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STATEMENT BY

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ON PATENT POLICY

BEFORE THE

SUBCOMMITTEE ON MONOPOLY AND ANTICOMPETITIVE ACTIVITIES

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

JUNE 26, 1978

Introduction

I am pleased to be with you today to discuss the National Institutes of Health's perspectives on patent policy. I will deal first with patent policy as it relates to biomedical research generally, and then discuss a specific patent policy issue--recombinant DNA inventions developed with the help of NIH funds.

General Department Patent Policy

Under current DHEW patent regulations, invention rights to discoveries developed under the Department's research support are normally allocated in either of two ways:

First, the Department may enter into an Institutional Patent Agreement (IPA) with a university or other nonprofit organization that has set up mechanisms for administering patents on inventions.

- In 1968, the present IPA's replaced agreements developed by the Department in the 1950's. These earlier agreements proved to be non-uniform and, in some instances, inconsistent. The legal basis for the establishment of the IPA program does not rest on specific statutory authority but rather on the general authority of the Secretary to prescribe regulations and set the terms and conditions for grants and contracts.
- The IPA offers the institution the first option to own all inventions made in performance of Department grants subject to a number of conditions deemed necessary to protect the public interest.

Detailed conditions are set forth for institutions to grant licenses, and a set of conditions for the distribution of royalties is included. Institutions must grant the Government a license to make the invention or have it made for Governmental purposes. Under patent law, the use of patents for research purposes is not an infringement, and ordinarily the invention may be used in research without payment of royalties.

- There are 72 IPA's now being administered by the Department. The Department Patent Branch reports that 167 patent applications were filed under IPA's from 1969 through the fall of 1974. Approximately $24 million is committed by private industry to the development of inventions on the basis of licenses granted under these patents.

Second, for those institutions or organizations that have not entered into a patent agreement with the Department, a somewhat different procedure is followed: In this situation, determination of ownership generally is deferred until an invention has been made, at which time an institution may petition the Department for ownership of the invention or a license under the invention.

- In the past, approximately 90 percent of all such petitions have been granted on the basis of a satisfactory plan proposed by the institution for developing or licensing. During the period from 1969 to the fall of 1974, the Department has reviewed 178 petitions for ownership from institutions not having IPA's and has granted

162 of them. The plans proposed by the institutions call for approximately $53 million to be invested by private industry for development under the licenses awarded through this mechanism. Since the review of the Department's patent policies has not yet been completed, it would be premature to comment on the GSA amendment to the Federal Procurement Regulations mentioned in your letter.

Patenting of Recombinant DNA Research Inventions

In June 1976, shortly before the release of the NIH Guidelines on recombinant DNA research, Dr. Robert M. Rosenzweig, Vice President for Public Affairs at Stanford University, sent me a letter asking NIH to review DHEW policies relating to the patenting of recombinant DNA research inventions. Dr. Rosenzweig noted that both Stanford and the University of California were applying for patent protection for recombinant DNA research inventions developed by their investigators under NIH support. However, in view of the intense public interest in this research generally, the two universities felt the need for a formal advisory opinion by NIH on the patenting of recombinant DNA inventions developed under NIH grants or contracts. A number of other universities indicated similar interest in obtaining the official views of NIH.

Prior to making an official pronouncement of DHEW-NIH policy with respect to patenting of recombinant DNA research inventions, NIH decided to solicit comments from a broad range of individuals and institutions including the scientific community, the public and the private sector.

The views of commentators were solicited on excluding recombinant DNA research inventions from IPA's, so that patents would be granted only for dedication to the public. Possible approaches include the following:

Recombinant DNA research inventions could be excluded from the IPA's. Alternatively, the IPA could require institutions filing patent applications for recombinant DNA research inventions to dedicate all issued patents to the public. Finally, a condition could be added to the institutional patent agreement requiring institutions to assign to DHEW all recombinant DNA research inventions developed under Department support. The Department, as the patent holder, could either dedicate the patent to the public or pursue licensing, with appropriate conditions attached. There was little support among commentators for any of these options. They preferred to have DNA research inventions covered under the IPA's.

Commentator views were also solicited on the possibility of extending NIH Guidelines to the private sector by requiring adherence to the Guidelines through IPA's. The commentators generally supported this extension of Guidelines to private industry through use of IPA's. However, a number pointed out that use of the patent system to achieve compliance with the Guidelines was at best a make-shift solution, because of the difficulty in exercising regulatory control through the patent process.

A review and analysis of comments received on the question of patenting recombinant DNA inventions were completed in December 1976 and referred to the Federal Interagency Committee on Recombinant DNA Research for their attention.

The Interagency Committee, convened by the Secretary of HEW with the approval of the President, serves as a forum to review Federal policy on recombinant DNA issues. It provides coordination among the agencies on recombinant DNA activities and makes administrative and legislative proposals when appropriate.

On the Committee are representatives of all Federal Departments and agencies that support or conduct such research or might have regulatory authority over it.

A number of the agency representatives referred the analysis to their patent counsels. Among agencies commenting were the National Science Foundation, the Defense Department, the Department of Agriculture, the Energy Research and Development Administration, and the Department of Justice.

All agencies on the Committee except Justice agreed that recombinant DNA research inventions should be handled on the same terms as other inventions under IPA's. The Department of Justice believed that, because of the great public interest in this field, ownership of any invention stemming from Government-sponsored recombinant DNA research should be held by the U.S. Government.

One question remains: whether the subject of the patentable processes (specifically recombinant DNA techniques) is of such a distinctive nature that financial return to the inventors should be denied. This position had few advocates among the commentators. There are no compelling economic, social, or moral reasons to distinguish these inventions from others involving biological substances or processes that have been patented, even though developed partially or wholly with public funds. Such inventions include vaccines for rubella and rabies, treatments for herpes infections of the eye, and treatments for uremia. The argument that commercial development of these inventions based on patent protection assures maximum benefits to the public applies as well to the putative benefits of recombinant DNA inventions.

It is recognized that Federal patent policies are under extensive review by the Executive Branch and the Congress. This may lead to actions that could affect the administration of Institutional Patent Agreements generally and the conditions for recombinant DNA research inventions specifically.

It is my decision, however, that recombinant DNA research inventions developed under DHEW-NIH support should, at least for the present, continue to be administered within current DHEW patent agreements with the universities. But such agreements should be amended to ensure that, in any production or use of recombinant DNA molecules, the licensees will comply with the physical and biological containment standards set forth in the Guidelines. This decision was announced in March 1978,

with the concurrence of the HEW Office of General Counsel and the Public Health Service. Mr. Chairman, I would like to submit for the record my decision, the supporting analyses, and all of the comments received. These documents are compiled in Recombinant DNA Research Volume 2, Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules," June 1976-November 1977.

In response to the question in your letter, the Harvard investigators who reported on inducing a bacterium to produce insulin were funded by the NIH, and the university has filed a patent application under its IPA. Several other patent applications have been filed in the recombinant DNA area. I am enclosing a list for the record, Mr. Chairman.

Also, in your letter of invitation you asked me to comment on the fact that in March 1977 NIH introduced the phrase "patentable material" into its standard justification for closing peer review meetings pursuant to exemption 4 of the Federal Advisory Committee Act (FACA). The Federal Advisory Committee Act used to include the same exemptions contained in the Freedom of Information Act (FOIA).

Passage of the Government in the Sunshine Act, effective in March 1977, eliminated the Federal Advisory Committee's use of FOIA exemptions and substituted the Sunshine Act's exemptions as reasons for closing advisory committee meetings. This change did not alter NIH's basic approach in using exemption 4. While the Sunshine Act became the source of exemptions in place of the Freedom of Information Act, exemption 4 is

essentially the same in both statutes. However, we took the opportunity occasioned by the passage of the Sunshine Act to change the standard language used by NIH in citing exemption 4. In so doing, we shifted to the current format to clarify the grounds on which meetings could be closed. In making this language change, no substantive shift from the prior practice was intended.

In fact, NIH's operating instructions to its Committee Management Officers, as revised in light of the Sunshine Act, continue to provide that exemption 4 is not to be used in situations when it is evident in advance that information covered by the exemption will not come up for discussion.

Mr. Chairman, that concludes my statement. I would be pleased to respond to any questions or comments you may have.