ENERGY RESEARCH

Deep Cuts Put Heat on Fusion, Labs

Republican leaders in Congress have not yet carried out their promise to kill off the Department of Energy (DOE), but they are starving some of its programs. Last week, a House and Senate conference committee agreed on some $300 million in cuts to the department's 1996 budget. As a result, Energy Secretary Hazel O'Leary will be forced to throttle back immediately on fusion research, hasten efforts to cut spending at DOE's larger laboratories, and think about selling off some of its smaller labs.

The energy and water appropriations bill, which President Bill Clinton is expected to sign once it clears both houses, makes deep cuts in both basic science and technology programs. (Additional cuts to DOE fossil-fuel programs are contained in another spending bill still pending.) Foremost among those is a 33% reduction in the fusion program—a move that O'Leary says is "myopic." However, O'Leary told *Science* she will avoid "blaming Congress" and instead focus on reforming the $18-billion-a-year department.

O'Leary says she's committed to saving $1.6 billion at in-house labs over the next 5 years—$200 million more than an earlier plan—by laying off workers and cutting red tape. Last week, a board created by the secretary to advise her on laboratory operations issued a report applauding the fiscal steps being taken by three labs—the National Renewable Energy Laboratory in Colorado, the Pacific Northwest Laboratory in Washington, and Los Alamos National Laboratory in New Mexico. But the board notes that other labs are dragging their feet. Brookhaven National Laboratory in New York and the Stanford Linear Accelerator Center, for example, have come up with only 0.2% in savings over 5 years, while Pacific Northwest plans to trim its budget by 10%, or more than $285 million. "Some labs have not got the ethic or have not begun their work," complained O'Leary.

While the larger labs will not be closed, some of their smaller cousins may be jettisoned, according to DOE sources. Two fossil-fuel technology labs in West Virginia and Pennsylvania along with a petroleum research facility in Oklahoma are likely targets for privatization, says Dan Reicher, DOE acting assistant secretary for policy, who is leading the department's privatization push. As many as eight to 10 of the smaller labs will be sold, he predicts, assuming that congressional delegations don't block the way.

In the meantime, DOE managers are struggling with the immediate problem of an unraveling magnetic fusion program. Even $15 million tacked on at the last minute to benefit the Princeton Plasma Physics Laboratory isn't enough to salvage DOE's vision of a commercial fusion reactor within the next 25 years, says O'Leary. The new budget may also be the nail in the coffin for the proposed Tokamak Physics Experiment at Princeton. "To my mind, that's a very sad day," she added.

The cut in the DOE fusion budget, from $368 million to $244 million, prompted O'Leary to cancel plans to have an outside task force offer advice on how to reshape the program. Instead, DOE officials will begin restricting the flow of funds immediately. "We don't have time to set up a task force," says one. "We've got to slow our burn rate now."

–Andrew Lawler

PATENTS

New Biotech Law Shores Up U.S. Firms

Patents are designed to protect companies that have come up with a novel product or have used a novel process to make it. But the bread-and-butter business of biotechnology companies often doesn't meet either criterion: They frequently use common genetic engineering techniques to produce naturally-occurring proteins. This week, however, President Clinton signed a law that could make it easier to patent some of these standard processes.

The bill, sponsored by Senators Edward Kennedy (D–MA) and Orrin Hatch (R–UT), sailed through Congress this year after a similar measure that also included chemical and pharmaceutical companies had bogged down last year in the House. It amends a section of the U.S. Code on patents by adding language that says that a familiar biotechnological process—using an organism or cell line to express a foreign gene, for example—can be considered novel if it uses or produces a novel material. In the past, companies have been able to patent genes or cell lines, but they haven't always been able to patent the entire process of using a particular gene in a particular cell line to produce a product. The new law will make that easier.

"It's tying the product to the process" by making the process patentable when it's used for a specific purpose, says David Beier, vice president of public policy for Genentech Inc. Biotech companies have been pushing for the law for years. "Process protection is more important for biotech than for any other industry because the end product, a protein, is frequently already patented or has been cited in a journal," Beier says.

The new law is designed to counteract a 1985 decision by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. The ruling, known as *In Re Durden*, involved a chemical process used to make compounds called oximes. The court said that even if a process uses or produces a novel material, it is not patentable if the outcome is obvious.

The ruling was a major blow to U.S. biotech companies, which often use processes that produce predictable results—inserting a gene into a cell line to produce a protein, for example. The *Durden* ruling conflicts with other decisions by the same appellate court, robbing U.S. patent examiners of clear guidelines. "Some patent examiners are more likely to give you those patents than others," says Lisa Raines, vice president for government relations at Genzyme Inc.

What stirred biotech companies into action, however, was the experience of Amgen Inc., with erythropoietin (EPO). Amgen discovered in the early 1980s how to apply recombinant techniques to make EPO, a natural hormone that stimulates red blood cell production and is used to treat kidney disease. Amgen had patents on the EPO gene and the genetically engineered host cell in which the gene is inserted, but U.S. patent law doesn't prevent foreign firms from making unpatented proteins and exporting them to the United States.

When the Japanese company Chugai Pharmaceutical obtained the necessary starting materials from another U.S. firm and used them to make EPO, the company was legally free to import the hormone into the United States. The U.S. firm had infringed patent law by producing the gene and cell line, a court ruled, but Chugai had not, because U.S. law doesn't bar the importation of products—generic drugs, for example—made with starting materials patented in the United States. As it turned out, Chugai's drug never reached the market because Amgen received a 7-year exemption from competition because the drug treated a rare disease. But the case "alerted the rest of the industry" to its vulnerability, Raines says. If the new law had been in effect, Amgen would have had more protection because it could have more easily patented the EPO production process, and that would have prevented Chugai from exporting its EPO to the United States.

Although the law won't help Amgen, it could have a dramatic effect on future products, Raines says. "It's an insurance policy," she says.

–Jocelyn Kaiser