

biotechnology patents, which typically have several novel components, bear the burden of additional filing fees and delays in protecting all parts of their inventions while the patent office drowns in the additional applications. "In order to patent a single invention, a biotech company is often forced to divide up the invention into its component parts and file separate applications," says Stewart. "The restriction practice is producing patents with such narrow claims to individual DNA sequences or different forms of the same molecule, making it difficult to protect the entire system."

As inventors and the legal community agree in principle to a major haul of patent office operations, controversy continues around the increase in user fees in light of the diversion of

patent office revenue to the General Fund. Approval of the 2003 national budget will allow Congress to draw on \$192 million in patent fees—a source of nontaxpayer revenue—to fund other federal programs. Although the President's proposed 2004 budget reduces the diversion to \$99.7 million, raising user fees to fund modernization of the patent office appears contrary to the PTO's mission to foster entrepreneurial spirit in innovative biotechnology companies. "Diversion of funds is the big issue," says Stewart. "It is not reasonable to divert almost \$100 million in user fees and ask inventors, especially of these small companies, to pay more—[it] seems very unfair."

Debra Robertson, San Diego, CA

universities and companies—those trials are beyond the jurisdiction of the ag minister."

Alemanno has appointed half the panel members, who tried to set out a universal protocol—an impossibility because releases have to be evaluated case by case depending on the species involved and the type of genetic modification. They also tried to apply the HACCP (hazard analysis critical control points) system, an approach used in food processing to control microbial and chemical contamination and never attempted with agbiotech research. The resulting draft is an odd text, repeating what has already been established in 2001/18 but with further restrictions that will be tricky to apply.

The Italian premier Silvio Berlusconi and other ministers have officially expressed their support for agbiotech research in the past, but the government has not yet opposed the agriculture minister's decisions—resulting in deadlock.

For almost three years, Italy has banned GM flour and starch that are sold everywhere else in Europe, and Alemanno recently opposed the government's attempt to reopen the issue, despite a lawsuit underway at the European Court of Justice. Sergio Dompé, president of the association of Italian biotech industries, says that when Italy takes up the EU presidency, "I can imagine two alternative scenarios: the Italian government can carry to Brussels the weight of its internal problems about GMOs slowing down the process toward the moratorium ending or, conversely, it can use the opportunities offered by the international stage to accelerate the process of solving its problems at home."

Anna Meldolesi, Rome, Italy

Italy employs further GMO delay tactics

The final hurdle before the moratorium on approvals of genetically modified organisms (GMOs) in Europe is lifted is supposed to be the approval later this year of new rules governing their labeling and tracing. However, on February 20 agriculture ministers from several member countries, led by Italy, added yet another obstacle by demanding that new rules be established for the coexistence of organic and GM agriculture before GMO approvals can resume.

The European Commission (EC) is already formulating a strategy to manage coexistence, suggesting that Italy is simply using the issue of GM thresholds for organic products as another delaying tactic. Moreover, Italy is set to hold the EU presidency from July to December and will therefore set the EU agenda at the time when the latest pieces of GM legislation are expected to be approved. Unfortunately, the way it is managing its own GMO issues casts doubts on its intention to resolve the problems concerning GMOs in Europe. Italy's agriculture minister is a fierce opponent of agbiotech and the country has not yet implemented into national law the EU directive on the release of GMOs into the environment (2001/18), the deadline for which was October 17, 2002. The government is dragging its heels by forming a panel to establish rules for open field trials of GMOs—an issue that is already clarified in 2001/18.

The latest episode in the saga began on November 15, 2002, when the agriculture ministry halted GMO field trials conducted by research institutes, even those already funded and authorized. On December 7, a dozen of Italy's leading scientists protested in the main national newspaper, asking the government for

clarification. A few days later, the president of the National Committee for Biosafety and Biotechnology, Leonardo Santi, set up a panel to establish guidelines for research involving GMOs. "The government's aim was to come to an agreement with the ag minister Gianni Alemanno and let trials resume. The panel was set up to answer that purpose," says Santi.

However, agbiotech researchers such as Roberto Defez of the National Research Council say the result could be counter-productive. "We wanted to overcome the deadlock with respect to the research institutes depending on the ag ministry," says Defez, "but now we have a panel writing the rules for all field trials, even those conducted by

US food aid still under GM cloud

Controversy over whether India should import a shipment of food aid from the US that is suspected to be contaminated with genetically modified (GM) corn has become murkier.

A consignment of 1,000 tonnes of corn-soya blend from the US is lying in Kolkata port awaiting clearance from the Environment Ministry's Genetic Engineering Approval Committee (GEAC), which regulates the large-scale introduction of GM drugs, plants, or food stuff. The shipment is the first of a 23,000-tonne food package that CARE-India and the Catholic Relief Services (CRS)—two American nongovernmental organizations (NGOs)—had proposed to import into India for distribution to school children under the 'midday meal' program.

Last November, the GEAC refused to clear the shipment as the two agencies failed to produce US government certification in writing that the consignment did not contain StarLink, a variety of GM corn that is approved as cattle feed in the US but not for consumption by humans. At that time, there were already reports of traces of StarLink corn slipping into US consignments to Japan, South Korea, and Australia. "We didn't want to take chances," the then GEAC chairman A.M. Gokhale says. "All we asked was a US government undertaking saying it was free of StarLink." As this was not forthcoming, GEAC refused permission for the import.

At its second meeting on March 6 to reconsider the issue, the GEAC stuck to its earlier decision disallowing the import. But the com-