NO ANIMAL PATENTS

EUROPEAN PATENT RULES EMERGE

STRASBOURG, France—Finally, nearly four years after it first saw the legislation, the European Parliament (Strasbourg, France) has given its opinion on the proposed European directive on biotechnology patents. The parliament voted 47 amendments, including provisions to ban patenting on all animals, including transgenics, and to disallow patents on "discoveries" of such things as partial cDNA sequences. The European Commission (EC, Brussels) will now amend the parliament's proposal, taking some but certainly not all of its concerns on board, before presenting the directive to the Council of Ministers—the ministers from each of the European Community member countries—this month or next month. Provisions for ethical assessments of what is patentable are likely to stay. Human tissue will be expressly unpatentable, despite concerns that this will limit the scope for the development of gene therapy in Europe. The directive should come into force in the second half of 1993.

The progress of the directive has been exceptionally slow: two years, rather than four, is a more typical delay between the first publication of the proposal and its final adoption by the Council of Ministers. The EC sent its proposals to the parliament in November 1988 but it took until July 1989 for the parliament to decide that the proposal should go before its Legal Affairs Committee. The committee considered the proposal at five separate meeting between January 1991 and January 1992 before presenting its report to the parliament's plenary session in Strasbourg in February 1992. At that session, parliament threw the report back to the Legal Affairs Committee, and it did so again in March and again in June.

Animal patents

The current form of the proposal—which, with its amendments, is a patchwork of legal niceties and political expediencies—contains elements that will be unwelcome to industry. First, there is the exclusion of all animals from patenting. This "last gasp" amendment, included by the parliament at its October sitting, could be disastrous for the development of transgenics. However, it is unlikely to be included in the final version of the directive. The EC will omit the amendment, according to the EC's Dominic Vandergheynst, "because it goes beyond" the Munich Convention, which established the European patent system. Article 53D of the convention, to which most of the European Community nations are signatories, excludes not "animals" but "animal varieties" from patent protection: this is intended to prevent dual intellectual-property protection—under both Animal Variety Rights and patents—and not to exclude animals from patents. According to Richard Bizley of the law firm Hepworth Lawrence Bryer and Bizley (Harlow, UK), who dealt with the Harvard mouse patent in Europe, any change in the Munich Convention is extremely unlikely on this, or perhaps any other, issue.

One possible complicating factor, however, is that biotechnology patents directive will go before the Council of Minister under the Danish presidency, which begins in January. The Danish Parliament has responded to Danish public opinion in coming out against animal patents. Therefore, the directive is more likely to emerge from the Council of Minister after June 1993, when the Danish presidency ends and the Belgian presidency begins.

Farmer's privilege

Industry is worried, however, about the provisions that extend the "farmer's privilege"—the right to propagate crops and animals without payment of any license fees—to patented products. "Farmer's privilege is of concern," says Brian Ager of the Senior Advisory Group on Biotechnology (SAGB, Brussels), an industry body. "One might ask why a particular group should be exempt." The farmer's privilege amendments almost certainly will remain when EC revises the patent directive. In response to strong pressure from the environmental and agricultural lobbies, the parliament essentially refused to give its opinion on the directive unless EC included the farmer's privilege provision. EC is morally—but not procedurally—obliged to keep it in.

The focus of lobbying attention will now turn away from the European Parliament and towards the Council of Ministers. That is to say, the national associations—in agriculture, environment, and industry—will lobby their respective national governments. —**John Hodgson**

urging regulators to focus on products rather than the process by which they are made. Second, the report suggests that regulatory agencies conduct "post-approval audits" to "indicate the magnitude of the social cost of regulatory delay," here reflecting a belief held by several board members that perceived regulatory barriers discourage researchers from pursuing worthy projects, particularly those that entail environmental release of genetically modified organisms. Thus, such audits would attempt to measure the hidden costs to the public when access to useful products is delayed.

And, third, the report urges that regulations be eliminated if they "prohibit producers from informing the public about their products." The aim here is to ease product-label restrictions, mainly at the Food and Drug Administration (FDA, Bethesda, MD) and the Environmental Protection Agency (EPA, Washington, DC), that "inhibit manufacturers from fully educating the public." An example of such restriction easing might include adding off-label uses of a drug to the drug's label. This recommendation, however, provoked criticism from FDA board representative Kathryn Zoon, who points out that "these restrictions provide substantial public benefits."

Capital formation

The report also recommends several measures to encourage capital formation through public-sector programs, changes in patent policy, and tax incentives. For instance, it says that there should be more joint ventures between federal and private-sector researchers, especially in areas where, despite potentially large benefits for consumers, market incentives "do not meet private-sector investment criteria." The report further notes that federal technology-transfer programs need "fine tuning" and that science-education efforts should be improved.

During 1991 hearings convened by the board, industry representatives pointed out that the U.S. venture-capital investment system, with its emphasis on quick turn-around, can play havoc with start-up companies that may require more time before products reach their markets. As remedies, the board urges tax-law changes to expand current research-and-development tax credits and other changes to allow losses to be "passed through to investors."

The report also endorses the general idea of patent reform but shies away from recommending specific changes in U.S. statutes, instead acknowledging that Congress's Office of Technology Assessment (Washington, DC) is addressing how to streamline the system.

—**Jeffrey L. Fox**