PATENTS

A MODEST PROPOSAL FOR EUROPEAN PATENTS

LONDON—More protection for biological materials, organisms, and the other products and processes of biotechnology. More definition. Less dispute. That's the message the European Commission has sent to the European Community (EC) member countries. With an eye to the advent of the "single European market" in 1992, when all trade barriers between EC members are supposed to have melted away, the Commission has proposed what amounts to a European patent law for biotechnology.

The proposals—a series of measures that each member state would have to incorporate into its patent laws—follow the existing European Patent Convention which now serves as the basis for the decisions of the European Patent Office (EPO). But because the Convention predates biotechnology's influence, the Commission believes current biotech patent decisions often are makeshift, whereas they should be based on new, specific guidelines.

While generally maintaining that living material should be patentable, the proposals except plants "produced by the nonpatentable use of a known biotechnological process." The logic is that, while plant and animal varieties themselves would not be patentable, methods for their production and uses of the varieties would be. However, one Commission spokesperson admits that the wording is so vague that it is unlikely to survive.

Microbiological processes—already patentable in most European countries—would be consistently defined throughout the EC to cover not only processes carried out with microorganisms but also processes performed upon them or which result in their production. Any human intervention beyond the selection of an available biological material can become the basis for patentability.

In line with current EPO practice, to "ensure that the necessary investment and research are undertaken," the Commission would allow patents on biological substances even if they are a component of already known natural material—pointing to the considerable difference between a substance in its unseparated, natural form and after isolation.

Many of the proposals consider the problems raised by self-replicating biological material. Purposefully replicating such material to improve it would be freely allowed on an experimental basis, but not commercially (unless the sale and intended use of the material entails its replication). Thus, barley could be grown from purchased patented seeds and beer could be produced with it and sold without royalty payments, but seeds could not be gathered from the barley for resowing without infringing the patent. Nor would it be permissible to import such second generation seeds that had been grown in a country where the plant was not patented.

Plant varieties will still fall under the plant breeders' rights schemes that exist in most EC countries, but the Commission does not believe these provide sufficient incentives or protection. Thus, it proposes that when patented material, such as a DNA sequence, is incorporated into a plant, the patent should remain in force despite the fact that the newly-created plant variety will have separate protection—thereby opening the way to patent transgenic plants (such as those containing an insect-resistant gene). Transgenic animals will also receive protection.

Also, arguing that it is in the public interest to maintain "a reasonable limitation of exclusive rights" in the agricultural sector, the Commission suggests that plant breeders' rights take priority over patent holders' rights in cases of new varieties that both contain patented material and represent "significant technical progress." Disputes about what constitutes significance and the royalties allowed the patent holder in such cases will remain for the court to settle.

Because it is difficult to establish infringement with self-replicating material that is available via a depository, the proposed measures would also reverse the burden of proof and make the user establish noninfringement.

Considerable debate still remains: Both the European Council and the European Parliament must still consider the proposals, and either body may suggest redrafting. The Council must then issue a directive compelling member states to adopt new legislation by a certain date. With unbridled optimism, the Commission declares this should be by the end of 1990.

—Peter Newmark