As originally proposed, the new budget formula would have shifted $105 million of WHO's biannual budget to underfunded countries in Africa and the European region over 6 years, while spending in Southeast Asia, the western Pacific, the eastern Mediterranean, and the Americas would decline. But according to the plan hammered out by delegates last week, LDCs will be exempt from any cuts, and the regions in line for reductions will be cut by no more than 3% per year over the 6-year period. Hence the Southeast Asian region will be cut by only 18% over 6 years, rather than 50%. With the exemptions and caps, $60 million of resources will be transferred to the African and European regions over 6 years. At that point WHO's executive board will review the changes, and the WHO will decide whether to transfer the remaining $45 million.

Some delegates were disappointed at the slow pace of the funding changes, but they backed the deal because it would avoid considerable bitterness in some regions and splits in the organization. But the chair of the Budget Committee, Nimal Seripala de Silva, calls the budget reform "a landmark decision. ... This is a wonderful present to our new director-general, Gro Harlem Brundtland." De Silva adds: "The present we have given to her will cater to the health needs of the whole world community in the 21st century."

–Lisa Schlein

Lisa Schlein is a journalist in Geneva.

BIOTECHNOLOGY

EU Ends 10-Year Battle Over Biopatents

Amid intense lobbying and appeals from opponents for more time, the European Parliament passed legislation last week that would make human gene sequences and transgenic plants patentable throughout the European Union (EU). These controversial provisions were included in the so-called "gene-patenting" directive, first introduced a full 10 years ago. Each member state must now redraft its national laws to comply with the directive to ensure that there are no internal barriers in the EU's common market.

The directive is a critical element in the EU's efforts to promote biotechnology, and the biotech industry is delighted. "It's an historic decision," says Anthony Arke, secretary-general of the Brussels-based trade association EuropaBio. Not surprisingly, opponents such as Dan Leskien, a lawyer for Friends of the Earth, Europe, are dismayed. The directive, he says, "is a disaster." Leskien and others object, among other things, to patenting human genetic material and other biological resources, which they believe are common assets of humankind.

The new legislation allows the patenting of partial and complete human gene sequences, but only if an industrial application is disclosed—in line with policies already adopted by most of Europe's national patent offices. Also, transgenic plants are patentable if the trait conferred, say, disease resistance, is applicable to more than one variety. What the directive does not allow is the patenting of any processes for human cloning, processes that modify the germline genetic identity of humans, and the use of embryos for industrial or commercial purposes. The directive should bring European laws more in line with those of the United States and resolve some disputes that have been simmering for years.

The European Patent Office (EPO), which is governed by the European Patent Convention, has been awaiting this directive with interest. Signatories to the convention include all 15 member states of the EU plus Switzerland, Lichtenstein, Monaco, and Cyprus. Inventors can make a single application to the EPO, which will cover as many member countries as they wish. Even though the EPO is not legally bound to follow the new directive, experts say that because it applies to 15 of the EPO's 19 members, it is certain to influence EPO thinking. That new thinking will soon be applied to two key biotech patent cases currently awaiting the outcome of appeals. Although not officially acknowledged, it is widely believed that these decisions have been on hold until the directive was passed.

"[The directive] makes clear the patentability of plants and animals in general."

—Conrad Becker

The first concerns Harvard University's Oncomouse, which is genetically engineered to be susceptible to cancer. The EPO granted Harvard a patent on the animal in 1992, 5 years after it received a U.S. patent, but the pressure group Compassion in World Farming (CWF) immediately challenged the European patent on the grounds that the European Patent Convention says a patent cannot be granted if it is contrary to morality. "Genetically engineering animals to develop a painful, lethal disease is morally unjustifiable," argued CWF.

In the event, the directive states that such a patent would be allowed only if there was substantial medical benefit to justify the animals' suffering. Hence the EPO appeal board will have to make its own moral decision. If the patent is revoked, Harvard could apply for patents in each European state, but they will follow the same guidelines as in the directive.

The second patent appeal is a test case brought by the Swiss drug and biotech company Novartis in an effort to clarify the scope of patents for transgenic plants. The EPO will not grant patents for new plant varieties on the grounds that they are covered by separate EU legislation. However, this legislation covers only one variety at a time, which is fine for traditional plant breeders but causes the biotech industry a problem because a gene can be inserted into a range of plants to confer a specific trait. Conrad Becker, head of patents and trademarks at Novartis, says, "After years of research, you can claim only one variety. In the meantime, another company can copy your work and gain protection for other varieties."

In an earlier case, a patent for a herbicide-resistant transgenic plant was first awarded by the EPO, then revoked on appeal in 1996 after Greenpeace pointed out that the patent in effect covered a new plant variety. Novartis and other companies then set about trying to overturn the precedent set by EPO's appeal board. Novartis applied for a patent on a transgenic plant and was duly turned down. They appealed, were turned down again, and are now awaiting the decision of the EPO's final board of appeal.

In this case, the new directive is expected to have a significant impact. Although it still excludes patents on new plant varieties, it says a transgenic plant is patentable if the genetic modification is applicable to more than one variety. Becker says the new directive "is a very good step forward," adding, "it makes clear the patentability of plants and animals in general."

Some researchers, meanwhile, remain cautious about the impact of the directive on research. Most existing national legislation exempts research from royalty fees, and Becker says he expects this to be continued as the directive is applied in each country. But, says biologist Roger Whittenbury of the University of Warwick in the U.K., "we'll have to wait and see."

–Helen Gavaghan

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