

REGULATION

BIOTECHNOLOGY PATENT REFORMS IN THE WORKS

WASHINGTON, D.C.—As deliberations on patent reform resumed recently in Congress, biotechnology's two trade organizations began pressing for key changes aimed at keeping U.S. industry competitive in the international arena. Meanwhile, the U.S. Patent and Trademark Office (PTO), besides trying to build a staff conversant with biotechnology, soon will propose reforms of its own to address uncertainties raised by the new technology.

The Industrial Biotechnology Association (IBA) and the Association of Biotechnology Companies (ABC), both located here, are urging Congress to strengthen and extend U.S. patent law. The two key areas, according to IBA director of government relations Lisa Raines, are patent term restoration for agricultural products and extending process patent protection to products manufactured abroad.

More than half of all U.S. biotechnology patents now being granted cover production processes rather than the products themselves. But a loophole in current U.S. law extends no protection to holders of such process patents when the products are manufactured abroad and then imported. Thus, for example, a patented process can be used with impunity outside the U.S. to make a particular product, which then may be sold below a fair market price when imported—a particular sore spot for small biotechnology firms. "Foreign manufacturers can now pirate U.S. technology without fear of lawsuits, giving them a considerable economic advantage," Raines says. "However, both Japan and Europe provide process protection."

The biotechnology community also is seeking patent term restoration for agricultural products, many of which are subject to extended premarket regulatory review. The aim here is to lengthen the period of actual patent protection by making up for the time lag after a patent issues but before the product is approved for sale. Such reform was instituted in 1984 for human pharmaceutical products.

According to Raines, several bills are pending in the House of Representatives and the Senate that address these issues. Process patent reform may be incorporated into the Omnibus Trade Bill (HR. 1155 and S. 539) now under consideration. Provisions for extending the patent lifetime of agricultural products have been linked as amendments to the Federal

Biotechnology Staff and Workload Trends in the U.S. Patent and Trademark Office

	As of Jan. '87	As of Jan. '86	As of Jan. '85
Examiners	31	32	28
Pending Applications			
• New (not yet acted on)	3307	3155	2202
• Tentatively rejected	1879	2173	1529
• Amended	651	445	172
TOTAL	5837	5773	3903
Total Completed (granted or abandoned in previous year)	2044	1573	1171
Approved Applications (previous year)	816	712	556
Percent Approved	40%	45.3%	47.5%

Source: Charles Van Horn, U.S. Patent and Trademark Office

Insecticide Fungicide and Rodenticide Act, but "it is not clear whether that will continue," she notes.

According to David Beier, a staff member of the House Committee on the Judiciary who spoke at a recent ABC meeting, passage of some reforms "is likely." However, differences in strategy between the House and Senate will need to be reconciled. Moreover, some reforms for harmonizing procedural differences between U.S. and other patent agencies—including Canada, Europe, and Japan—also are being considered.

Meanwhile, the past several years have seen considerable expansion in the activity of PTO's biotechnology group, directed by Charles Van Horn (see Table). Efforts now are underway at PTO to clarify if and when

applicants for patents must deposit microorganisms or cell lines. Many inventors routinely deposit strains in centralized facilities, such as those provided in Rockville, MD, by the American Type Culture Collection. However, some companies resist doing so, arguing that written descriptions of experimental procedures are sufficient to describe their work for "those skilled in the art," thus fulfilling patent law stipulations. Some researchers also argue that legal requirements are satisfied if, say, monoclonal antibodies are supplied even though the cell line from which they derive is withheld. PTO currently disagrees and will soon publish proposed rules on such issues, bringing an opportunity for industry to comment.

—Jeffrey L. Fox

INTELLECTUAL PROPERTY

ANIMALS RULED PATENTABLE

WASHINGTON, D.C.—In April, the U.S. Patent and Trademark Office (PTO) ruled that animals may be patented, thereby extending this protection to virtually anything biological.

The PTO decision revolves around a procedure for making oysters polyploid, which was described in a 1984 patent application from Standish K. Allen, Jonathan A. Chaiton, and Sandra L. Downing of the University of Washington (Seattle). It was rejected originally as "obvious" and also because animals were considered unpatentable. However, PTO's Board of Patent Appeals and Interferences—taking into account the Supreme Court's 1980 ruling on *Diamond v. Chakrabarty* which pertained to microorganisms and PTO's 1985 decision on *Ex parte Hibberd* which extended patent protection to plants—said that because other "man-made" life forms are "non-naturally occurring" they too are eligible for patent protection. The patent application still was reject-

ed, however, as the appeals board agreed that the would-be inventors' claim to polyploid oysters—which are better tasting than the diploid variety—was obvious based on a previous method of making these oysters. This rejection will be appealed in the courts.

Jeffrey Miller, the patent attorney with Seed and Berry (Seattle, WA) who represented the researchers, says that the board's decision "is very significant." By "clearing the way to patent animals, the industry has gained; it means you have the right to exclude others from making and selling your product," he adds.

The decision specifically excludes patenting humans, but it still raises some intriguing possibilities. "Could you patent some aspect of human beings?" asks Robert Benson of the law firm Leydig, Voit & Mayer (Chicago, IL). "Could you patent some *in utero* method of making human beings resistant to future diseases?" —JLF