Dole Blasts HEW for "Stonewalling" Patent Applications

Senator Robert Dole (R-Kan.) has accused the Department of Health, Education and Welfare (HEW) of deliberately suppressing the development of biomedical technology in an ill-considered attempt to curb the rising cost of health care. By reversing its longstanding policy of permitting universities to collaborate with the private sector, Dole charged, HEW has effectively destroyed the process by which research breakthroughs are transferred from the laboratory to the public.

Dole said that in the last year, HEW's Office of General Counsel has "stonewalled" 29 requests from universities for ownership rights to medical breakthroughs developed with NIH support, including potential advances in diagnosing and treating cancer, arthritis, hepatitis, and muscular dystrophy. In each case, the university's request was endorsed by its sponsoring institute within NIH, Dole said, and in 13 cases, private firms had offered to develop the product.

"HEW's decision to effectively suppress these medical breakthroughs is without precedent and is so unconscionable that I feel they are properly called horror stories," Dole said. "Rarely have we witnessed a more hideous example of overmanagement by the bureaucracy."

To support his charge that HEW is "lashing out at medical science out of a sense of frustration about the cost of health care," Dole quoted a passage from an internal memorandum of HEW general counsel:

> Historically, the objectives of our patent policies have been to make inventions developed with government funding available to the public as rapidly and as cheaply as possible, goals which are sometimes incompatible. While these objectives are basically sound, recent experience with the high cost of proliferating health care technology stances in which the Department would wish to restrain or regulate the availability and cost of inventions made with HEW support, sometimes encouraging rapid, low cost availability, at other times restraining or regulating availability.

HEW established its policy of allowing nonprofit institutions to retain ownership rights to discoveries made with government funding 10 years ago, in response to a 1968 General Accounting Office (GAO) investigation of NIH pharmaceutical programs. Despite the hundreds of millions of dollars spent on government-sponsored drug research, GAO found no evidence of any drugs developed with NIH support ever reaching the public. GAO blamed the poor record of "technology transfer" on HEW's practice of retaining all rights to inventions.

To encourage commercialization of discoveries made by its grantees, HEW agreed to give ownership rights to the university where the research was conducted, allowing it to apply for patent rights and to license private companies to develop and market the products. Petitions for invention rights were reviewed by the sponsoring NIH institute (e.g., the National Cancer Institute in cooperation with HEW patent counsel), whose recommendations were forwarded to the assistant secretary of health for final approval.

A year ago, however, HEW decided to have all petitions for ownership rights reviewed by its Office of General Counsel. Last May, staff of Senator Gaylord Nelson's (D-Wis.) monopoly and anticompetitive activities subcommittee reported that HEW had stopped processing the applications altogether. Nelson and Dole were both told that all patent matters were being deferred, pending completion of an overall review of patent policy within HEW. (Institutions that ent arrangements with HEW, known as institutional patent agreements or IPAs, were not affected by the review.)

HEW has been flustered by the attacks on its patent policy. According to Barry Walker, HEW Office of General Counsel, Dole's accusations are simply not true. "We've added an additional layer of review within the general counsel's office," Walker told *BioScience*, "but there's no policy change implicit in that. We're just taking a closer look at things that used to go through routinely." This has produced "an administrative bottleneck," Walker concedes, but the "logjam" is now being broken. "I've been coming in weekends trying to get these things done," he added.

HEW patent counsel, however, say that Dole's charges are not only "substantially correct" but also "correct in most of the particulars."

"There is no real review of patent policy going on," one lawyer explained. "In deciding to 'study' the problem, they essentially made a policy decision to hold up approval for inventions they thought would result in more costly technology. No one has worked on [ownership applications] for months, much less come in on weekends."

In the meantime, Dole has asked GAO to begin a "full-scale investigation" of HEW's medical technology transfer program. Dole said he also plans to introduce a bill to establish a federal patent policy giving universities and small businesses the right to patent inventions developed with government funds. He has already introduced an amendment that would relieve HEW's Office of General Counsel of responsibility for administering patents; patent matters would be handled by the Office of Health Technology proposed in Senator Edward Kennedy's (D-Mass.) bill establishing the National Institutes of Health Care

A Longstanding Debate

Dole's actions are only the latest incident in a government-wide debate over who should own the rights to inventions developed with government money. The question arose more than 30 years ago during the postwar boom, when the government began pouring tax dollars into university research. In recent years, the debate has gained heat but shed little light, according to NSF General Counsel Charles Herz.

"The ongoing debate over government patent policy is a thicket a prudent man hesitates to enter," Herz told Nelson's monopoly subcommittee. "In that debate reasonable men can and do espouse remarkably diverse and divergent approaches, often heatedly, with equal and great conviction. Perhaps the difficulty is that much of the debate has the character of philosophizing in a vacuum."

Nelson is apparently undaunted by the thicket. His monopoly subcommittee began a two-year study of patent policy last December and has kept doggedly at it. The hearings have conformed rather precisely to Herz' characterization. Supported by a bizarre coalition consisting of Ralph Nader, Senator Russell Long (D-La.), Admiral Hyman Rickover, and the Justice Department's Antitrust Division, Nelson insists that the American public is being "robbed blind" by university inventors acting in "collusion" with private industry.

"The American taxpayers are dealt a one-two punch," Nelson contends. "First they are forced to pay through the nose for this risk-free, tax-supported research and development. Then they pay dearly all over again, for the grossly inflated prices these companies charge for the products they market under the patent rights given to them by the government."

On the other side, representatives from universities and from the federal agencies that sponsor their research argue that, without the incentive of patent protection, many useful discoveries would never reach the public at all. "When that happens, it is the public which suffers the greatest harm," explains Thomas Jones, vice president for research at the Massachusetts Institute of Technology.

Testifying before the monopoly subcommittee on behalf of six university associations, Jones said that it can cost "ten times, a hundred times, or even a thousand times more to transfer a basic, university-generated invention to the marketplace than it did initially to invent it." Since there is tremendous risk that the investment of time and money will never pay off, Jones explained, industry is understandably reluctant to make the effort without the assurance of patent protection.

Current federal patent policy varies from one agency to another. The Department of Energy, for example, holds statutory "title" to the results of research it has paid for, but is allowed to waive its patent rights in favor of the university that conducted the research. NASA, on the other hand, retains all rights to inventions developed under its aegis, but tries to license their development to private firms. HEW and NSF deal with patent rights in two ways: universities may apply for rights to patent on a case-by-case basis, or they may apply for an institutional patent agreement.

Under the HEW and NSF IPAs, the university automatically receives ownership rights on research it conducts with support from the respective agencies. To qualify for an IPA, the institution must show that it operates an effective technology transfer program. At last count, 72 institutions held IPAs with HEW and 19 with NSF.

Last February, the General Services Administration (GSA) published a newly worded, uniform IPA, which could be used by all federal agencies that were not required by law to retain patent rights. GSA said the new IPA regulations were "permissive"—no agency was required to enter into IPAs with its grantees against its better judgment. For agencies that did elect to use IPAs, the new form would prevail, effective 20 March.

At the last minute, Ralph Nader and associate Sidney Wolfe publicly protested that the "new" GSA policy would allow institutions to "reap hundreds of millions of dollars of profits from work supported by the federal government" in the next ten years. Taking his cue, Senator Nelson complained to the Office of Management and Budget that the GSA rules should be held up until his subcommittee had time to hold hearings on the issue. At OMB's request, the effective date of the GSA rules was delayed for 120 days.

Nelson held several days of hearings on the IPAs, but was unable to come up with a cogent argument to block the regulations. Testimony from various witnesses established that the income from patent royalties of all universities was no more than $9 million a year. Universities holding NSF IPAs reported a total royalty income of $5,000 for 1978, while the HEW stable showed a gross royalty of $765,293.02. Moreover, the universities were required to use all net royalty income to support further research and education.

Far from reaping windfall profits, MIT's Jones contended, most universities' licensing programs operate consistently in the red. Ironically, MIT has proved an exception to this rule, ever since Jay Forrester developed the magnetic core memory for computers. The invention was developed through government funding; the government received a royalty-free right and license, and MIT got a lump sum royalty payment of $13 million from IBM.

Nelson's staff worries that recombinant DNA technology may prove to be an even greater bonanza than the computer memory core. In fact, several congressional committees have harbored vague suspicions that there is something improper about researchers Herbert Boyer and Stanley Cohen having a financial interest in the development of their discoveries. Nonetheless, after a lengthy analysis, NIH Director Donald Fredrickson ruled that recombinant DNA technology could be handled through normal IPA procedures (see April *BioScience*, p. 290).

Proposed Legislation

Despite all the sound and the fury about IPAs, the GSA regulations went into effect on 18 July. In fact, the Nelson hearings may have been much ado about nothing, since the GSA regulations do not attempt to resolve the basic question of who shall have patent rights.

The bill Dole plans to introduce in mid-September is a compromise measure, providing incentive for private development while protecting the government's financial interests. According to the draft version of the bill released last month, nonprofit organizations and small businesses would automatically retain ownership of inventions they developed through government grants or contracts. The government would be entitled to a share in the profits, however, if the research institute makes more than $250,000 in net income from licensing the invention or more than $2 million in sales. The government would be allowed to keep up to 50% of the profits, not to exceed the amount it spent in grant or contract support.

—Nancy K. Eskridge