the importation of a product made abroad by a process that would infringe a U.S. patent.

These criticisms and observations, while not wholly without merit, tend to ignore the limitations in scope of current U.S. biotechnology patent protection. The PTO has relied upon *Durden* in rejecting patent claims to recombinant processes and will probably continue to do so until that case is limited judicially or legislatively. Since the functional nature of crucial process intermediates, namely host cells, is not fully protected by product-patent protection, limiting *Durden* only with respect to biotechnological subject matter should not be viewed as an act of industrial favoritism.

Overruling *Durden* alone by enacting Title I of the act would probably not guarantee adequate patent protection for biotechnology processes. While a U.S. company or university would more readily obtain its patent coverage for biotechnology process under Title I, it would probably be limited to a claim under the Tariff Act's Section 337 or the patent law's Section 271(g) in enforcing its patent against a foreign importer, and both of these statutes have their limitations. Section 337 does not provide for an award of damages caused by infringement. Damages can be recovered under the patent laws, but they can be mitigated by the good faith of the U.S. importer and seller. Title II, which makes the importation or sale of a patented biotechnological material or biotechnological material made by a patented process an act of infringement compensable by damages, does not suffer from these shortcomings.

On the whole, the pending act is probably the best compromise that could have been struck between the need to preserve the standards of patentability under U.S. law and the need to protect the unique nature of biotechnological subject matter by closing the gap in legal protection created by *Durden* and *Amgen*. It would put U.S. patent owners on an equal footing with their overseas competitors. Most importantly, it will provide an additional incentive for U.S. biotechnological research. ///

Healy's strategic plan for NIH faces uncertainty

WASHINGTON, D.C.—The strategic plan for the National Institutes of Health (NIH, Bethesda, MD) was completed recently, but the fate of this much-delayed document remains uncertain. Because the plan's champion, NIH director Bernadine Healy, stepped down at the end of last month, the impact of the plan on NIH is in considerable doubt. In addition to unclear signals about priorities in biomedical research coming from the Clinton administration and as-yet unannounced new leadership for NIH, the plan is being made public at a time when the stagnant NIH budget is undermining efforts at innovative strategizing.

Plan

The plan itself, called "Investment for Humanity: A Strategic Vision for the NIH," is a carefully groomed document that encompasses virtually everything that falls within NIH's collective portfolio. In its 100 or so pages, the plan emphasizes interdisciplinary research, much of it of the type and quality that vanguard university investigators say they are doing. Gene therapy is one example of such research, as it involves experts in molecular biology, biochemistry, and clinical research. Another example is rational drug design, which involves experts in recombinant DNA technology, X-ray crystallography, organic chemistry, and computer modeling.

The plan thus endorses a great deal that the university and industry research communities already cherish, despite the controversies that flared up while it was being prepared. These controversies centered on concerns by researchers that the plan would champion applied research rather than basic research, forcing scientists down corridors that they did not want to go down. More specifically, researchers worried that critical decisions on research directions would come from NIH, instead of the research community.

The NIH plan backs many programs that further the interests of those who work in biotechnology. For example, in the section entitled "Molecular Medicine," the human genome project, understanding the molecular basis of disease, and human gene therapy are described as being among the "highest priorities" at NIH.

In another segment of the strategic plan, entitled "Biotechnology and Bioengineering," NIH claims partial credit for the "tremendous growth and success of the U.S. biotechnology industry." Arguing that current activities "pale in comparison to the discoveries we can expect in the future," the strategic plan identifies four areas for NIH to sponsor research initiatives of "particular promise for commercialization." These include biological response modifiers and monoclonal antibodies, cellular engineering and tissue engineering, transgenic animal models and other animal models, and bioengineering. In other sections, the plan outlines the importance of budget planning for NIH, as well as the need for the research community to give due consideration to the social, economic, and ethical impact of its biomedical research efforts.

Uncertainty

Since the plan was made public, Healy has presented it in meetings to various scientific societies and to leaders from interested industry groups. However, observers within NIH and outside the institutes wonder whether her efforts to fortify support for the plan have come too late. They also are dubious about whether the plan's precepts have taken root among enough of the institute directors, who have continued to implement policies at NIH since Healy's departure.

Perhaps more fundamentally damaging, some observers question what the plan really embodies beyond the gloss of its general recommendations. "It seems a compendium of everything NIH does," says one skeptic. And since the plan contains little or nothing in the way of specific funding priorities, this skeptic asks "why is it strategic, and how is it a plan?" —**Jeffrey L. Fox**

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