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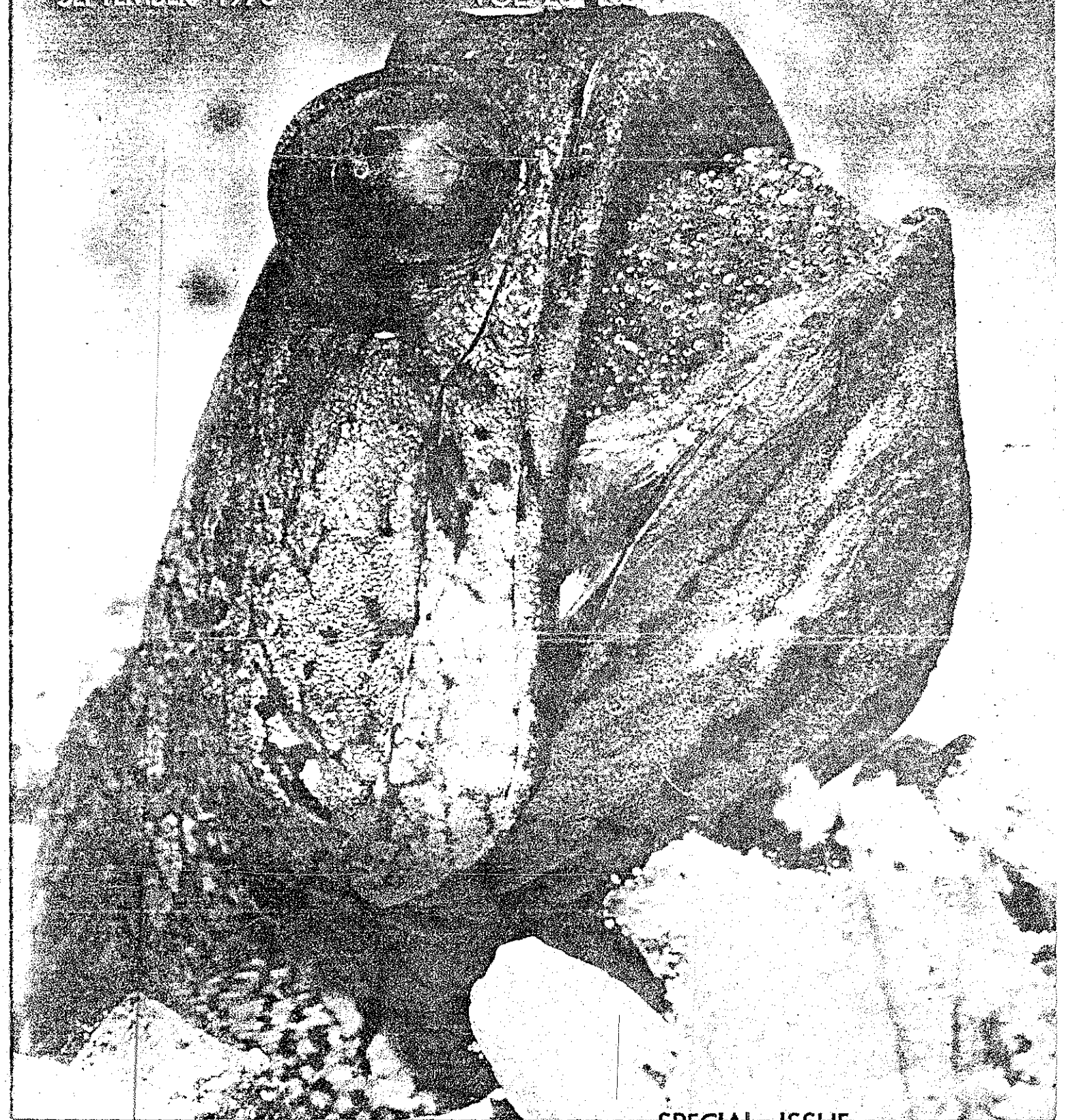

SPECIAL ISSUE

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

Controversial Bill on Patent Policy Gains Support of Accounting Office

WASHINGTON

The General Accounting Office has thrown its support behind a controversial bill to provide uniform patent protection for government-financed inventions.

The measure, S 414, was introduced in February by Senators Birch Bayh, Democrat of Indiana, and Robert J. Dole, Republican of Kansas. Their bill would allow small businesses, universities, and other non-profit organizations to obtain limited patent protection on discoveries made by employees working under government-financed contracts and grants.

Although many consumer advocates have argued that such discoveries ought to be the property of the government, Senators Dole and Bayh maintain that when the government retains patent rights on inventions, there is "a very great chance that they will never be developed."

Of the 30,000 patents that the government now holds, fewer than 4 per cent have ever received licenses, according to officials. Licensing is a procedure on which investors insist before they will put money behind inventions.

"We believe a clear legislative statement of uniform, government-wide patent policy is long overdue," said Elmer B. Staats, the U. S. Comptroller General, in testimony before Mr. Bayh's Subcommittee on the Constitution, part of the Senate Judiciary Committee.

Moreover, Mr. Staats said, even when federal agencies have tried to turn over patent rights to individual researchers or institutions, the delays in getting the rights transferred have been long and costly.

No Uniform Policy

Although the federal government now supports an estimated two-thirds of all research in the United States, it has never established a uniform patent policy for the inventions that result.

Various agencies have different patent arrangements.

They range from exclusive agreements that give inventors and research institutions the first option on all new inventions to policies that almost automatically turn over inventions to anyone who wants to develop them.

In recent years, however, even agencies with liberal policies have begun to adopt more stringent ones, Mr. Staats said.

He said he hoped "an easing of the red tape leading to determinations of rights in inventions would bring about an improvement of this record." Mr. Staats said he based his comments on a review of the current patent procedures at several selected agencies, including the Department of Health, Education, and Welfare, the National Science Foundation, the Department of Energy, and the Department of Defense.

Details of that review are scheduled to be released in June.

Although the Comptroller General said he viewed the Bayh-Dole measure as a solution to many problems, he had some reservations about the bill.

Under its provisions, the accounting office would be required to report each year to the Committee on the Judiciary on how well federal agencies were carrying out the act.

Mr. Staats said that would not be feasible unless his agency were given adequate funds to oversee the patent activities.

Senator Bayh indicated, however, that the bill could be modified to provide the funds the G.A.O. needed.

A measure similar to the Bayh-Dole bill, HR 2414, has been introduced in the House of Representatives by the chairman of the House Committee on the Judiciary, Rep. Peter W. Rodino, Jr., Democrat of New Jersey. —ANNE C. ROARK

Higher-Education Bills in Congress

WASHINGTON

Following is a summary of bills of interest to higher education that have been introduced in Congress. Copies of bills may be obtained from Senators (Washington 20510) or Representatives (Washington 20515).

SENATE

S 927—Smithsonian. To authorize the Smithsonian Institution to plan for the development of the area south of the original Smithsonian Institution Building. By Senator Jackson (D-Wash.) and two others.

S 1048—Aquarium. To designate an aquarium to be built in Baltimore as the "National Aquarium." By Senators Mathias (R-Md.) and Sarbanes (D-Md.).

S 1050—Taxes. To permit a taxpayer to claim an income tax credit for amounts paid as tuition and fees to provide a higher educa-

S 1051—Taxes. To provide a federal income-tax credit for certain educational expenses. By Senator Roth (R-Del.).

S 1095—Taxes. To provide a federal income-tax credit for tuition. By Senator Packwood (R-Ore.) and three others.

S 1099—Health professions. To provide for increases in the amount of the monthly stipend paid to participants in the Armed Forces Health Professions scholarship program. By Senator Thurmond (R-S.C.).

S 1107—Wages. To encourage youth opportunity by extending the sub-minimum wage enjoyed by full-time students to all persons between the ages of 16 and 20. By Senator Stevenson (D-Ill.).

S J Res 62—Museums. To declare May 18, 1974, to be "National Museum Day." By Senator Pell (D-R.I.).

HOUSE OF REPRESENTATIVES

HR 3416—Health professions. To provide for unbiased consideration of applicants to fed-

Education Act of 1965 to provide for a National Student Financial Assistance Data Bank. By Representative Biaggi (D-N.Y.).

HR 3529—Curriculum. To amend the General Education Provisions Act to prevent the use of federal controls over curriculum. By Representative Martin (R-N.C.).

HR 3537—Young people. To establish a Congressional award program for the purpose of recognizing excellence and leadership among young people. By Representative Natcher (D-Ky.).

HR 3769—Student loans. To amend the Higher Education Act of 1965 to raise the limits on insured loans for certain postsecondary students; to make such loans easier to obtain and repay; to assure greater certainty of loans as a reasonable portion of students' total need-based assistance or cost of attendance; to reduce the cost of insured loans to the federal government; to expand and integrate the role of state guarantee agencies as loan consolidators, loan serv-

Status

As of 5 p.m. on May 23
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ACTION REAUTHORIZATION (S
Senate bills would reauthorize
federal volunteer agency throug
Administration request to end th
also extend the "University Ye
which provides funds for college s
areas for 12 months.

DEPARTMENT OF EDUCATIO
bills would create a Cabinet-level
They would consolidate, under a
programs from the Education Div
Health, Education, and Welfare,
programs for nursing and othe
education-related activities of th
and certain science-education
Science Foundation. The Senate
vocational-rehabilitation prog

GOVERNMENT ETHICS (HR
clarify sections of the Ethi
1978 requiring top-level fed
their income and other financia
flict-of-interest provisions of the
former federal officials be barre
senting" their new employers
before their former federal age
they had been "personally and su
in office. The ban would be for
government.

LOBBYING DISCLOSURE (H
would require any organizatio
$5,000 a quarter or employs a
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General.

NATIONAL SCIENCE FOUND
(S 527, HR 2729). Senate bill wo
billion for the National Science
1980, including $87.7-million for s
House bill would authorize about
tion, including $86.2-million for
ate bill would allocate $175.5-m
biological, behavorial, and socia
bill would allot $158.2-million.

NURSE TRAINING (HR 3633,
bills would authorize $103-millio
tance for nurse-training progra
ize $24-million for enrollment
for nurse practioner and traine
million for student loans and

REGULATORY REFORM (S
bill, S 262, would require regula
economic, health, and safety ef
Agencies would also have to pr
tives to accomplish the goals of
tration bills, S 755 and HR 3263,
propose the most cost-efficient
choice. All three bills would gi
Senate power to veto regulatio

PATENT PROTECTION (S 4
House bills would allow non-pr
businesses to retain title to g
tions for up to eight years. Bo
provisions requiring inventors
reimburse the government for
innovation.

VETERANS' BENEFITS (S
bill S 330 would provide for
Administration decisions, reme
fees for veterans making clai
publish proposals of its reg
introduced as S 870 and HR 32
which certain veterans could u
beyond the current 10-year
eliminate the "85-15" rule,
veterans and other student-ai
rolled in any one class.

FIRST CONCURRENT BUDG
(S Con Res 22, H Con Res 107)
overall ceiling of $532-billion
fiscal year that begins Oct.
million more than the $5.2-bill
ed for higher education.

San Francisco Examiner
Jan. 10, 1979

Attorney fired in dispute over drug patents

Chicago Tribune

WASHINGTON — Norman Latker, a government patent counsel who told Congress that the Department of Health, Education, and Welfare delayed the release of potentially lifesaving drugs to the public, has been fired.

For more than two years, inventions by government-funded scientists have been caught in an HEW bottleneck because of a dispute over whether universities and private firms or the federal government should retain patent rights.

At stake are millions in profits for scientists, universities and drug companies as the drugs — developed under government grants at taxpayer expense — enter the commercial market.

While senators, university officials, and inventors have condemned HEW policy, they have praised Latker, HEW's chief patent counsel, for fighting behind the scenes to release cancer-fighting techniques and other new technology from the department.

Now Latker, 47, is looking for a job after 22 years with the federal government — 15 of them in HEW's patent office.

Latker said he did nothing heroic or outlandish. "The worst thing I could have done as HEW might see it was to tell the truth when I was questioned before Congress. I didn't think anyone would want me to lie."

Latker's superior, however, says he used government personnel, materials, and facilities for personal purposes, and misused the free mailing privilege.

Last June, Latker told a Senate committee hearing that HEW had held up patent rights on inventions developed by scientists with federal funds.

"I didn't think I had any choice but to respond truthfully," he said, "although I avoided interpreting what the holdup meant."

Unless some patent rights are transferred to pharmaceutical firms, the companies will not invest the millions needed for clinical testing and clearance through the Food and Drug Administration for eventual public use.

In August, Sen. Robert Dole, R-Kan., accused HEW of "pulling the plug" on biomedical research in an attempt to hold down medical costs.

Latker also provided information for Dole, which was used to write legislation making it more difficult for HEW to hold onto patent rights.

The day after Dole launched his attack, HEW Secretary Joseph Califano ordered his aides to release some of the patents, which had been delayed as long as two years. However, only half of the 29 patent projects identified by Dole were released.

Once Califano released some of the patents, Latker said, "he went looking for the guy who blew the whistle."

Latker admitted he wasn't hard to find, since he was the only one who had argued with his superiors over the patent policy. He had also been reprimanded for sending out public statements critical of the delay, "although I also sent out public statements that agreed with HEW's decision."

On Nov. 9 his superior, Richard Beattie, asked for his resignation, Latker said. "He really berated me, saying that it boggled his mind that I could criticize the department. He also told me that I should have learned to say 'no.'"

John Blamphin, a press spokesman for HEW, said, "Latker was dismissed for a number of improper activities and not, as he has reportedly claimed, for the disagreements over departmental patent policies, or because of any testimony before Congress, or any disclosure he may have made about the department."

Latker's activities, Blamphin said, included the use for personal purposes of government personnel, materials, and facilities. Blamphin said Latker also mailed non-government material under government frank.

Dr. Ralph Davis, patent manager at Purdue University, said that the firing is not only an issue involving Latker's future, but also the future of lifesaving inventions. "He cared about the public; he cared about people more than policy," Davis said.

According to Dr. Davis, the federal government owns about 28,000 patents, but less than 1,500 have been licensed for commercial use. "What is there to gain by holding on to the rights," he said, "when they don't have the resources to get new products on the market?"

SOCIETY OF UNIVERSITY PATENT ADMINISTRATORS

November 9, 1979

Mr. Stuart E. Eizenstat
Assistant to the President
for Domestic Affairs & Policy
The White House
Washington, D. C. 20500

Dear Mr. Eizenstat:

Our Society and its members were pleased to see the Domestic Policy Review initiated by President Carter in 1978 result in his recent announcement of industrial innovation initiatives. We were particularly pleased to see that in the Fact Sheet which was released through the White House the President specifically supported the retention of patent ownership by universities and small businesses in recognition of their special place in our society.

We have considered that the statement in the Fact Sheet relative to this recognition and support, emphasized as it was by its specific recitation and isolation from the President's decision to seek a uniform government patent policy with exclusive licenses in the field of use, is indicative that the Administration fully supports the University and Small Business Patent Procedures Act, S. 414 and its companion Bill in the House, H. R. 2414. The university community firmly believes that these Bills are a strong and meaningful first step in a government policy which will strongly motivate innovation.

Our one concern with the Fact Sheet pronouncement was that S. 414 and H. R. 2414 were not specifically singled out as the Bills which respond to the President's innovation initiative favoring universities and small businesses. We urge that as the President's advisor on domestic affairs and policy issues you will take steps to clearly and positively endorse S. 414 and H. R. 2414 on behalf of the Administration.

I will be pleased to have your prompt confirmation that the Administration does clearly and positively endorse and support S. 414 and

H. R. 2414 as meaningful innovation initiatives which should be promptly enacted into law so that such information can be immediately disseminated to the Society's membership.

Very truly yours,

Howard W. Bremer

Howard W. Bremer
President

HWB:rw

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

TO : James Hinchman
Assistant General Counsel

DATE: January 9, 1977

FROM : Senior Fellow, NCHSR

SUBJECT: Patent Policy Study

Since I'm leaving town today 'til the end of the week, I have only skimmed the January 5 Report prepared by Norman Latker and am dictating some quick reactions which I probably won't even have a chance to proof-read.

With a few significant exceptions, (see page-by-page comments below) I believe the Report is a basically accurate statement of DHEW's historical approach to patent policy and a justification for its current policy.

But therein lies the rub. As I understand the Secretary's charge, it is to review HEW's patent policy in terms of its current utility to the Department. To do this, I submit that we need to start with DHEW objectives, and while Norman Latker does not state any, the implicit sine qua non of his report is that the patent policy objective is to promote private development of DHEW supported inventions and to minimize the cost of administering patent policy.

To be responsive to the Secretary's request, I would suggest that we need to (1) reach agreement on current objectives; (2) see what options we can develop to respond to those objectives; and (3) consider the tradeoffs involved in each of the options.

In this connection, I would propose that the primary goal is not to promote any and all further private development of HEW supported inventions, but to promote cost-effective development of HEW supported inventions and to discourage trivial and unjustifiably costly innovations. I would also suggest that equity to all-at-interest be an important objective. The addition of such objectives are likely to both increase the options proposed by Latker and to markedly change judgements about the tradeoffs involved. For example, Latker places high stock in minimizing development subsidies and the cost of administering patent policies. But, a comparison of such increased costs with potential reductions of HEW expenditures for Medicare and Medicaid reimbursement may show that these are good investments even though they were not so in the 1960's.

In addition to the above general proposed approach to the Secretary's request, I would suggest that the following inaccuracies and omissions of the Latker Report need to be changed:

Page 3: The Report states that there are "assertions throughout the December 22 Report on Health Technology Management" which deny the difficulties in moving scientific ideas into commercial products. The Technology Management Report has only three statements about patent policy and none of them assert anything about the well-known difficulties of nurturing ideas into end-use products.

Page 15: The Report sets forth the major conditions which are currently attached to IPA's, but does not make it clear that these conditions are complied with in terms of the universities' judgement as opposed to HEW's judgement and oversight. (or did I musunderstand Bernie's comments?)

Page 19: The Report states that the Health Technology Management Study presumes Department ownership of inventions to control their entrance into the marketplace. The Technology Management Study made no such statement; moreover, I personally think that conditions attached to assignment of rights might be a more productive approach if we can be clever enough to come up with such conditions.

Pages 21 - 22: The Report offers five options. It does not offer such options as (1) deferring determination of rights except in those cases where it can be determined in advance that it is in the Department's interest to extend the first option to the grantee or the contractor; (2) a similar exception clause built into the option under which the Department takes title to all inventions; and (3) an option under which HEW continues to grant first option to universities through IPA but defers determination to contractors.

Page 26: The Report states that rights in some cases will be lost due to the failure of the non-profit organization to file patent applications if it has no guarantee of ownership. I would suggest here that times have changed since the IPA policy was developed and the universities are today desperate to obtain research funds; thus, this important problem might be counteracted by the simple device of requiring (as a condition of a grant) that applications be filed when appropriate. Moreover, we might sweeten the pot by adding a small amount of grant funds to cover the relevant associated expenses.

Page 28: The Report states that the December 22 Report on Technology Management will be viewed by some as "thought-control" or "book burning." These are inappropriate red-herring terms which should be deleted.

Sherry Arnstein

cc: David Cooper
Chris Bladen
Norman Latker

COMMENTS OF NORMAN J. LATKER, PATENT COUNSEL, DHEW, ON "LEGAL ANALYSIS OF PUBLIC DISCLOSURE REQUIREMENTS RELEVANT TO APPLICATIONS FOR BIOMEDICAL RESEARCH GRANTS"

By

James H. Wallace, Jr.

Thomas C. Arthur

Outside of a generally adequate review of the relevant laws which may be brought into question by the Congressional charge to this Commission, the resulting analysis and recommendations by the Wallace paper on the policy of managing research information are seriously defective.

Certainly no thinking person can categorically oppose "public participation" or "openness" in the development of public policy in the abstract, especially in the climate created by the abuse of trust by some Government agencies whose need to meet assigned objectives required higher degrees of privacy than available to most Government agencies such as N.I.H. Notwithstanding the need to correct abuses in these situations, it is also clear that if "openness" at the discretion of any person is to be the rule in all situations, some other societal values may well suffer or be defeated. Thus, in every situation where the question of "public participation" arises, the human and economic values to be gained or lost must be objectively evaluated and a determination made on whether the result sought by the program in question is enhanced, unchanged, or defeated by random public participation.

In this regard, the handling of this assignment is a failure in that the paper insists throughout without supporting data that this is a situation between "conflicting interests" requiring a compromise position which appears to be administratively unworkable and impairs the objectives of the program.

From opening to conclusion, the paper repeatedly assumes a need to balance "public participation" and "private deliberations" while shifting the burden of proofs to those who argue that private deliberation should prevail. Substantially, all the arguments supporting "openness" are generalizations based on the belief that the public's right to know (which is erroneously ascribed to be a first amendment guarantee) will necessarily enhance the protection of those human subjects involved in 40% of NIH's research proposals, and that further, the free exchange of scientific ideas (whether supported by clinical evaluation or not), will result in their swiftest development. Whether such generalizations are correct can only be determined when examined against fact.

The Wallace presumption that random public participation is inherently useful is in direct conflict with the following findings of the President's Biomedical Research Panel:

1) "There does not appear to be any direct, necessary, or inherent connection between disclosure of such information and protection of human subjects in research under the present system of Federal regulations and review bodies, nor did testimony before the Panel argue for such full disclosure." (See page 3 of Panel Report.)

2) ". . . uncontrolled disclosure of research information seems to offer neither compelling grounds nor a convincing record that it serves the aim of protecting human subjects of research." (See page 3 of Panel Report.)

But most important, the Panel did conclude on the basis of its study (including review of all requests to DHEW for research proposals) that private deliberation of peer review groups and release at the discretion of investigators of their research proposals and its results clearly outweighed in terms of identifiable human values the need for random public participation.

Thus, the Panel found:

> ". . . clear evidence that the existence of a licensable patent right, which is contingent on protection of intellectual property rights, is a primary factor in the successful transfer of research innovation to industry and the marketplace. In light of the effect of disclosure of research information on intellectual property rights, and in light of the importance of such rights to the transfer of research innovations to the delivery of health care, it is clear that the present mechanism of complete 'openness' ensures public accountability at the cost of sacrificing protection of intellectual property rights of demonstrable potential benefit to the Nation."

Further,

> "The Panel is concerned that the failure to protect and define such right may fatally affect a transfer of a major health innovation. (See pages 8-14 of the Panel's report.)

I support these findings and hope others here today will amplify on how the "public participation" thesis will seriously affect if not defeat the successful technology transfer function developing and carefully nurtured between Government, non-profit organizations, and industry in answering human needs.

Even the Wallace paper makes clear the jeopardy that intellectual property rights are placed in, if before a peer review group that is open to random public scrutiny. I think it should be emphasized that this jeopardy is not removed in situations where public participants chose not to be present at peer review meetings.

The paper's failure to understand the need to assure optimum transfer of innovation from the bench to the patient is illustrated on page 49:

> ". . . a researcher may prefer to develop his commercial ideas with public money, and thus be able to negotiate with private parties only after the utility of his idea has been proven. While this is obviously in the researcher's interest, as it would give him more bargaining power, it is not necessarily in the interest of the public." (Emphasis added.)

This latter sentence requires explanation, since it directly conflicts with the announced intent of the Government's patent policy covering innovations arising from Government sponsored research at non-profit institutions and the need to expedite their utilization and the constitutional intent to promote the arts and sciences through the guarantee by Congress of rights to creators. (See Art. I, Sec. 8.)

While there are many statements in the Wallace paper of a policy and administrative nature which should be equally challenged, time does not permit full analysis. Notwithstanding, I do wish to speak to a few statements with the clear intent of questioning the drafters' objectivity;

1) In support of "public participation" the drafters imply that the possibility of public surveillance is necessary to insure that another "CIA" situation does not occur at NIH (see page 53). No analogy exists. Even after discovery of these alleged abuses, to my knowledge the CIA was not restructured to permit random public participation on CIA advisory groups, since privacy is still an element necessary if CIA is to meet its objectives, just as it is perceived necessary for peer review.

   The analogy with city councils is equally erroneous, since such councils do not ordinarily deal with intellectual property matters as does NIH.

The drafters' implication that NIH's continued world renowned excellence is dependent on the fear of media exposure fails to consider its past performance and is hardly conducive to attracting high-level participation on peer review groups.

2) On page 54 of the paper Wallace indicates that some of the Panel's contentions are "based on its fallacious survey results." How they are "fallacious" is not explained, though on page 51 the paper indicates "while the Panel's survey showed that only three groups interested in protecting human subjects had made FOIA requests, we have been informed that these three requesters accounted for a significant portion of the total requests." (Emphasis added.) The "we have been informed" language seems to imply that Wallace discovered the truth from sources other than the Panel and/or the Government and implies the basis for the "fallacious survey results" comment.

The Panel on page 17 clearly states ". . . the request of one public interest group for appreciable numbers of research applications raises the prospect of large-scale multiple requests under a short deadline for reply." (Emphasis added.)

Further, the same data made available to the Panel by NIH and other information clearly indicating the source and number of requests on human subjects was available to the drafters through the Commission, Panel, and NIH for their review.

The handling of this matter raises the spector of a less than zealous investigator ready to accept the current climate of institutional conspiracy without justification. It is also clear that the drafters made no separate review of the public requests that both the Commission and the Panel were charged to review, but have chosen to critique the position of the Panel on the data without an independent review. Accordingly, if the paper is intended to respond to the Congressional charge of reviewing these requests, it fails.

3) Most important is the paper's misinterpretation of the Panel's recommendation. First, the Panel advised that peer review be a private deliberation. Second, it recommended legislation be passed to protect intellectual property rights. In support of the latter, the Panel discussed at length the Energy Research and Development Agency (ERDA) precedent wherein Congress created an Exemption 3 amendment to ERDA legislation returning to

the ERDA Administrator the authority to protect technical information without regard to the standards or procedures of FOIA (see page 13 of the Panel Report).

The only sensible implication to be drawn from the Panel Report was to amend the PHS Act in a similar manner. The Wallace report touches on this recommendation on page 63 by merely indicating that amending "the Federal patent laws" cannot entirely resolve the problem of protecting intellectual property.

While the Wallace statement is correct, it ignores the clear intent of the Panel to follow the very important ground already plowed by ERDA in Congress in protecting intellectual property rights in similar situations, through amendment of the Agency's implementing statutes.

As noted above, I believe the Wallace recommendation unworkable (as well as unjustified), since the idea portion of a proposal cannot be realistically separated from the totality of the scientific discussion in the proposal and its disposition. The Commission may well wish to examine situations where patentable inventions occurred in order to determine whether it would have been possible to segregate the licensable result from the research proposal at the time the proposal was first received. Further, it is well known that secondary or tertiary leads not presumed to be the idea for which funding is sought may emerge as the real values of a proposal and could be lost through failure to make

appropriate efforts to segregate. If the segregation of ideas is not possible, it serves little purpose to discuss the remainder of the recommendation in detail. However, there can be little doubt that it carries with it a heavy administrative load also unjustified, unless some value is derived from random public access.

My unhappiness with this paper leads me to wonder whether consideration should be given to opening this question -- if this was not done -- to proposals from other legal and scientific scholars with appropriate credentials to speak to this immensely important problem.

DRAFT

To: Julius B. Richmond, M. D.
Assistant Secretary for Health

From: Lowell Harmison, Ph.D.
Science Advisor
Office of Health Policy, Research
and Statistics

Subject: Request by Stanford Research Institute for Rights to Inventions made under Subcontract with NHLBI

It is important to recognize that your concurrence in Mr. Feiner's April 5, 1978 recommendation to deny SRI's request for invention rights to inventions made by SRI in performance of a subcontract with NHLBI would be a precedent-setting decision reversing long standing Department practices.

Mr. Feiner indicates in the last paragraph of his memorandum that:

> "The factual decision as to whether it would be necessary to grant the petition for waiver is yours to make." (Emphasis added)

Accordingly, it is clear that Mr. Feiner's recommendation is one of policy for your decision, rather than law permitting no discretion.

Brief Summary of Facts

Approximately two years ago SRI (April 26, 1976) filed a petition for rights to six inventions which contribute to a combination B-scan and ultrasonic imaging systems which provide simultaneous display of

the B-scan and Doppler information. It is envisioned that the system will be useful in diagnosing cardiovascular diseases in the carotid and femoral arteries and for breast-scan applications.

At the time of the petition SRI advised that they were negotiating a license to the invention rights with Picker Corporation in light of Picker's past and prospective contribution in development of the system. The petition advises that the relationship between the parties began with an earlier program involving Picker development of an SRI acoustic imaging camera. SRI advised that before collaborating with Picker in that case, extensive negotiatons were also held with General Electric and N. V. Philips, with Picker being the only company indicating a desire to proceed. In light of SRI's prior involvement with Picker on this closely related technology, the petitioner indicated that the transition to this collaborative effort was natural.

At the time of the petition SRI advised that "Picker is presently funding the development of the subject imaging system within SRI at the rate of $170,000 per year, and by the end of 1977 (21 months away) will have expended approximately $500,000 in this effort." (Parenthetical clause added) "This does not include the marketing expenditures Picker will make assuming this petition is acted on in a favorable fashion." (Emphasis added)

The petition indicated that by the end of 1977 SRI would have received $680,000 out of $1,800,000 funded by HEW, the balance going to Mayo Clinic for clinical testing of the prototype. In addition, Picker

will have contributed $500,000 in aiding SRI in completing the prototype in addition to future marketing costs.

The petition was reviewed by the Director of NHLBI (the funding Institute) and NCI (who NHLBI indicated had a current interest in the technology). Both Institutes favored the grant of the petition. NHLBI indicated:

> "In view of the investment by Picker Corporation to date, it is appropriate that Picker be granted an initial period of exclusive licensing as requested to assure expeditious completion of the instrument and introduction to the market."

Above is only in slight variance to the facts as set forth in the first paragraph of Mr. Feiner's memorandum, though it is in greater detail in order to enable response to Mr. Feiner's recommendation.

It seems also important to note that SRI is an Institutional Patent Agreement holder, which gives them first option to grant inventions. This suggests that their experience under the IPA because of certainty of rights lead them to seek the collaborative aid known to be needed from industry as early as possible. That is the intent of the IPA and appears to have prompted SRI's action in this case.

Mr. Feiner's April 5, 1978 memorandum

A number of the statements made in the April 5, 1978 memorandum require further amplification before an educated policy decision can be made on this case. Each statement which requires review is quoted and followed with comments.

In the first paragraph:

> "There is no indication that SRI contributed a significant amount of its own."

This statement reduces to zero the value of SRI's past and future inventive contribution to the system or maintaining managerial effort for identifying patentable subject matter, filing patent applications and negotiating collaborative arrangements with industry in order to expedite delivery of inventive results to the public. Even discounting the inventive contributions (though it is clear that SRI did not enter into the contract with an "empty head") and the management costs involved in identifying these inventions and expediting their delivery to the public, the cost of filing and prosecuting the six patent applications involved is calculated to amount to between $12,000 to $18,000. None of these costs have been reimbursed.

In the second paragraph:

> "In this instance the contribution of the Government is clearly not small."

While the grant of the petition in this case is better supported by the test "to call forth the private risk capital necessary to bring the invention to the point of practical application," it seems reasonable to suggest that the $680,000 subcontract cost (not all of which was devoted to making the inventions) is small when compared to the $500,000 Picker contribution and the additional Picker dollars necessary to establish an assembly line to convert the prototype to

a production model which may run many hundreds of thousands of dollars. (The need for additional funds was confirmed by NHLBI, who also advised that work on the prototype would require another six months.)

In the third paragraph:

> "There appears to us to be no clear basis for finding that the waiver of patent rights is necessary to call forth the capital to bring the invention to the point of practical application, that is, to make the inventions' benefits available to the public on more than an experimental basis. The SRI application indicates that the invention may already be at that point and, hence, no grant of greater rights would be necessary. Even if this is not the case, it is not clear that it is necessary to waive the rights to the invention to SRI in order to call forth the risk capital that would be necessary to bring the invention to that point."

First, it is already clear that Picker has expended $500,000 to produce the prototype, and an additional large investment will be necessary to market a production model. The idea that Picker's $500,000 should be viewed as something other than risk capital would suggest that the Department is willing to take advantage of Picker's naivete' in making that investment, while SRI's petition languished in the Department for over two years.

Second, the further suggestion that the Department should take advantage of Picker's involvement without knowing their rights and "hope" that the continued funding will be necessitated because of that involvement will signal future licensees that it is hazardous to expeditiously commit capital to collaborative projects with Department contractors without prior certainty of their rights. This would result in delay of technology transfer and the innovative process.

In the third paragraph:

> "If the Picker Corporation is willing to develop the invention under a limited exclusive license from SRI, it presumably would be willing to do so under a similar license issued by this Department ..."
> (Emphasis added)

As indicated, this is a presumption, and even if correct, eliminates any incentive on the part of SRI in continuing to aid Picker in further development. Further, the suggested procedure implies that the innovative process is static rather than a dynamically changing situation requiring SRI's continued involvement. The changing nature of this particular system was alluded to in both the NHLBI and NCI recommendation to grant the petition.

In the third paragraph:

> "These Regulations (41 CFR 101-4) provide that exclusive licenses may be given for inventions which are not developed under non-exclusive licenses, under a basic

standard that is similar to the standard for greater rights determinations under contracts." (Parenthetical clause added)

The statement fails to note that prior to any grant of such license, the Department must first take title from SRI and make the inventions available for non-exclusive licensing for six months, possibly delaying Picker's involvement (if still interested) for that time period. Further, the memorandum fails to note that the OGC has taken the position that Department granted exclusive licenses must retain the right to sue infringers in the Government. Thus, if the invention is infringed, the licensee must convince the Department of Justice to protect its rights. The Department of Justice has never taken sure action, and because of the state of the law, it is widely believed it will not, prior to legislative clarification. This single point significantly changes the rights obtainable by Picker, through a license from the Department.

More serious in this case is the fact that before the Department could grant an exclusive license through the procedure recommended, it would need to provide public notice which provides to the same competitors that refused to involve themselves in this opportunity when first contacted by SRI the ability to now take advantage of Picker's $500,000 investment. (It seems doubtful that another developer would appear under any circumstances if SRI is unwilling to contribute to the completion of the system.)

The memorandum's suggestion that public notice was not provided in the AS&E case is incorrect. Notice was provided in that case even though not required by the Federal Procurement Regulations, and was the instance that lead directly to the two lawsuits filed by AS&E against the Department for breach of contract.

The fourth paragraph is entirely inaccurate. The Institutes involved have handled numerous petitions from non-profit organizations for ownership of invention rights and are specifically asked whether such petition should be granted. The petition made clear that upon obtaining title SRI would negotiate a license with Picker. The suggestion that SRI's argument is essentially that they assumed that the waiver would be granted and proceeded accordingly ignores their petition, the Institute recommendations and an understanding of technology transfer and the innovative process.

Conclusions

1) Concurrence in Mr. Feiner's recommendations ignores the equities of SRI and Picker.
2) Concurrence would ratify the concept that "risk capital" is only those sums expended after the date of the grant of a petition as opposed to funds expended before the grant.
3) Concurrence would logically require the same action in future cases where a non-profit petitioner was able to persuade, as in this case, a prospective licensee to commit any capital prior to action by the Department.

4) Because the community involved in technology transfer is very small and is already distressed by the implications of the AS&E case, concurrence would negatively affect the environment of give-and-take necessary to the chemistry of technology transfer by creating uncertainty in Department dealings in this area. Past experience indicates that uncertainty of ownership in inventions based on specious policies results in a withdrawal of resources by non-profit organizations in identifying inventions, filing patent applications and seeking licensees.

Lowell Harmison, Ph.D.

cc: Douglas Frye, NHLBI/NIH
Roger Powell, NHLBI/NIH

appropriate efforts to segregate. If the segregation of ideas is not possible, it serves little purpose to discuss the remainder of the recommendation in detail. However, there can be little doubt that it carries with it a heavy administrative load also unjustified, unless some value is derived from random public access.

My unhappiness with this paper leads me to wonder whether consideration should be given to opening this question -- if this was not done -- to proposals from other legal and scientific scholars with appropriate credentials to speak to this immensely important problem.

Vice President for Research
303/491-7194

Colorado State University
Fort Collins, Colorado
80523

PATENT BRANCH, OGC
DHEW

AUG 28 1978

August 22, 1978

Mr. Norman J. Latker
Patent Counsel
Department of Health, Education
and Welfare
Washington, D.C. 20201

Dear Mr. Latker:

I would like to apologize for the error I made in my communication of August 9 to the IMURA members and hope it has not caused you any inconvenience. Attached is a copy of a second memorandum which should correct the first. Thank you for bringing this matter to my attention.

Sincerely,

Cynthia J. Hanson
Assistant to the Vice President
& Patent Officer

CJH:mn
Attachment

Vice President for Research
303/491-7194

Colorado State University
Fort Collins, Colorado
80523

MEMORANDUM

TO: IMURA Members

FROM: Cynthia J. Hanson

SUBJECT: Memo Dated August 9, 1978

DATE: August 18, 1978

The subject memo was incorrect in stating that Mr. Latker, Patent Counsel, HEW, had requested us to assist in obtaining support for the Uniform Patent Policy for Small Business, Nonprofit Organizations, and Universities. This request came from SUPA, the Society of University Patent Administrators and not from Mr. Latker. The information from SUPA contained information from Mr. Latker. As you know, it is not appropriate for federal agency staff members to support legislation and therefore my memo was incorrect. Would you please destroy it so that it does not, by chance, get transmitted to Washington.

CJH:mn

Vice President for Research
303/491-7194

Colorado State University
Fort Collins, Colorado
80523

MEMORANDUM

TO: IMURA Members

FROM: Cynthia J. Hanson
University Patent Officer

SUBJECT: Uniform Federal Patent Policy

DATE: August 9, 1978

I have been requested by Mr. Norman Latker, Patent Counsel, Health, Education and Welfare, to assist in obtaining support from this region in the implementation of a uniform Federal Patent Policy for small business, nonprofit organizations, and universities receiving federal funding for research and development activities. Specifically, Mr. Latker requested contacting research administration individuals in this region and that they in turn contact their congressional delegation indicating a position of support for a Uniform Federal Patent Policy. A new bill is being prepared and is to be introduced in the Senate in the near future. This bill is entitled the "University and Small Business Research Utilization Act of 1978" and a copy is enclosed for your review. Also enclosed is a copy of my letter which was sent to all Colorado congressional delegates. I would like to request that, as soon as possible, you contact your respective Senators and Representatives as well in support of the proposed act. If I may provide any additional information please do not hesitate to contact me.

Enclosures
cc: Mr. Norman Latker ✓
Mr. Howard Bremer