Europe Tries to Untangle Laws on Patenting Life

Attempts to strengthen biotechnology patent protection in Europe are facing a series of obstacles raised by a 1973 convention that prohibits patents on plant and animal varieties

Brussels

VARIETY MAY BE THE SPICE of life. But in Europe, the biological definition of variety is standing firmly in the way of those seeking to patent new types of living plants and animals.

The current situation on biotechnology patents is, as one industry scientist describes it, "highly confused." There is uncertainty over precisely what can be patented under European law, and this is causing problems both for researchers and the industry—especially in sorting out intellectual property rights in collaborative or sponsored research.

A small biotechnology company in one European country, for example, which is working with a seed company in another to develop a new strain of potato, is unsure about who will have what type of rights over the plants that result from the collaboration. And Harvard University has had a patent application for a genetically altered mouse turned down by the European Patent Office on the grounds that transgenic animals cannot be patented (see box, p. 1003). The mouse strain has, however, been patented in the United States.

In an attempt to reduce the confusion, the European Commission—the executive body responsible for carrying out the activities agreed to jointly by the 12 member states of the European Economic Community (EEC)—has recently published proposals for "harmonizing" national patent laws by establishing a legal framework under which genetically manipulated plants and animals could be patented.

The commission argues that all European national patent laws should be based on the premise that "a subject matter of an invention shall not be considered unpatentable for the reason only that it is composed of living matter." In other words, biotechnology inventions should receive the same treatment as any other invention.

The European Patent Convention (EPC) of 1973 in fact specifically adopts this approach for microorganisms, since it states that "microbiological processes or the products thereof" are not excluded from patent protection. Higher life forms are another matter, however, for the convention also contains a clause stating that patents cannot be granted on plant and animal varieties.

Clause 53(b) in the convention states that "European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals." Critics of any attempt to patent living organisms have seized upon this clause to support their case, and they have been bolstered by traditional plant breeders who see strengthened patent protection as a direct threat to the existing system of legal protection known as plant breeders' rights.

The main thrust of the commission's proposal is that all EEC member states should interpret the clause in a way that would to a large extent define away the problem. The goal of this strategy, which was initially suggested in a report by the Organization for Economic Cooperation and Development (OECD) is to avoid the daunting prospect of renegotiating the convention.

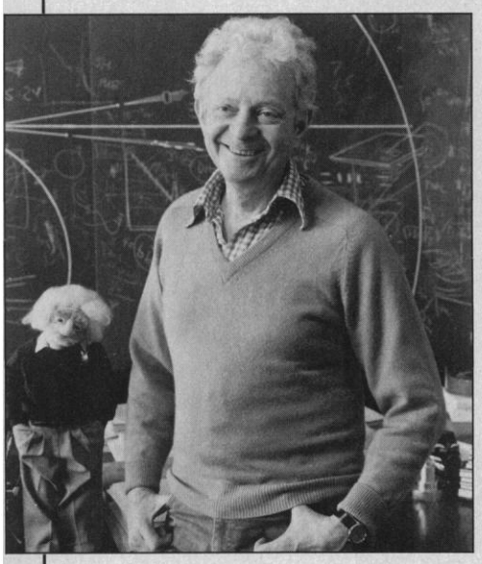
In particular, the commission is proposing that all EEC countries adopt in their national legislation a narrow definition of the concept of "variety." The OECD had suggested that, rather than starting from a biological definition based on stable genetic differences (however small), the concept be confined to those plants or animals a country wants to protect through a system of breeders' rights. In essence, a new plant or animal would be considered a new variety only if it is explicitly described as such.

A former official of the International Union for the Protection of New Plant Varieties (UPOV) is reported to have likened this to allowing someone to circumvent a temporary ban on importing pigs into a country with foot-and-mouth disease by arguing that he was merely importing vertebrates.

The commission's proposals have not yet been approved by the Council of Ministers representing member states, or debated by the European Parliament. But they have been attacked by environmentalist and animal rights groups. "This directive must be the ultimate expression of anthropocentricity, since it shows that the European Commission believes the world of living organisms revolves around mankind," Joyce de Silva of the British-based group Compassion in World Farming told a meeting in Brussels 2 weeks ago organized by the International Coalition for Development Action and the Green Alternative European Link.

Europe's biotechnology industry is cautious about the new proposals. While welcoming their general aims, some industry spokesmen have expressed concern that the proposals do not go far enough in allowing

Lederman to Leave Fermilab



Leon Lederman

After 10 years of running Fermi National Accelerator Laboratory and overseeing the construction of the world's most powerful particle accelerator, the Tevatron, Leon Lederman is heading back to the classroom.

Laboratory spokeswoman Margaret Pearson says Lederman, 66, will leave his job as Fermilab's director in mid-summer to join the Department of Physics at the University of Chicago. "He is eager to get back into teaching," says Peter Meyer, chairman of the department. To warm up for his lectures next year Lederman will teach an undergraduate course on physics this spring. In addition to teaching, Lederman, who shared the 1988 Nobel prize for physics (*Science*, 4 November, p. 669), is expected to pursue his own research. He also will advise Illinois Governor Jim Thompson on science and technology matters. ■ MARK CRAWFORD

patents on new plants and animals. They also argue that too many concessions have been made to traditional plant breeders.

Industry is also concerned about the lack of precision in the Commission's proposals as they currently stand. "It is unclear what the directive is really saying," says Ken Baker, head of biotechnology for the European division of Monsanto. "Much of it hangs on the definition of a variety, which is not clear; and if that is not clear, you are going to end up with a document which is imprecise."

Some of industry's concerns are specific. They include a clause, added at a late stage in the drafting process, which specifies that plants and plant material cannot be patented if they have been produced by the non-patentable use of a previously known biotechnological process. J. H. Duesing of the agricultural division of CIBA-GEIGY Ltd. in Basle, Switzerland, told the Brussels meeting that this language could "exclude from protection beneficial pest-resistant plants created by tissue culture or protoplast fusion."

The biotechnology industry's criticisms have, at least in public, been relatively muted, reflecting a feeling that the directive points in the general direction that industry favors. (A competing draft directive, compiled by the agriculture directorate and said to advocate active support for plant and animal breeders' rights, is being kept tightly under wraps by the Commission.)

Gaining public acceptance will be more of a problem. Already Denmark, for example, which is a member of the EEC but has not signed the Patent Convention, has a law on its books prohibiting the patenting of plants and animals. This law would probably have to be changed if the directive is approved by the EEC's Council of Ministers; but already this possibility has sparked a sharp public debate in Denmark.

In West Germany, where opposition to genetic engineering has erupted from the merger of two powerful strands that feed the Green movement and its sympathizers—namely criticism of modern technology and defense of the natural environment—the political prospects for the directive are equally uncertain.

In this situation, there is a growing feeling that a clear decision on the patenting of novel life forms will not be obtained either through a process of political consensus-building, or by seeking a ruling on the scope of existing legislation. What will be required is a clear signal from Europe's political leaders about the importance they attach to patent rights on living organisms for the future health of their biotechnology industries. ■ DAVID DICKSON

No Patent for Harvard's Mouse?

The European Patent Office (EPO) in Munich has provisionally rejected an application from Harvard University for a European patent on a mouse that has been genetically altered through the insertion of an artificial cancer gene.

The decision is likely to lead to a major legal controversy, since it is the first to have been made in Europe on an application for patent protection for a transgenic animal. As a result, the eventual outcome of what is being seen as a key test case will be closely watched by molecular biologists and biotechnology companies on both sides of the Atlantic.

The Harvard mouse was developed by Philip Leder of Harvard Medical School and his coworker Timothy Stewart, now with Genentech in San Francisco. By introducing an activated *myc* oncogene into an early mouse embryo, they created an animal that is highly susceptible to cancer, and is able to play an important role in research into, for example, the detection of carcinogens or the evaluation of potential anti-cancer drugs.

Harvard was awarded a U.S. patent on the same mouse last April, and the rights to the patent are now owned by Dupont, which paid for the research. The university has already responded to the arguments put forward by the EPO for rejecting the European patent application. If the rejection stands, Harvard would essentially be prevented from obtaining patent protection in any country in Europe.

The EPO's detailed response to Harvard's arguments—which will have to be considered by a panel of three EPO lawyers—and the eventual outcome of any appeals process, will carry the same significance in Europe as the 1980 Chakrabarty decision, which allowed the patenting of microorganisms, did in the United States. As in the U.S. case, the appeals process is being seen by both sides as a way of clarifying current uncertainties in European law over the extent to which plants and animals can be patented.

But in contrast to the U.S. patent decision on the *myc*-mouse, which was made with relatively little public debate—although it subsequently led to several congressional calls for a moratorium on the further patenting of animals—the EPO has apparently decided that it is unwilling to take this step without substantial further discussion of the issue.

The letter of rejection to Harvard from the EPO examiner states that the decision was based on the fact that the European Patent Convention of 1973, under which a European patent is automatically valid in each of the 11 states that have signed the convention, prohibits the patenting of "transgenic animals per se." The EPO has referred Harvard in particular to a clause in the convention that forbids the patenting of plant and animal varieties (see accompanying story). It has also suggested that the *myc*-mouse does not meet the patentability criterion of non-obviousness."

Less expectedly, the EPO has also quoted a separate article in the Convention which says that no patent can be granted on an invention "whose exploitation would be contrary to *ordre publique* or morality."

By invoking this little-used clause as a reason for denying patent protection to transgenic animals, the EPO is suggesting that the patent application raises social and ethical issues that it may not be competent to judge. "In rejecting the application, they seem to be saying 'let's go for the overkill in a big way,' using the rejection and the subsequent appeals procedure as a device to make sure that all the issues are properly considered," says one British patent official.

European groups that are opposed in principle to the extensive patenting of living organisms have reacted cautiously to the EPO's decision, pointing out that it is merely the first step in what promises to be an extensive legal tussle.

"It is certainly good news, and I think that it is a very positive decision," says Henk Hobbelink of the Seeds Action Network in Barcelona. "It is certainly not going to be the last word, and if the directive being proposed by the European Commission goes through in its current form, it is quite certain that it will then be possible to patent transgenic animals."

John Clarke, a patent attorney for Harvard University, said last week "the EPO could still send us a letter saying 'you have convinced us we were wrong' and grant us the patent. If not, and the rejection is upheld, then we will have to decide whether to continue with the patent claim." ■ D.D.