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United States Senate

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

June 16, 1978

Dr. Donald Fredrickson
Director, National Institutes of Health
9000 Rockville Pike
Building 1, Room 124
Bethesda, Maryland 20014

PATENT BRANCH, OGC
DHEW

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Dear Dr. Fredrickson:

You are invited to appear before the Monopoly and Anticompetitive Activities Subcommittee at 9:30 o'clock on the morning of Monday, June 26, to testify at a hearing on the history, legal basis and implications of Institutional Patent Agreements (IPAs) as an implement of Government patent policy.

The hearing will be held in Room 318 (Caucus Room) of the Russell Senate Office Building. It will be the fifth and final day of hearings on IPAs (May 22-23; June 20-21 and 26).

Also scheduled to testify on June 26 are Dr. Frank Press, the President's science adviser, and Lester Fettig, Administrator, Office of Federal Procurement Policy.

As you know, the General Services Administration announced in February that an IPA was being incorporated in Federal Procurement Regulations for Government-wide use effective March 20. At my request, Administrator Fettig agreed to stay the new patent regulation for 120 days, until July 18, to permit it to be scrutinized by congressional committees and the Executive Office of the President.

On the first two days of hearings on IPAs (May 22-23), the subcommittee received testimony from Norman Latker, patent counsel of the Department of Health, Education and Welfare; Charles H. Herz, general counsel of the National Science Foundation; Philip Read, director of Federal Procurement Regulations, General Services Administration; and a representative of the Association of American Universities, among others.

During Mr. Latker's appearance it was learned that HEW is now administering 21 IPAs, that the processing of deferred determinations -- requests from non-IPA institutions for award of patent rights after an invention has been made -- was stopped in August 1977 in connection with a review of the department's

patent policy by the Office of General Counsel, and that there is a backlog now of between 25 and 30 deferred determination cases.

Recent staff inquiries have ascertained that the review by the Office of General Counsel is continuing and that no decision on the department's patent policy is expected by the date of your appearance before the subcommittee.

In your testimony, please address the following questions:

1 -- In the Congressional Record of May 19, at page S7881, I inserted a statement and two memorandums by the Congressional Research Service headed, "Patentable Material and the Freedom of Information Act." Please respond to the points raised in the material, including the question of why NIH in March 1977 introduced the phrase "patentable material" into its standard justification of the closure of peer review meetings on exemption four grounds.

2 -- On June 12 The Washington Post printed a story from The Boston Globe reporting that a team of Harvard University biologists "has found a way to use a common bacterium to manufacture the medically valuable hormone insulin." The story continued:

> The unprecedented scientific achievement appears to open the way to eventual mass production of almost any protein -- including human hormones -- by microscopic "factories" of bacteria.

The story did not say whether the team's work was supported by HEW, but if it was and there is something patentable in the discovery, Harvard presumably could seek to file a patent application in accordance with its IPA and the recent NIH ddcision that, at least for the present, recombinant DNA inventions developed with HEW support can be patented under IPAs.

Please discuss the recent NIH decision in view of the potentially momentous discovery by the Harvard team.

3 -- If the newly worded IPA contained in the GSA amendment to the Federal Procurement Regulations is allowed to go into effect after July 18 as is, will it be mandatory that HEW adopt it in place of the IPA HEW has used since 1968? If HEW will have the option of continuing to use its own IPA or of switching to the new one, which course would you recommend?

It would be greatly appreciated if you could deliver 10 copies of your prepared statement by Friday, June 23, and 50 copies on the day of the day of the hearing. Thank you.

Sincerely,

Gaylord Nelson

GAYLORD NELSON
Chairman

GN/gsy

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