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United States Senate

SELECT COMMITTEE ON SMALL BUSINESS
WASHINGTON, D.C. 20510

March 17, 1978

Honorable Lester Fettig
Administrator
Office of Federal Procurement
Policy
Office of Management and Budget
Executive Office Building
Washington, D. C. 20503

Dear Mr. Fettig:

Under the authority conferred on you by the Office of Federal Procurement Policy Act, I ask that you stay the March 20 effective date of a General Services Administration amendment to the Federal Procurement Regulations providing for the use of Institutional Patent Agreements in contracts with universities and nonprofit organizations for experimental, development and research work.

Delaying the effective date of what GSA published in the Federal Register of February 2 as a final rule (43 FR 4424) will permit Congress to hold hearings on the history, legal basis and implications of Institutional Patent Agreements as an implement of Government patent policy.

The act cited (Public Law 93-400) directs you to "prescribe policies, regulations, procedures, and forms," which shall be in accordance with applicable laws and shall be followed by executive agencies in the procurement of--

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(B) services, including research and development; and

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I believe you have the authority to stay the GSA amendment. Certainly the amendment is bold enough and broad enough to warrant your attention, for it would apply to a majority of the agencies through which President Carter's 1979 budget proposes to obligate $3.561 billion for research and development support to colleges and universities.

Also, postponing the effective date of the GSA amendment so that it may undergo congressional scrutiny would be fully compatible with your own announcement in the Federal Register of March 8 (43 FR 9545) of a project to replace the Armed Services Procurement Regulation, the Federal Procurement Regulation and the National Aeronautics and Space Administration Procurement Regulation with a single, uniform regulation to be called the Federal Acquisition Regulation (FAR). Since GSA and the Department of Defense have been assigned the principal roles in drafting the FAR, the GSA amendment should be scrutinized before its adoption into current regulations. That would avoid the possibility of its being transferred bodily by GSA from current regulations into the draft of the single, uniform regulation.

As GSA noted when it published this amendment on February 2, the Committee on Intellectual Property and Information, Federal Coordinating Council for Science, Engineering, and Technology, recommended that universities and nonprofit organizations with satisfactory technology transfer programs be granted rights to inventions made under contracts with Federal agencies. Institutional Patent Agreements permit those institutions to retain the rights to inventions and related patents that result from such grants and contracts.

Questions should be asked about the GSA amendment authorizing and inviting wide use of a standard Institutional Patent Agreement (IPA) from the standpoint of--

1. Its history. Expanded use of the IPA was proposed by an interagency committee in 1975. What happened between than and February 2 of this year? Is the GSA amendment an expression of Government patent policy by the Carter Administration, or is

it the will of a prior administration being discovered only now in the fine print of procurement regulations?

2. Its legal basis. The IPA is founded not on statutory law, but on the memorandums and policy statements of President Kennedy in 1963 and President Nixon in 1971. Indeed, the GSA amendment marks a major new phase in the evolution of policy by exception, since the IPA is founded on the "exceptional circumstances" and/or "special situations" clauses in these presidential patent policy statements.

The text of the standard IPA contained in the GSA amendment itself relies upon an exception. When a university decides to retain the rights to inventions resulting from Government-sponsored research, it shall, says the IPA, "make them available through licensing on a nonexclusive, royalty-free, or reasonable royalty basis to all qualified applicants," except that:

> The institution may license a subject invention on an exclusive basis if it determines that an exclusive license is required in the public interest because (A) it is necessary as an incentive for development of the invention or (B) market conditions are such as to require licensing on an exclusive basis in order to bring the invention to the point of practical application.

As one might have guessed, exclusive licenses are the rule and not the exception under patent rights awarded by the Department of Health, Education and Welfare pursuant to the IPA--containing comparable language--that it has been using for a decade or so.

3. Its implications as an implement of Government patent policy. Whether recombinant DNA research inventions developed with HEW support should be administered in the same way that drugs and other university discoveries are ought to be a major

policy question on its own right, yet the National Institutes of Health have decided, at least for the present, that they can be under current HEW patent agreements. The GSA amendment could expand the IPA into all the areas like this one not covered by statutory requirements, in the same way that air expands to fill a vacuum.

Further, questions should be asked about differences between the standard IPA contained in the GSA amendment and the IPA that HEW has been using, including these:

1. The HEW agreement permits a university to assign its invention rights to a "nonprofit patent management organization." The GSA version would do the same but omits the word "non-profit." Granted that both nonprofit and for-profit patent management organizations will attempt to maximize their returns in promoting the licensing of university discoveries, what is the reason for the change?

2. The GSA amendment appears to go beyond HEW's IPA--it may be nothing more than greater candor--in allowing an agency, at the request of the university, to "use its best efforts to withhold publication" of invention disclosures until a patent application is filed. Does that mean an agency could collaborate in withholding publication of a scientist-inventor's research results until his university secured its commercial rights in them? Would the GAS amendment create a new class of information that could be withheld from public disclosure under the Freedom of Information Act? Would this standard IPA create new grounds for closing a meeting under the Federal Advisory Committee Act?

3. The HEW IPA allows a university to grant an exclusive license under a patent or patent application for a period of up to three years from the date of the first commercial sale of a product or process embodying the invention, while the standard IPA contained in the GSA amendment would extend that period to five years. Why extend the monopoly period, especially when the monopoly afforded by exclusive licensing is supposed to be an exception to standard practice?

My request that you stay the effective date of the GSA amendment stems from the fact that the Senate Small Business Committee's Monopoly Subcommittee, which I chair, held three days of hearings in December, 1977, to open a long-term study of Government patent policy. It is examining three problems:

(1) The problem of increasing economic concentration brought about by granting patent monopolies for discoveries which result from Government-financed research and development contracts.

(2) The problem of assuring that newly acquired technological information developed at Government expense and not of a classified nature is diffused throughout society. The American people foot the bill. Do they receive commensurate benefits from this work?

(3) The problem of whether the Federal Government is getting all that it pays for with its research and development dollar. Is the Government giving away more than it should in arranging for such work? Is it possible to recover part, or perhaps all, of our expenditures for research and development?

Whether the Government-wide approach to university research and development advocated in the GSA amendment has sufficient public safeguards, and how it might affect development of drugs and the current laboratory interest in patenting living organisms, are matters the Congress will wish to address.

Your action to stay the effective date of the GSA amendment will make it possible for Congress to do so, and would be most appreciated.

Sincerely,

Gaylord Nelson

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Chairman

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