Worker who gave tip on drug patent backlog is fired

By Barbara Reynolds
Chicago Tribune Press Service

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

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

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, a 47-year-old native Chicagoan, 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."

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 limited patent rights are transferred to pharmaceutical firms, the firms will not invest the millions needed for clinical testing and clearance through the Federal 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 Sen. Dole, which was used to write legislation making it more difficult for HEW to hold on to patent rights.

The day after Sen. Dole launched his attack, HEW Secretary Joseph A. 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 Sen. 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'."

Beattie, who was recently promoted to [illegible] told [illegible]



Norman Latker

of Latker's firing. He did not comment on the reasons for the firing.

AN HEW spokesman said the department will prepare a detailed list of reasons for Latker's firing.

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 nongovernment 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 life-saving 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."

BARRY LESHOWITZ, a former aide to Sen. Dole and now a scientist at the University of Arizona, said: "Latker never went to the press. Congress came to him and he cooperated. It is now clear that HEW will not alter its policy of holding up patents if they fired the only guy who tried to get inventions to the public."

Latker said he is still worried about the closed atmosphere in HEW. "People are scared to death to say anything that challenges the department line," he said. "Scientists can't operate that way. They have to be free to explore new ways."

Another problem for Latker is personal. Eight years ago he signed a waiver placing him in a special civil service [illegible]ory, which may mean he is not

The Washington Post

BUSINESS & FINANCE

SUNDAY, APRIL 8, 1979



By William Coulter for The Washington Post

Patent Bill Seeks Shift To Bolster Innovation

By Bradley Graham
Washington Post Staff Writer

The U.S. government deals about $26 billion each year to businesses and universities for research and development, and thus provides seed money for several thousand inventions.

Just who these inventions ought to belong to has been a matter of contentious debate over the years.

On one side are the "titlists"—mostly consumer advocates and trust busters —who believe what the government pays for belongs to the people and no one producer should be granted a patent monopoly.

Opposing them are the "licensers"— mostly business people, university researchers and patent attorneys—who claim that if the titlists have their way, the inventing process will suffer. They say inventors must be allowed to profit through exclusive licenses on their inventions. Their motto: That which is available to everyone is of little value to anyone.

Neither Congress nor the president has been able to decide which bunch to side with, though not for lack of trying. Back in 1943, President Roosevelt proclaimed the need for a uniform government patent policy. This was followed by a decade or two of congressional discussion, then a couple of middle-course and elastic presidential orders, and finally more congressional discussion. But no uniform policy.

Left to themselves, federal agencies have improvised. You can guess the result. Today 22 different funding agencies dispose of patent rights on government-financed research in 22 different ways.

For government contractors, this potpourri of agency policies has led to confusion and discouragement. Federal officials, too, don't much like the arbitrariness of the current system. They'd prefer to operate under the instruction and legal protection of a congressional order.

Beginning this week, Democratic Sen. Birch Bayh of Indiana and Republican Sen. Robert Dole of Kansas will hold hearings on legislation that would tilt toward the licensers. The senators are promoting a bill to give universities, other nonprofit groups and small businesses the rights to inventions made under federal research and development contracts.

Noticeably missing from the proposal is any provision for large corporations. The bill's sponsors say that to include them would invite automatic defeat, which is what happened a couple of years ago when a similar patent licensing bill was introduced. Consumer advocates and antitrust lawyers at the time cried giveaway, monopoly and profiteering, and that was the end of that.

But it's not only the exclusion of big business this time that has the Bayh-Dole forces feeling optimistic so soon after the legislative embers from the last fight have cooled. They feel the mood of the country has swung in their favor. A heightened national concern over the wan

See PATENTS, M2, Col. 1

Patent Ownership Question Heats Up Again

PATENTS, From M1

ing of American innovation has prompted review of all policies which touch on the inventive process.

"I think the climate is better now than it has been in years," said Arthur Obermayer, president of Moleculon Research Corp. in Cambridge and an official of the Small Business Research Association.

A White House advisory panel made up of private patent experts and headed by Robert Benson, an Allis-Chalmers Corp. lawyer, recommended to President Carter several months ago establishing a more relaxed and uniform government patent policy.

One critical problem now is that lots of inventions simply are not getting out to market. The government holds a portfolio estimated at between 25,000 and 30,000 patents. Uncle Sam's predominance in R&D since World War II has generated in the government's hands the largest number of patents in the nation.

Federal officials are quick to cite examples of government inventions that have been developed for commercial use. The list includes granular fertilizer, the aerosol dispenser, dehydrated potato flakes and frozen orange juice concentrate. But studies show that all of their examples add up to less than 4 percent of the government's whole portfolio.

"Experience has shown that the government is not in a position to take advantage of its ownership of patents to promote enterprise," the advisory panel reported to Carter. "Private companies, on the other hand, who are in a position to use the patent grant are ordinarily unwilling to take a nonexclusive license under a government-owned patent and commit the necessary funds to develop the invention, since it has no protection from competition."

The Bayh-Dole bill is a sort of testimonial to Norman Latker, a hero among university researchers and licensing proponents. Latker was patent counsel at the Department of Health, Education and Welfare until his unceremonious firing in December for what officials say was conduct and judgment not up to the department's professional standards. Latker's fans say he was let go for doing his job too well.

Latker, now in private law practice, is not your usual firebrand. He spent 22 of his 48 years in government service and from that acquired an appreciation for authority and a strong sense of working within the system. But even stronger was his zealousness for spurring innovation.

He is credited with developing an elaborate arrangement at HEW, called an Institutional Patent Agreement, which easily transferred patents out of the government. That was fine with the Republicans in the Nixon and Ford years. But to the Carter people it appeared Latker was giving away the store.

Senior officials at HEW ordered an extra step to review all Latker's decisions. As a result, the decisions on pending patent requests were delayed. The universities were miffed. They started complaining to Congress. Latker complained, too.

That's when Bayh and Dole stepped in. Dole charged HEW with "pulling the plug" on biomedical research by holding up action on important new drugs and medical devices. HEW responded quickly. It released some patents—and it also let go of Latker.

The upcoming debate over the bill Bayh and Dole subsequently introduced promises to raise questions of importance to the structure and inventive strength of the U.S. economy. Some key issues will be:

- Between the titlists and licensers, which approach encourages the greatest dissemination of new information? The government's record of commercialization is certainly poor, but the contractors' isn't much better. Several studies have shown that no more than 13 percent of patents obtained by contractors ended up in commercial use.
- Would giving away patents to government contractors result in the build-up of undue monopoly powers? There is little sure evidence either way.
- Won't contractors who get patents enjoy windfall profits? The licensers answer no, but if not, then why are they so insistent the government give away its patents as an incentive to inventors? The licensers say it is to build a protective moat around their inventions, to make sure competitors don't take advantage of them. Their attitude on this might best be summed up as "what have we got to lose" or "better safe than sorry."

But just in case excessive profits do result from a patent giveaway, Dole-Bayh includes a pay-back provision requiring inventors who make large profits to reimburse federal agencies for the support they received in creating the innovation.

- Will companies really stop taking government work if there's no change in patent policy? They haven't yet, at least not in great hordes. And it isn't simple patriotism that keeps them bidding on contracts. Money, ideas, skills and training still flow with government sponsorship. On the other hand, it is generally agreed that the current system tends to favor large corporations with the time and legal staff to wade through the agencies.

Whether government officials even have the right to give away patents for federally financed inventions is subject to dispute. Nader's Public Interest Inc. challenged the practice several years ago, claiming Congress never has granted legislative authority. But the challenge was dismissed on the grounds that Nader's group lacked standing, and the merits of the case never were decided.

White House officials have taken no formal position yet on the patent question. And critics of the Bayh-Dole proposal are sure to make themselves heard before the administration takes sides.

But a sign that the times indeed have changed is suggested by the muted response so far from traditionally staunch titlists. An aide to Sen. Russell Long (D.-La.), a veteran apostle of government-held patents, has told Bayh's staff that the senator won't "actively oppose" the licensing bill. (Another Long aide, however, said publicy that Long hasn't made up his mind. The Justice Department's antitrust lawyers, normally hostile to anything smacking of monopoly, say they're reassessing their position on government patents.

Trouble still may come from such licensing opponents as consumer advocate Ralph Nader, Admiral Hyman Rickover, and Sens. Edward Kennedy (D-Mass.) and Gaylord Nelson (D-Wis.). In this regard, it may not help that big business, though excluded, has thrown its support behind the bill. General Electric, which next to the government files the most patents each year, calls the measure a step in the right direction.

SCIENCE & GOVERNMENT REPORT

The Independent Bulletin of Science Policy

Vol. IX No. 13 P.O. Box 6226A, Washington, D.C. 20015 August 15, 1979

"Technology Transfer" Becomes a Trendy Item

In that long tradition of sudden, but usually short-lived, fascination with accelerating the payoffs from government investment in research and development, Washington has lately been directing attention to "technology transfer."

This amorphous successor to oceanography, desalination, cancer, nutrition, ecology, civilian technology, and so forth, was the subject of hearings last month before the House Subcommittee on Science, Research, and Technology. Rep. Wes Watkins (D-Okla.), who chaired the hearing, said the subcommittee "fully intends to take whatever steps are necessary" to increase the productivity of the federal research dollar. But it's still unclear—perhaps even to Watkins—what those steps will be.

In a press release made available at last month's hearing, Watkins said he was cosponsoring a bill (HR 4672) introduced by Subcommittee Chairman George B. Brown (D-Calif.) "to establish centers to adapt federal research results into marketable goods and services by linking the federal agencies doing research with universities, state and local governments and industry."

Congress Completes Work On NIH Budget; Details — Page 4

According to Brown, the "National Science and Technological Innovation Act of 1979" would create an Office of Industrial Technology in the Department of Commerce and establish centers for industrial technology.

"The centers for industrial technology would be located at universities or other nonprofit institutions," Brown said. "They would conduct research supportive of technological and industrial innovation, assist in the evaluation of technological innovations, advise industry, and train entrepreneurs."

Despite the emphasis on new innovation centers, the ostensible topic of the Watkins's hearings was the role federal laboratories play in the process of technology transfer. But no one seemed to want to talk about federal laboratories.

Richard C. Atkinson, Director of the National Science Foundation, had many words to say on the subject but even he seemed to have other agendas on his mind.

Atkinson admitted that the federal laboratories eat up a huge portion of the overall research budget. This year alone, Atkinson said, federal research spending will amount to nearly $30 billion. Only $5.5 billion—spread among 450 institutions—is spent at colleges and universities; the 779 federal laboratories get more than that, he said.

Atkinson apparently was not advocating a cut in the federal laboratory budget but he was quick to point out "that even a small change in the efficiency of a system of such size could substantially enhance research, innovation, and commercial use of research results."

Among the specific proposals that the NSF Director said might help the federal laboratories run more efficiently is a new "policy statement" at the national level, requiring federally supported laboratories to "devote some deliberate fraction of their resources to

(Continued on Page 2)

In Brief

True to the style that he followed during his 30 months as chief of HEW, Joe Califano was a blaze of activity right up to his last minute in office. One of his very last official acts was to send a letter to Assistant Secretary of Health Julius Richmond, urging him to get the Food and Drug Administration to make Eli Lilly and Co. revise the obfuscating warning that it's trying to get away with on the dangerous drug Darvon.

The Carter White House, which most of official Washington has written off as an irremediable basket case, didn't invite Califano to the swearing in of his successor, Patricia Harris.

Asked recently at a press briefing to explain why, after three years to prepare for next week's United Nations Conference on Science and Technology for Development (UNCSTD), the US delegation still lacked instructions, Ambassador Jean Wilkowski said that "it's like preparing your income tax return. Things get left to the last minute."

What's apparent—though, of course, no official will come out with it—is that the US regards UNCSTD as a nuisance that must be endured, and that its goal for the Vienna meeting is to minimize the political turbulence, rather than accomplish anything substantive.

. . . New Patent Legislation Gaining Ground

(Continued from Page 1)

university or industry cooperation."

The problem, he said, is that the federal laboratories are under the control of federal agencies with particular missions. If the laboratories spend too much of their time on activities unrelated to those missions, they are assumed to be over-staffed and over-budgeted.

Other witnesses, who represented universities, corporations, and government agencies, also called for government support, or at least promotion, of formal cooperative programs among their institutions. Sharing equipment would save money, and the collaboration of scientists could inspire new ideas, they argued. But there was little discussion of how those cooperative programs might be designed or what research might be conducted under their auspices.

In fact, little if anything was said about the actual research conducted at the federal laboratories or about any reallocation of the resources they now consume.

One of the few clearcut recommendations offered at the hearings called for requiring federally financed researchers to state the potential practical application of their work before the work is begun.

W. Novis Smith, director of research and development at the Thiokol Corporation-Chemical Division, Trenton, NJ, said he would go so far as to require researchers to create what he called a "viable commercialization scenario" as part of their projects, wherever possible.

Some researchers took exception to such suggestions. The scenarios, they said, would not only commit them to talk to industrialists, but would also force them to produce. The requirement, they argued, is incompatable with basic scientific research.

Meanwhile if the amount of Congressional talk about patent legislation is any indication, strong legal protection for inventors is gaining support as a way to get innovations out of the laboratory and into the marketplace.

One sign of this is that the Bayh-Dole bill, S 414, to provide patent protection for researchers is gaining steady support on Capitol Hill, while its critics are growing increasingly silent.

The bill, similar to one introduced in the House, would allow non-profit organizations and small businesses to retain title to government-financed innovations for up to eight years. To avoid excessive profits, the bill includes a "pay back" provision requiring inventors who make large profits to reimburse agencies for the support they received in developing the innovation.

HEW Patent Aide Reinstated

Norman J. Latker, the controversial government patent expert who was fired last year, has been reinstated.

For over a decade, Latker worked in the patent office of the Department of Health, Education, and Welfare. Shortly before he was dismissed last fall, the 22-year veteran of government service had openly criticized his superiors for attempting to withhold patent rights from university researchers conducting government-financed research and develoepement projects.

Officials in the department said Latker had been let go because he had not met department "standards" and because of "specific instances" of misconduct associated with lobbying for more liberal patent procedures. HEW officials have maintained, for example, that the patent officer used government stationary and equipment to lobby for legislation that they felt would bring windfall profits to universities. But Latker argued that protecting the patent rights of government-sponsored researchers was the only way to assure that innovations get into the marketplace. Moreover, he claimed that official charges were never brought against him.

A civil-service review board now says that the dismissal was illegal and must be overturned on procedural grounds. For several weeks HEW officials refused to comment on the matter, but now indicate they do not plan to appeal the decision.

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BOB DOLE
KANSAS

STANDING COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
BUDGET
FINANCE
SELECT AND SPECIAL COMMITTEE:
NUTRITION AND HUMAN NEEDS

United States Senate

WASHINGTON, D.C. 20510

December 1, 1978

Rear Admiral A.J. Baciocco, Jr.
Office of Naval Research
Ballston Tower 1823
800 N. Quincy Street
Arlington, Va 22017

Dear Admiral Baciocco:

It is my understanding that Mr. Norman Latker is presently being considered as a candidate for the position of patent counsel with the Office of Naval Research.

My contacts with Mr. Latker stem from work done by members of my staff in conjunction with a bill, S. 3496, that I introduced along with Senator Birch Bayh and 14 others of my colleagues last September. This bill represents, in my opinion, the culmination of interagency examination of federal patent policy extending over a period of more than 10 years. It aims at establishing uniform federal patent procedures for small business and nonprofit organizations.

Mr. Latker, perhaps more than any other official in government, is responsible for the federal patent policies adopted in several agencies of the government. The Institutional Patent Agreements used by the National Science Foundation are modeled after the innovative policies utilized for the past 10 years in HEW. In addition, the Department of Energy's patent legislation has been influenced to a considerable degree by the diligent efforts of Mr. Latker, and other concerned attorneys in the Executive branch. In view of the accomplishments of Mr. Latker, it was natural for me to turn to him to help my staff formulate the legislation I recently introduced.

In the past 10 years, Mr. Latker has been responsible for introducing more than 75 life-saving inventions to the public market. These inventions have attracted considerable sums in investment capital. I should like to point out that, prior to Mr. Latker's institution of IPA's, there is documented evidence in the GAO indicating that virtually no inventions could be traced to any HEW R & D effort.

Mr. Latker is recognized through the research and legal communities as a leader in the field of patent law and technology transfer, and he is

.../...

often consulted in his role as expert by agencies and research institutions throughout the world. His list of publications and presentations testify to his leadership in the field. Mr. Latker has spent his career instituting successful approaches to the transferring of federally-supported inventions to the public.

In addition to his professional expertise, Mr. Latker's integrity and the loyalty to the principles of our government that he has shown as a public servant would make him, in my judgement, a most sought-after candidate for any position he applies for.

It has been my experience that organizations often benefit from the introduction of someone from the "outside", who can bring new ideas and new perspectives, as well as fresh insights.

I can but higly recommend Mr. Norman Latker to your attention, with the hope that you will consider his candidacy in the most favorable way.

Sincerely yours,

BOB DOLE
United States Senator

BD:bl

Mr. Latker, Patent Counsel for the Department of Health, Education, and Welfare, is in charge of the Patent Branch, Office of the General Counsel. This Branch is responsible for administration of the Department patent program and for legal services to the Department relating to and involving patent, inventions, and other forms of intellectual property resulting from the Department's one-billion-seven-hundred-million dollar annual research and development program. He also advises the Veterans' Administration and the Agency for International Development on an ad hoc basis.

He is currently a member of the Executive Subcommittee of the Committee on Government Patent Policy of the Federal Council for Science and Technology, and Chairman of the Subcommittee on University Patent Policy. He served on the inter-agency committee which drafted the new patent section for the Federal Procurement Regulations. He recently served on the patent Task Force advising the Commission on Government Procurement and the committee assigned to draft the ERDA patent provisions.

In the past he had been Patent Counsel to the National Institutes of Health; served on the Staff, Judge Advocate of the Air Force Systems Command, Washington, D. C.; was Assistant to the Chief Patent Advisor, Army Ordnance Tank Automotive Command, Detroit Arsenal, Warren, Michigan; and was a Patent Examiner in the United States Patent Office.

Mr. Latker was born in 1931 and raised in Chicago, Illinois, where he attended public schools through high school. He received his Bachelor of Science and J. D. in Law from the University of Illinois.

JAN'79

DHEW R & D IN LIMBO

Mystery Surrounds Former Licensing Head



Norman J. Latker

Editorial

Norman Latker, up to December 13, 1978, had been working as a patent attorney for the U.S. Government for the entire 22 years of his professional career and for the last 10 years, at least, he was instrumental for licensing all patents and know-how of the Department of Health, Education & Welfare (DHEW) — the results of the many billions of dollars spent each year in the Institutes of Health and indirectly in the 70 odd institutions, e.g., Johns Hopkins University, California Institute of Technology, Northwestern University, etc., supported by grants from the various agencies of the huge DHEW.

So successful was he in this last position that some 100 inventions were licensed to 70 companies in the U.S. and in such countries as Germany, France, Japan, etc., whereas in the many years prior to 1968, nothing was ever licensed.

Because of his success he was made chairman of a U.S. Government inter-agency group, the "Ad Hoc Committee on University Patent Policy," to study licensing, resulting in other agencies such as Agriculture, National Bureau of Standards, etc., following the example set by DHEW.

The then President of the U.S.A., Gerald Ford, in fact sent him a very congratulatory letter during his term of office which is reproduced here.

THE WHITE HOUSE
WASHINGTON

March 9, 1976

Dear Mr. Latker:

Dr. Betsy Ancker-Johnson has called my attention to the important service which you rendered in connection with the Senate-Executive Branch negotiations which led to the passage of the Federal Nonnuclear Energy Research and Development Act of 1974.

It is a tribute to your skill and resourcefulness in the drafting of the Patent Policy Section of this legislation that it was accepted almost unanimously, and without the alteration of a single word, by both houses of the Congress. You improved upon the original Senate language so that I was able to sign this measure into law without fear of abridging the research and development effort upon which our energy future depends. I congratulate you for this accomplishment.

Although my schedule precluded the convening of a formal signing ceremony, I am pleased, nevertheless, to forward the enclosed presidential pen which I was unable to present to you personally. Please accept it as a tangible reminder of my appreciation.

With warm regards,

Gerald R. Ford

Mr. Norman J. Latker
Chief, Patent Branch
National Institutes of Health
Room 5A03, Westwood Building
Bethesda, Maryland 20014

It was with considerable surprise that we recently learned that Mr. Latker had been summarily dismissed, with no reasons being given in his notice of dismissal letter — a copy of this is also reproduced here. We talked to Mr. Latker and found that he is not clear as to the why and wherefore and so we contacted the DHEW and finally reached an official spokesman — Mr. John Blamphin, who at first declined to discuss the reasons but when challenged said that they could not give them to us, but "a response is being developed." It seemed unusual. Either there were reasons, or not, or possibly they were seeking to find a nice way to

Again, on our further insistence three reasons were given which may or may not be complete. These were read by Mr. Blamphin from a detailed report he promised to send us — but which has not been received as of press time:

1. Mr. Latker used Government postage to send out releases to holders of Institutional Patent Agreements with the DHEW.
2. Mr. Latker advised a group of University grantees who are believed to be preparing a suit against DHEW.
3. Mr. Latker was lobbying Congress, and such a position should not have been taken by a Government employee.

As to No. 1 — Dr. Dvorkovitz & Associates is on the mailing list referred to — along with about 70 U.S. University Administrators. We have been receiving such releases since 1968 and can see no difference in what we received at any time — unless of course there was a basic change in policy recently that we did not know about.

As to No. 2 — The universities which include the most famous names in U.S. Education are as much part of America as, and in fact predate, DHEW. As far as we have been able to determine, they are not preparing a suit against DHEW but are only involved in trying to explain their position on a certain matter — "Peer Review" — which they feel would threaten the benefits so far obtained from the official DHEW Patent Policy that, so far, has been changed. In a telephone conversation where one of our reporters questioned Mr. Latker on this particular subject, Mr. Latker said, "I did nothing more than state the official DHEW policy on 'Peer Review' to the concerned and affected institutions who asked about the DHEW position. This is based on an official policy going back to DHEW then General Counsel, William Howard Taft, IV, on this question and which was never changed by the DHEW Counsel's Office or any appropriate official of DHEW."

As to No. 3 — We understand from the office of Senator Robert Dole, who was the Congressional contact involved, that Mr. Norman Latker did nothing different from 1000 other DHEW employees and any such reason to dismiss Mr. Latker should involve the dismissal on the same day of the other 1000 DHEW executives.

We have just had access to Mr. Latker's personnel file and find that DHEW has now inserted an official reason for his dismissal. We quote the reason in its entirety: "Services no longer required."

We are aware of Mr. Califano's crusade against smoking, and whether or not he is successful in his

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

NOV 16 1978

TO BE OPENED BY ADDRESSEE ONLY

Norman J. Latker, Chief
Patent Branch
Business & Administrative Law Division
OGC, GS
Room 5A-03 Westwood Building
Bethesda, Maryland 20014

Dear Mr. Latker:

This is to notify you that your services as Supervisory Attorney-Advisor (General) in the Office of General Counsel of this Department will be terminated, for the reasons stated to you in our meeting on Thursday, November 9, effective close of business December 13, 1978.

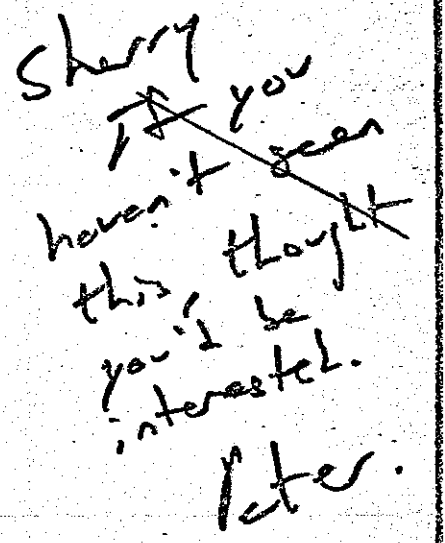
Very truly yours,

efforts will have relatively little impact on America, as compared to the damage that this arbitrary dismissal of Mr. Latker will do to America. If you subscribe to the domino theory then this action could result in all the research money spent by DHEW and all other Government Agencies such as Defense, Energy, etc., to be completely wasted — with absolutely no practical results. At the very least it will mean that lifesaving drugs and diagnostics, prosthetic devices that will allow the handicapped to live a successful life, etc., will not be produced or used and that eventually some of the world's great medical researchers will become disillusioned and leave both their profession and the great Institutes of Health that up to now are the envy of the world and should be the pride and joy of the American people.

We think this matter is of interest to any scientist or engineer working in a U.S. Government Institute or working on one of the many grants given to the Universities and Industries of America. Probably this accounts for over 60% of all the research done in the USA.

Today, we hear constantly about a drastic drop in inventions and innovations and committees are formed daily, and editorials written daily, in an attempt to find the reason and to find a solution.

Actions like this taken by DHEW under Mr. Califano's direction seem to us a sufficient cause for this drop in itself — inventions and innovations must be nursed and not smothered or strangled by removing the incentive — the satisfaction an inventor always has to see his brainchild brought to fruition. Because of the importance of this subject we will continue our investigative reports and hope in the next issue of UNIT to give a more complete story. We would welcome any letters for, or against, and certainly, we would welcome letters or phone calls from anyone knowing more facts about this matter.



advantaged the distinguished Senator from Indiana. He accepted it in the finest spirit and the recognizes that the Senator from Louisiana has some problems with this bill now and, as is characteristic of the Senator from Indiana, he is willing to try to work out these concerns with the Senator from Louisiana.

It will take some time. In the meantime, we shall proceed with the FTC bill and dispose of it on Friday or before Friday noon, at which time, the patent bill automatically will come back before the Senate. If the two Senators are still working on this matter, I shall do everything I can temporarily to lay this patent bill aside further so that they will have more time. But eventually, the Senate ought to dispose of the bill.

It was called up in good faith. The agreement was gotten in good faith; nobody charges anything to the contrary. But I feel obligated to try to dispose of the bill at some point. I think both sides ought to have a reasonable opportunity, however, to work out their concerns. I am prepared to move to the other bill as soon as the distinguished Senator from Indiana speaks to the matter.

Mr. BAYH. Mr. President, I appreciate the almost impossible task that our distinguished majority leader, the Senator from West Virginia has, in trying to reconcile the different interests, different positions, different schedules, different workloads of all of us who are trying our best to fulfill our responsibility. I think it would not be wise to insist on getting a vote, a passage vote, on this measure at this time because of the concerns of the Senator from Louisiana.

I think the matter before us is important, certainly the FTC measure is important; the windfall profit tax being worked on by the Senator from Louisiana is important. Certainly, there is no other than the Senator from Louisiana, so I am sympathetic to him. I hope in the interim, we can do our best—I know the Senator from Louisiana will, but I hope other Senators will, also to work out an agreement for speedy consideration of S. 414.

I say to the Senator from Louisiana and the majority leader that I have a little obligation to those people who have been counting on me to be the chief spear carrier on this measure. We have had hearings in the Committee on the Judiciary, we reported it out without any dissenting votes. It has been out here for 3 months. I should not want anyone to interpret my willingness now to accommodate the Senator from Louisiana as being a retreat from the bill, because I think S. 414 is important.

In the debate that transpired on the Stevenson-Schmitt amendment, there were several questions—I thought good questions—raised by the Senator from Louisiana about the inability to get patent rights under the present system. Although I know of no examples of frustrated inventions from the large companies covered by the Stevenson-Schmitt amendment, I do have a list about half as long as my arm of specific patents that did have difficulty getting developed from universities and small business. One of them involved a diagnosis for cancer that has not yet been marketed because of HEW patent policies. I think we can deal with this issue as far as small businesses and universities and nonprofit organizations are concerned to the satisfaction of the Senator from Louisiana.

I hope the payback provision in our bill, under which the Government will recover the money it invested in the initial research will satisfy him. If not, I hope we can at least agree to disagree and let the Senate work its will on this bill. In that spirit, I am more than happy to relinquish the floor at this time.

Mr. ROBERT C. BYRD. Mr. President, will the distinguished Senator yield?

Mr. LONG. Yes.

Mr. ROBERT C. BYRD. I should like to acknowledge the interest the Senator from Kansas has had in this matter. He is also involved in the conference on the windfall profit tax. If I understood him correctly, I think possibly he appreciates the need at this point to move on with the other bill.

Mr. DOLE. Mr. President, I must say I am surprised I did not find the distinguished Senator from Louisiana as a cosponsor of this amendment. It is my hope that he will be leading the charge on the bill, because there are numerous protections of the Government interest, as the Senator from Louisiana may have already determined, in addition to marchin rights and the payback provision.

I certainly agree to that request as long as the bill is not brought up before the week of the 18th. Some of my colleagues who would not like it brought up, say, next Thursday or Friday when they will not be present. Senator THURMOND, for example, cannot be here next Thursday or Friday. This would come back, as I understand it, and be the pending business, unless it is further laid aside until the following Monday.

There is some hope that we may be finished with the windfall profit tax conference. Of course, maybe the Senator from Louisiana would be willing to lay that aside for a year or 2. That would be all right with some of us.

I am very pleased to accommodate the majority leader and the distinguished chairman of the Committee on Finance.

Mr. BAYH. Mr. President, if the Senator will permit me just one word, I want again to express my appreciation to my friend and colleague from Kansas for the role he has played in this. We have been a two-horse team and it has pulled pretty well until we got to this bend in the road. Now, I guess, we are going to have to let the horses rest temporarily and, hopefully, we shall be able to have the Senator from Louisiana driving the wagon when we get it started again.

UNANIMOUS-CONSENT AGREEMENT

Mr. ROBERT C. BYRD. Mr. President, I ask unanimous consent that the majority leader may be authorized, so as to protect Senators against the possibility that this bill might be before the Senate next week, that the bill in no event be called up next week, that, in no event, it be before the Senate, that it be temporarily laid aside beyond next week and that the majority leader be authorized, at any time, beginning with Monday, the 18th of this month, again to call up the patent bill and make it the pending business before the Senate. In this way, I shall protect all Senators against the likelihood of the bill's being up next week by virtue of its automatically coming back before the Senate upon the disposition of the FTC bill. But I would have the authority, then, to call the bill back up the week after next or at any time beginning with that Monday.

The PRESIDING OFFICER. Is there objection?

Mr. LONG. Reserving the right to object, the Senator is not setting the 18th, is he?

Mr. ROBERT C. BYRD. No, I am just giving the majority leader, authorizing him, after consultation with the distinguished acting Republican leader—and of course, I shall consult with the Senators involved here—to call the bill back up before the Senate at any time beginning with the 18th of February.

Mr. LONG. Yes. Of course, I do not have my schedule with me. That is why I hope I shall be able to consult with the Senator before it comes back up.

Mr. ROBERT C. BYRD. Yes, I shall consult with the Senator.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request of the majority leader?

Without objection, it is so ordered.

Mr. ROBERT C. BYRD. Mr. President, with apologies to the Senator from Indiana, the Senator from Louisiana, and the Senator from Kansas and other Senators, and also with expressions of appreciation to them for their understanding and cooperation, I am authorized after consultation with the distinguished acting Republican leader, to call up the FTC bill. In the meantime, I suggest the absence of a quorum and ask that I may be recognized following the quorum call.

The PRESIDING OFFICER. Does the Senator make that a unanimous-consent request?

Mr. ROBERT C. BYRD. Yes.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will call the roll.

The second assistant legislative clerk proceeded to call the roll.

Mr. ROBERT C. BYRD. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

FEDERAL TRADE COMMISSION ACT OF 1979

Mr. ROBERT C. BYRD. Mr. President, under the agreement of yesterday, I now ask the clerk to lay before the Senate S. 1991.

The PRESIDING OFFICER. The bill will be stated by title.

The legislative clerk read as follows:

A bill (S. 1991) to amend the Federal Trade Commission Act to change procedures for agency adjudications and rulemaking, to extend authorizations for appropriations for the Federal Trade Commission, and for other purposes.

The Senate proceeded to consider the bill, which had been reported from the Committee on Commerce, Science, and Transportation with an amendment to

MEMORANDUM

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

NJL

TO : James Hinchman
Assistant General Counsel

DATE: January 9, 1977

PATENT BRANCH, OGC
DHEW

JAN 17 1978

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

NOV 8 1977

MEMORANDUM TO: Heads of POC's
Assistant Secretari
Heads of OS Staff O
Principal Regional Officials

SUBJECT : Patent Policy and Procedures

As you may be aware, the patent policies of Federal agencies are coming under close scrutiny. I am concerned about these developments as they relate to Departmental policies. Accordingly, because of the cross-cutting and legal implications of policies and procedures involving the granting of patents by the Department, I have asked the General Counsel to conduct a review of the Department's present patent policy, including the policies and practices relating to the granting of patents, the reservation of rights with respect to patents, financial support of the development of patentable products and processes, and the granting of licenses and exclusive licenses.

I have asked the General Counsel to submit his report to me by February 15, 1978.

Joseph A. Califano, Jr.

Official fired after revealing HEW sat on miracle cures for 2 years

POTENTIAL cures for muscular dystrophy, schizophrenia and 20 other possible medical breakthroughs that might have saved hundreds of lives were kept from the public for nearly two years by the government, charges a group of senators. And the official who finally blew the whistle to Congress has been fired.

The senators claim the Department of Health, Education and Welfare knowingly sat on the patents for the medical data and devices — apparently to cut government health research costs. Finally a HEW patent official, Norman Latker, complained. As a result, Latker was kicked out of his job without severance pay after 22 years of government service.

By NORMA LANGLEY

According to Sen. Robert Dole (R-Kans.): "HEW pulled the plug on development of research and withheld from the American public potential cures and revolutionary diagnostic techniques for treating such diseases as cancer, arthritis, hepatitis and emphysema."

The medical techniques that were stonewalled by HEW also included:

- A blood test that would show the presence of cancer long before tumors appear on X-rays.
- A method of determining the best cancer treatment without using the patient as a guinea pig.
- A new arthritis remedy.
- An appliance to help babies with cleft palates.
- A new breathing device for asthma sufferers.
- A thermometer that pinpoints the optimum temperature needed to kill individual cancer cells.
- Medicine to prevent raging fevers from striking children born without normal resistance to disease.
- A new antibiotic.

Dole said one of the worst examples of HEW stonewalling was the revolutionary new blood test for detecting cancer of the breast, digestive tract and pancreas. It was developed by one of the world's most prominent research centers.

Latker says that the day after Dole demanded action on his complaint, HEW Secretary Joseph Califano ordered that half the new drugs and treatments be released to the inventors. Then Latker says, Califano came looking for the whistle blower.

Latker's job was returning the patent rights to inventors who used government money to start their research. Most of the inventors are leading scientists who exchange the patent rights for National Institutes of Health grants to study hundreds of medical problems.

When the grant money is used up, the normal procedure for the last 10 years has been to quickly return patent rights to the inventor. Drug firms then would put up millions of dollars to make some of the treatments available to the public.

Latker took over the patent transfer office 10 years ago and made it a model of efficiency. He returned many patents that proved worthless, and some that proved very valuable when put into production — including the vaccine for rubella. But, Latker said, "as soon as Mr. Califano came in, he shut us down."

Inventors and drug companies began to complain to senators. Last August Latker was called to testify before a congressional committee. He told them his office had processed 30 inventions that his superiors would not release.

Dole demanded an explanation from Califano and quickly found 15



Norman Latker: Kicked out without severance pay for blowing whistle on U.S. agency.

rights for a limited time to their inventions. Sen. Bayh's wife, Marvella, suffers from inoperable cancer.

After several months of harassment, Latker says, he was finally fired in November.

He was offered no severance pay and is not eligible for a pension until 1994.

John Blamphin, Califano's spokesman, denies that Califano had any personal interest in Latker. "Mr. Califano was not involved in the firing," Blamphin said.

Latker was dismissed for a number of improper activities he explained, including using his office, materials and personnel to lobby for the Dole bill; mailing a congressional press release from his office, and helping the Association of American Medical Colleges prepare a lawsuit against HEW.

"These activities are explicitly forbidden a government employee to engage in," Blamphin said.

As for the delay of the patent releases, Blamphin said that "the public has some rights. They funded the research and they have rights that have to be balanced against a private company developing the treatments." Occasionally the government does indeed develop a product itself. But mostly, sources say, HEW and other government agencies are simply reluctant to look like they're giving away taxpayers' money to private industry.

Latker called this profit motive on behalf of the taxpayer ridiculous. "One in a million of these inventions would really return important money," he contended. "Remember, if HEW thought they had a winner, they would have continued funding them."