

# European Parliament Backs New Biopatent Guidelines

STRASBOURG, FRANCE—After being subjected to one of the most intensive lobbying campaigns they have ever experienced, members of the European Parliament last week approved the outline of legislation that will determine what biotechnology inventions can be patented in the European Union (EU). It backed proposals that would permit the patenting of genes and genetically modified animals under specific conditions, while banning patents on plant and animal varieties and techniques directly related to human germline manipulation or human cloning.

The vote—by a surprisingly lopsided margin of nearly four to one—was a victory for Europe's biotech industry, which has long argued that a new, continent-wide policy is needed to replace the outdated current law, framed 30 years ago. But the proposals still have a long way to go before they become law, and opponents—mostly environmental and animal-rights lobbyists—have vowed to continue fighting them.

The new proposals are the latest in a 9-year effort by the European Commission, the EU's executive, to streamline and harmonize Europe's biotechnology patent system. European biotech companies have long argued that the 1973 European Patent Convention needs to be updated. They also complain that inconsistencies among national patent laws can be problematic, because even when the European Patent Office in Munich, Germany, does grant a patent, it must be validated in each country. "This lack of harmonized patent protection has contributed to Europe's biotechnology industry lagging significantly behind the United States and Japan. Patent protection is crucial," says Catherine Péchère of the European Federation of Pharmaceutical Industries' Associations.

The commission tried to respond to such concerns 2 years ago when it sent draft legislation to the European Parliament that would have permitted patents on a range of biotechnology inventions throughout the EU. But the proposals provoked a howl of opposition from groups rallying under the banner "no patents on life," claiming that the rules would have allowed patents on parts of the human body. The Parliament rejected the proposals and sent the commis-

sion back to the drawing board.

This time around, the commission prepared its case much more carefully. Says EU Commissioner Mario Monti, who was chiefly responsible for developing the new version: "In the new proposal, we want to address those concerns and guarantee research and business within clear limits and ensure respect for the integrity of the human body."

The revised proposals try to make a clear distinction between a discovery and an invention. A discovery of a gene, for example,

Indicator	Europe	USA
Turnover (\$ millions)	1,873	12,893
R&D expenditure (\$ millions)	1,653	6,943
Number of companies	700	1,300
Number of publicly quoted companies	50	300
Number of employees	27,500	118,000

SOURCE: ERNST & YOUNG

would not be patentable by itself, whereas an invention—defined as a technical process with an industrial application—could be patented. Although "an element of the human body in its natural environment" couldn't be patented, the proposals state that "an element isolated from the human body or otherwise produced by means of a technical process shall be patentable even if the structure of that element is identical to that of a natural element."

These proposals won a key endorsement last month from the Parliament's legal affairs committee, led by Willi Rothley of the Parliament's Socialist group. But the committee offered several amendments that would strengthen the ban on patenting human genetic code without reference to an industrial application, bar patents for genetic modification of animals unless there is "substantial medical benefit," prohibit patents on plant or animal varieties, and set up a bioethics committee. All the committee's amendments were acceptable to the commission, says Monti, and many were supported by Parliament.

The biotech industry and patient groups mounted a fierce lobbying campaign to per-

suade the Parliament to approve the proposals, arguing that they will help foster the development of new medicines. Its efforts are widely credited with the dramatic shift in parliamentary support. Gordon Adam (Socialist) said during the debate last week that "there has been a barrage of misinformation orchestrated by the Green movement. ... Opponents should ponder what it is they are trying to prevent." This view was echoed by fellow Socialist Kenneth Collins: "The debate is shrouded in misinformation. Biotechnology is a tremendously important sector in the EU. If we reject this directive, patenting will continue, but we'd have less control over it."

Not surprisingly, the biotech industry is pleased with last week's vote. "We welcome their approval and the distinction made between discoveries and inventions," says Péchère. "I'm very pleased," adds Alastair Kent, president of the European Alliance of Genetic Support Groups. "It's now very clear what can and what cannot be patented. We've learned from the U.S. experience and added more ethical elements. The balance between suffering and medical benefit in granting patents on genetically modified animals is very welcome. Broad patents without much application would also be much less possible," he says.

But one amendment, approved by Parliament, has raised concerns within industry. It would require patent applicants to declare the geographical origin or name and address of the human donor of any biological material, and swear that it had been obtained legally or with consent. "This amendment is not realistic and undermines patient confidentiality. We shall be fighting it," says Péchère.

The opponents have also not yet given up. They argue that the proposals would stifle research in the public sector, increase the cost of health care, and shift control of genetic resources into the hands of a small number of powerful companies. "People have been hoodwinked by the arguments. The directive is essentially the same as last time, and our root-and-branch objections hold," says Ian Taylor of Greenpeace. "We shall continue to make clear our opposition." In last week's parliamentary debate, Nuala Ahern (Green) said: "Genetic resources must not be controlled by a small number of companies. Treatments could become prohibitively expensive. We are moving toward a U.S. model of health care, and if we do so, our citizens will never forgive us."

The proposals are now back in the commission's court. It must now redraft them and submit them to the EU's Council of Ministers later this year. After that, they will go back to Parliament.

—Nigel Williams