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SELECT COMMITTEE ON SMALL BUSINESS

WASHINGTON, D.C. 20510

May 2, 1978 PATENT BRANCH, OGC
DHEW

MAY 9 1978

Nelson

Norman Latker, Patent Counsel
Office of the General Counsel
Office of the Secretary
Department of Health, Education and Welfare
Washington, D. C. 20201

Dear Mr. Latker:

You are requested to appear before the Monopoly and Anticompetitive Activities Subcommittee at 9:00 o'clock on the morning of Monday, May 22, 1978, 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 of the Russell Senate Office Building. Witnesses from the National Science Foundation and the General Services Administration are also being requested to testify.

As you know, I asked the administrator of the Office of Federal Procurement Policy to stay the March 20 effective date of a GSA amendment to the Federal Procurement Regulations providing for the use of IPAs in contracts with universities and nonprofit organizations for experimental, development and research work. He granted a stay of 120 days, until July 18, to permit further consideration of this amendment by the Executive Office of the President and certain Congressional committees.

As patent counsel for the Department of Health, Education and Welfare, which has used an IPA since 1968, you oversee administration of its patent program and provision of legal services to HEW relating to patents, inventions and other forms of intellectual property resulting from its \$2 billion annual research and development program.

In addition, you have served on the executive subcommittee of the Committee on Government Patent Policy of the Federal Council for Science, Engineering and Technology, and as chairman of the Subcommittee on University Patent Policy. You also served on the interagency committee that drafted the new patent section for the Federal Procurement Regulations. Given your prominent role in patent matters over the years, your testimony will be invaluable.

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In your testimony, please discuss the history and legal basis of HEW's IPA and note:

(1) Whether HEW regulations covering inventions resulting from research grants, fellowship awards and contracts for research (45 CFR Parts 6 and 8) have been amended since January 7, 1969; and

(2) The statutory or other authority for Sec. 8.8 of those regulations headed, "Screening of compounds generated under DHEW grants and awards" (34 F.R. 201, Jan. 7, 1969).

Please attach to your prepared statement a list of all universities and other nonprofit organizations which hold an IPA administered by HEW, as well as:

(a) A list of the patent management organizations with which these IPA holders have agreements assigning them the rights in subject inventions, and an example of such an agreement; and

(b) A list of approved patent management organizations, if any, not presently having an agreement with an IPA holder.

Further, please furnish a list of IPA holders, patent management organizations and non-IPA holders having agreements with drug screening organizations for screening services to be performed at nongovernmental facilities pursuant to Sec. 818(c) of the regulations referred to above.

Based on the written annual reports HEW receives from grantees as required by Article XI of the IPA, please answer:

(1) How many licenses have been granted to the inventor or to associates of the inventor?

(2) How many subject inventions covered by IPAs failed to be marketed because the developer/licensee miscalculated the market or for such other reasons as insufficient financing, multiple infringers or simple inability to convert the invention into a commercial product? How many of these inventions have been relicensed?

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9. (3) What are the average annual expenses reported to HEW by IPA holders?

10. (4) How many IPA holders are in the black with respect to their efforts to commercialize subject inventions?

11. (5) What is the gross amount of royalties received by IPA holders as reported to HEW in the written annual reports they were required to provide on or before last September 30?

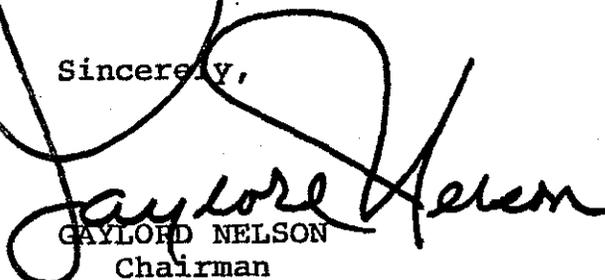
12. Also, please supply a copy of your Information Item No. 59 pertaining to the subcommittee's December hearings on patent policy, plus any subsequent items in the series dealing with the subcommittee's study of Government patent policy or these hearings.

13. Finally, in your testimony please address the question on intellectual property rights -- and the degree of protection they do receive or should receive in the peer review process.

A separate letter is being sent to Secretary Califano explaining that your appearance as a witness is essential to the subcommittee's examination of the history, legal basis and implications of IPA's as an implement of Government patent policy. A copy of my letter to you will be enclosed. It would be greatly appreciated if you would provide us with 10 copies of your prepared statement by May 18 and 50 copies on the day of your appearance before the subcommittee.

If you have any questions about the hearing, please communicate with Gerald Sturges of the committee staff at 224-5175. Thank you.

Sincerely,


GAYLORD NELSON
Chairman

GN/gsy

Encl.