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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

BY

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BEFORE THE

SUBCOMMITTEE ON MONOPOLY AND ANTICOMPETITIVE ACTIVITIES

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

MONDAY, MAY 22, 1978

Mr. Chairman and Members of the Subcommittee:

My name is Norman Latker. I am the Patent Counsel for the Department of Health, Education, and Welfare. (Also chairman of Ad Hoc University Subcommittee and Vice-Chairman Exe. Subcommittee and NOT as a spokesman for Dept. patent policy.

In response to your invitation I will testify on the history and legal basis of the Institutional Patent Agreement (IPA) program in HEW. I will also endeavor to answer the specific questions with regard to IPAs which you stated in your letter of May 2. The Sec. has recently ordered a review of that policy. Further review is also being conducted by the White House.

History of IPA Program

The concept of the IPA first appeared in section 2(b) of the Federal Security Agency Order 110-1 of December 30, 1952, copy attached as Item 1. Section 2(b) was later adopted as 45 CFR 8.1(b) of the Department of Health, Education, and Welfare Regulations after the Department was established by Reorganization Plan No. 1 of 1953. During the years 1954-1958, 18 IPAs were executed. The terms of these agreements were not uniform, and in some instances inconsistent. In 1968, the Department replaced these agreements with the uniform agreement in present use.

In 1965, the Federal Council for Science and Technology's (FCST) Report on Government Patent Policy impliedly endorsed the Department's IPA program as being consistent with President Kennedy's October 10, 1962 memorandum on Government patent policy. Page 16 of the Report is attached as Item 2. A rationale for the IPA program is found in the July 1975 Report of the University Patent Policy Ad Hoc Subcommittee of the Executive Committee of the Committee on Government Patent Policy of FCST. The report is attached as Item 3.

Legal Basis for IPA Program

The legal basis for the IPA program since its inception has been the authority of the head of an executive department under 5 U.S. Code 301 to prescribe regulations for the governing of his department and for the performance of its business. While there are no statutes or judicial decisions which establish precise criteria as to all the terms and conditions which a federal agency may include in its contracts and grants, judicial decisions and opinions of the Attorney General indicate that an agency has discretion to award contracts and grants upon the terms and conditions it deems appropriate to discharge its statutory duties. Among the cases supporting this proposition are Perkins v. Lukens Steel Co., 310 U.S. 113 (1940); King v. Smith, 392 U.S. 389 (1968); and Contractors Association of Eastern Pennsylvania v. Secretary of Labor, 442 F.2d 1959 (1971).

Thus, the overall authority of the head of a department to prescribe regulations for his department and to prescribe the terms and conditions of his department's grants and contracts supplied the legal basis for the establishment of the IPA program in HEW. After the issuance of the Kennedy and Nixon statements on patent policy, the IPA program was examined in the light of those policies and determinations were made by the Department that the IPA program was consistent with those policies. As I previously indicated, the determination to continue the use of IPAs after the issuance of the Kennedy statement was impliedly endorsed by the report of the Federal Council for Science and Technology in 1965. That report stated that examples of exceptional circumstances under the Kennedy patent policy under which a contractor may acquire greater rights than an exclusive license at the time of contracting include instances "where the public interest will be advanced by leaving principal or exclusive rights to a nonprofit educational institution that agrees to administer inventions in a manner deemed by the agency to be consistent with the public interest."

A July 1975 report of the University Patent Policy Ad Hoc Subcommittee of the Executive Committee of the Committee on Government Patent Policy of FCST noted with approval the position taken by FCST in 1965 (page 3, fn. 5).

Responses to Specific Questions of the Subcommittee

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.

Response: 45 CFR 6.3, "Licensing of Department Owned Patents", was amended on October 19, 1969 to more specifically describe the Department's licensing program. Further, 45 CFR Parts 6 and 8 have been overtaken in part by the later issued Federal Procurement Regulations in 41 CFR 101-4, "Licensing of Government Owned Inventions," and 41 CFR 1-9, "Patents, Data and Copyrights," and therefore 45 CFR Parts 6 and 8 are considered superseded by the FPR's to the extent they are inconsistent or expanded by the FPR's.

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. 101, January 7, 1969).

Response: The authorities for this section are the same authorities as those which I have discussed for the IPA program. Sec. 8.8 was issued in response to a recommendation by the Comptroller General:

> "... that the Secretary of HEW develop and put into effect such policies and procedures as are necessary to provide adequate screening and testing of compounds resulting from HEW-supported research in medicinal chemistry to facilitate the development of potential drugs for the prevention and treatment of diseases and disabilities of man." Page 32 of August 12, 1968 Report to Congress, B-164031(2) on "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry."

A copy of the GAO report is attached as Item 4.

3. Please attach to your prepared statement a list of all universities and other nonprofit organizations which hold an IPA administered by HEW.

Response: Attached as Item 5 is a list of all universities and other nonprofit organizations holding IPAs with HEW as of December 7, 1977.

4. 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.

Response: Attached as Item 6 is a list of patent manage- organizations known to have such agreements with IPA holders. A copy of an agreement between such a patent management organization and an IPA holder is attached herewith as Item 7.

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

Response: We have approved no patent management organizations not presently having an agreement with IPA holders.

6. 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 non-governmental facilities pursuant to Sec. 8.8(c) of the Regulations referred to above.

Response: The following is a sample covering a three-year period of universities which have entered into such agreements:

Clarkson College
Wayne State University
Polytechnic Institute of Brooklyn
Bucknell University
Roswell Park Memorial Institute
Medical College of Virginia
William Marsh Rice University
New York Botanical Gardens
Carnegie-Mellon University
Boston University
Lehigh University
Carson-Newman College
University of North Carolina
University of Arizona
University of Massachusetts
University of Calif. at Santa Barbara
University of Georgia
University of Connecticut
University of Virginia
University of Texas at Austin
University of Indiana Foundation
Johns Hopkins University
Duke University
Vanderbilt University
New Mexico State University
Louisiana State University
Shaw University
Virginia Polytechnic Institute
Southern Research Institute
Columbia University
Yeshiva University
Jefferson Medical College
University of Houston
University of North Dakota
University of Chicago
University of Montana
University of Oklahoma
University of Maryland
University of Florida
University of Oregon
University of Southern Cafilfornia

Because of the magnitude of agreements and files involved, we were unable within the allotted time to provide a precise count and list of all agreements.

7. How many licenses have been granted to the inventor or to associates of the inventor?

Response: While the Department requires that licensees of IPA holders be identified on an annual basis, we do not require that they be identified as being the inventor or an associate of an inventor. Selection of licensees is left to the discretion of the IPA holder. From a cursory review of our files, it appears that the number of licenses granted to inventors or associates of inventors is quite small, if any.

8. 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?

Response: Since the innovative process is dynamic rather that static, and inventions are moving through different stages of development at any given time, your question can only be responded to on the basis of averages compiled from past studies which have covered long periods of time. Most of these studies, including an informal sampling conducted by HEW in 1974, indicate that approximately one of every 3 to 4

inventions held by universities is eventually licensed, and of those licensed, approximately 1 of every 9 to 10 inventions held by universities reaches commercial utilization. Of course, the 6 of 9 to 10 inventions never licensed must be presumed to be viewed by industry as being commercially unattractive or possibly inoperative. We do have some examples of inventions that have been relicensed after withdrawal of a prior licensee.

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

Response: HEW does not require IPA holders to report their annual expenses, since the university management office handles inventions derived not only from HEW support but from other federal agencies, the university itself, and private sponsors. It is our understanding that such offices would not be able to identify that portion of expenses devoted to the administration of HEW generated inventions.

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

Response: In light of the fact that HEW has no means of determining what a university management office's expenses are as explained above, it is not possible for HEW to determine whether the university may be in the black, notwithstanding knowledge of gross royalties collected on HEW inventions. We

would, however, direct your attention to the report on the 1973 survey of university patent programs made by Northwestern University, which attempts to respond to questions 9 and 10.

11. 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?

Response: For the year ending last September 30, 1977, the IPA holders reported a gross royalty of $765,293.02.

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 of these hearings.

Response: We understand that Mr. Sturgis his copies these items.

13. Please address the question on intellectual property rights--and the degree of protection they do receive or should receive in the peer review process.

Response: While the establishment of policies on the peer review process is outside my domain, it is the current policy of the Department generally to close meetings of peer review groups among other reasons to protect against disclosure of research designs and protocols submitted with grant applications to the extent that such disclosure would affect

future patent or other valuable commercial rights. Attached as Items 8 and 9 are the reports of the National Commission for the Protection of Human Subjects and the President's Biomedical Research Panel on this subject. These advisory groups were directed by Congress in Title III of the Health Research and Health Services Amendments of 1976, P.L. 94-278, to investigate and study the implications of public disclosure of information contained in research protocols, hypotheses and designs submitted to the Secretary of Health, Education, and Welfare in connection with applications or proposals for grants, fellowships or contracts under the Public Health Service Act.