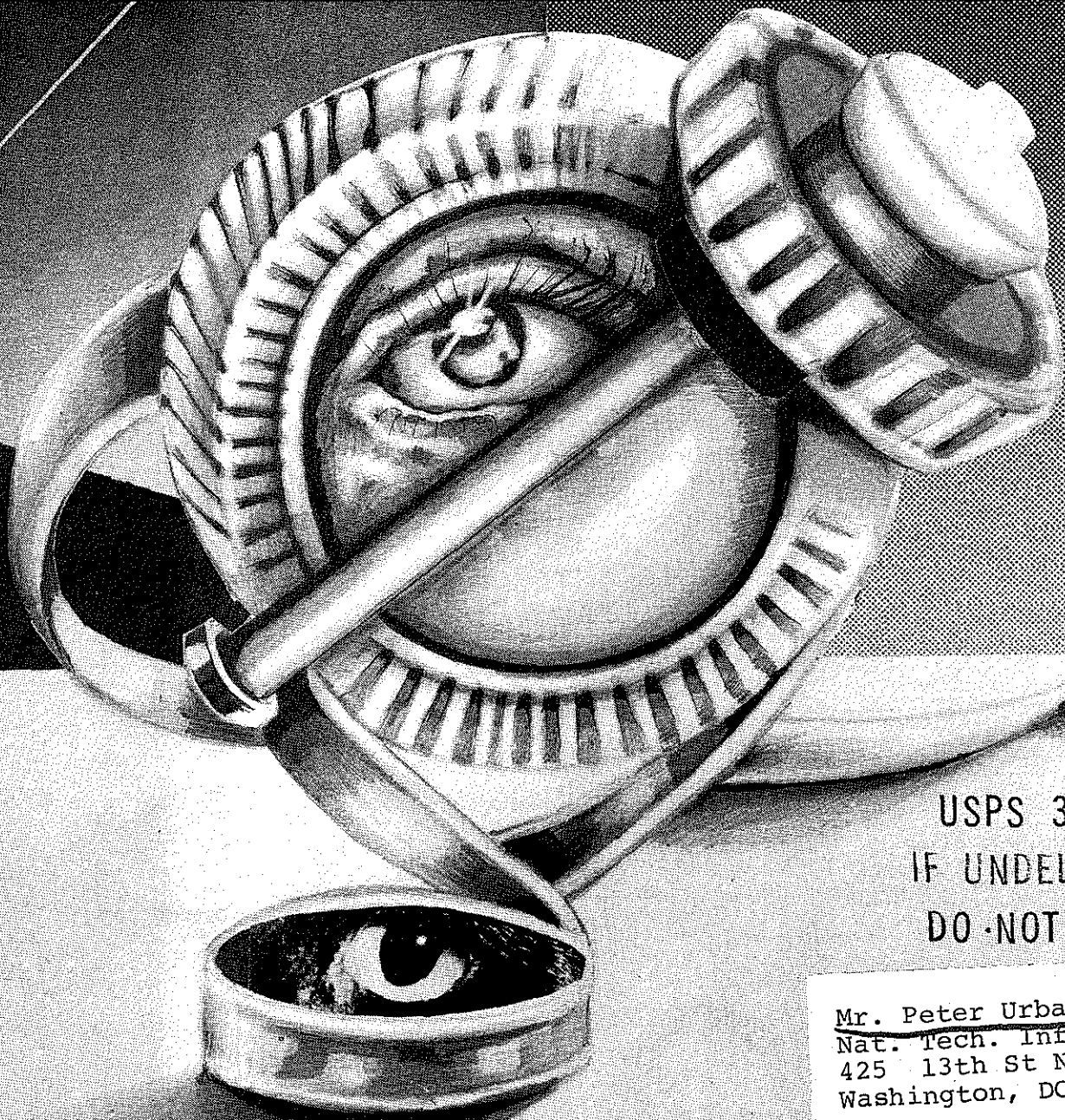


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Sen. Robert Dole

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By Barbara Reynolds

WASHINGTON - In laboratories half a world apart, two government-funded scientists have developed cancer-fighting techniques that might revolutionize cancer treatment.

But for nearly two years these developments, and scores of others, have been caught in a bottleneck within the U.S. Department of Health, Education, and Welfare.

THE REASON IS a dispute over whether universities and foundations or the federal government should retain patent rights on such innovations. The controversy has delayed the clinical testing of the discoveries by pharmaceutical firms, which eventually would market them.

At the Weilmann Institute in Israel, Dr. Michael Sela - the research organization's president - invented an early-detection blood test for breast and digestive-tract

Patent squabble stalls progress

cancer.

At the University of Arizona, Dr. Sydney Salmon discovered a simple lab test that could be performed in test tubes rather than on humans. The test could eliminate painful, ineffective drugs.

WHILE THE DEBATE continues over the issue, some of the inventions have become little more than curiosities in scientists' notebooks.

For example, Sela petitioned HEW in November, 1977, for rights to his discovery so that patent protection could be transferred to a private company interested in testing and marketing it.

After several months of silence from HEW, the pharmaceutical firm lost interest. Companies will not invest the millions needed to perfect an invention and bring it through HEW's Food and Drug Administration for clearance without a limited patent to protect against competitor copying.

INVESTIGATORS IN THE office of Sen. Robert Dole, R-Kan., where complaints about the delays have been collected, said Sela also has lost interest, and any possible breakthrough in cancer diagnosis has disappeared.

Sheridan Neimark, counsel to Yeda, the commercial arm of the Weizmann Institute, said: "HEW is operating on the foolish notion that by giving up patent rights, they are giving away government money. If they don't give them up, they are actually losing money, since the research projects soon become worthless and forgotten."

"The tragedy is that Dr. Sela might have something that could have saved thousands

of lives. However, because of government blindness, maybe thousands might die, who knows?"

Salmon's invention is in the same state. **"IF SOMETHING ISN'T** done," Salmon said, "I don't think any commercial company will be interested. My invention will just languish. It's hard to explain how frustrating all this is."

At HEW, officials gave various explanations for the delay.

A spokesman for the National Institute of Health said it is studying HEW policy to determine whether patent rights should remain with anyone other than the government.

The NIH is a part of HEW and is the principal biomedical research agency of the federal government. There are 11 institutes under NIH, all named after diseases, such as the National Cancer Institute. With a current budget of \$2.8 billion, it supports 40 percent of the nation's medical research.

Privately, some scientists within HEW are condemning the policy of holding up patent rights. One scientist blamed HEW lawyers rather than scientists.

"THEY ARE THE NEW breed of bookburners who think resisting new technology, they can bring down rising health costs," he says.

One HEW official said, "The tragedy is that all these scientists want to do is get on with their work. They don't have lobbyists. They don't know what the hell is going on in Washington. They are scientists, not politicians, and this issue is riddled with politics."

Whether the issue is more political than scientific or, possibly, profit-oriented, is unclear. However, pressure often eases the logjam.

AT A PRESS conference, Dole accused HEW of suppressing critical lifesaving drugs and medical devices, and destroying new medical technology in an attempt to hold down the cost of medical care.

"HEW has decided to pull the plug on development of biomedical research," Dole charged. "They have decided to withhold potential cures and revolutionary new diagnostic techniques for treating such diseases as cancer, arthritis, hepatitis and emphysema."

The day after the press conference, HEW secretary Joseph Califano ordered the stalled inventions released. "Some are still being held, but we were told to get a lot of them out in a hurry," an HEW official said.

For nearly 10 years, HEW had relinquished temporary ownership of inventions to foster their commercial use. It began this policy in 1968 after the General Accounting Office (GAO) could find no evidence of a single pharmaceutical developed with NIH support ever reaching the public. A GAO report concluded that HEW's retention of all right to inventions was the primary reason.

Researchers new cry: Patent or Perish

vitamin D was the eye opener.

Massachusetts Institute of Technology, the University of Illinois, Stanford, and Cornell University have been in the forefront of those recognizing how important patents can be to a university, both financially and as an incentive to the scientific faculty to seek practical innovations.

Stanford recently revealed that since 1970, its office of technology and licensing has distributed more than \$750,000 to faculty members from the proceeds of patent licenses.

THEODORE WOOD, manager of Cornell's department of patents and licensing, said Cornell has received more than \$1 million in patent licensing fees over the last nine years. Of this, \$768,000 went to faculty members or departments. The rest covered operating costs of Wood's office.

Since 1976, Cornell has handled its own patent moneys. Before that they were

handled by Research Corp. in New York City, which represents 300 universities and similar institutions on patent matters. The fact that this corporation has so many clients shows how extensive the change has been in the university faculty attitude toward patents.

It was not just the money that changed the professors' minds. They discovered that letting their research findings go directly into the public domain appeared to be the surest way to stifle them instead of encouraging their development into useful, marketable products.

Cornell's Wood said the biggest spur to this change of mind was testimony by officials of the federal Labor and Commerce departments and the Department of Health, Education, and Welfare that very few firms are willing to try to develop products without strong patent protection. They consider it much too difficult to make sustained profits from something that anyone can pick up and duplicate.