymes in Jonesboro, Arkansas, uses *Agrobacterium* transformation for her lines of biofuel corn. She says she is "excited" about the news of Scotts' success, but doesn't plan on redeveloping her products without *Agrobacterium* to take advantage of the regulatory loophole. "It takes too long to go back and do it all again," she says. "However, it would be advantageous to consider this loophole for new products."

Eric Rey, CEO of Arcadia Biosciences in Davis, California, says his company has no desire to bypass the approval process, as they do not see any benefit, cost or otherwise. "It's not worth going out of our way to avoid [USDA] review," he says.

Besides, the USDA's imprimatur remains valuable to some companies as a stamp of approval to offset public fears fomented about biotech crops. "They like the fact that they get the good housekeeping seal," says Arnold Foudin, a former regulator at the Animal and Plant Health Inspection Service (APHIS), the branch of USDA that regulates biotech crops.

Foudin, who retired in 2008, says APHIS officials and industry players have known for nearly two decades that it was possible to skirt USDA review by going the non-plant-pest route. "The idea of escaping plant pest rules has been kicking around in our community for quite a long time," adds Greg Conko, a senior fellow at the Competitive Enterprise Institute in Washington, DC.

For example, a developer of a GM petunia (containing a petunia chlorophyll A/B binding promoter with a petunia MYB transcription factor controlling the anthocyanin pigment pathway with no selectable marker) successfully argued in 2008 that the plant fell outside of USDA's jurisdiction because it did not use plant pests. But none of the big biotech players have tested the system. "Nobody petitioned us to delist any organisms" from the plant pest list, Foudin says. "The players who could have afforded it didn't want to because it would have disturbed a system they like. Most big players love the current game because it prevents public sector or USDA or small developers from getting in."

The current regulatory system is based on old laws interpreted creatively to give APHIS authority to regulate. The plant pest hook was sufficient back when products were simpler and fewer. Now that transformation systems and the donor organisms for genetic material are diversifying, USDA may find GM crops increasingly falling beyond its purview.

Still, USDA could have captured GM bluegrass with another provision in its regulations known as the noxious weed program. If the agency decides that a plant belongs on the federal noxious weed list, it can regulate it. USDA found that Scotts' bluegrass qualified as a noxious weed, but decided its impacts were not negative enough to warrant a spot on the federal list. "The fact that it chose not to [put GM bluegrass on the list] is perhaps an indication that APHIS prefers not to regulate new GM plants anymore if it can reasonably avoid it," says Tom Sappington, an entomologist with the Agricultural Research Service, the research arm of the USDA. The agency "may want out of this business that it was not particularly designed to conduct in the first place," he says, adding, "The political cross fire APHIS gets placed in by a diversity of stakeholders every time it must make a decision on a GM crop also is an incentive to get out." Sappington says he does not have inside information on APHIS' intentions.

USDA has been trying to revise the regulations for years, and has considered widely varying proposals. As the industry awaits a new system, it may see more bluegrass-like decisions from APHIS.

Emily Waltz *Nashville, Tennessee*