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Chairman Nelson. Our first witness this morning is Mr. Norman Latker, Patent Counsel of the Department of Health, Education and Welfare.

STATEMENT OF:

NORMAN LATKER,

PATENT COUNSEL, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

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Mr. Latker. Thank you, Mr. Chairman.

Mr. Chairman, did you want me to proceed?

Chairman Nelson. Go right ahead.

Mr. Latker. My name is Norman Latker. I am the Patent Counsel for the Department of Health, Education, and Welfare. I am also the Chairman of the Ad Hoc University Subcommittee and the Vice Chairman of the Executive Subcommittee of the Subcommittee on Intellectual Property which is a subcommittee of the former Federal Council for Science and Technology. I am not quite sure what its name is now.

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.

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 of which is 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 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 non-profit 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 which I mentioned previously to 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.

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 with 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. Section 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's 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.

Mr. Sturgess. Could I interrupt you there? I wonder in your dual capacity as the Chairman of the Patent Subcommittee which played a key role in the government wide IPA, you just noted the report of the Federal Council of Science and Technology of 1965 offered examples of exceptional circumstances under the Kennedy policy under which a contractor may acquire greater rights, yet when the draft of the government wide IPA was sent around for comment in 1976 the Interior Department, Office of the Solicitor wrote:

"We also note that the exceptional circumstances and special situations language of current FPR provisiond are being used as justification for use of institutional patent agreements. We find this questionable since such language has previously been used only in specific cases where it was determined to be in the government's interest to make an exception in order to obtain research which otherwise would not be done. It is not clear that the proposed arrangement for institutional patent agreements fits this category, since the proposal appears to be of more benefit to the institutions than to the government. Giving institutions an advantage not enjoyed by private concerns, which are generally in a better position to assure successful development and marketing cannot be justified unless it is shown to be of special benefit to

the government in advancing the development of the technology. At present, no such benefit is apparent, and use of the exceptional circumstances and special situations language appears to be unjustified."

That appears to be the end of the quote from the Department of Interior. What about this challenge raised in the comment -- the staff can find no evidence in documents tracking development of the government wide IPA that Interior's objection was even considered? Does it not count at least as much as the 1975 Federal Council interpretation that you cited?

Mr. Latker. Well, all the ~~agencies,~~ [redacted] science agencies, and other agencies such as GSA and Justice, are part of the subcommittees that make up the Federal Council. That ~~was~~ appears to be an opinion of Interior at ~~that~~ a particular point of time. I ~~think at a later date they~~ believe Interior favorably commented on the 1975 report which clearly identified the IPA as an exceptional circumstance situation. ~~In fact, I think there was~~ I believe there was unanimous agreement ~~by~~ on that point by all the agencies that participated ~~in~~ on the university subcommittee ~~on the point that I made and at that particular point in time,~~ ~~yes,~~ I ~~think~~ believe that was Interior's position at the time they served on the Subcommittee. They may have changed ~~but it was later changed by Interior and Interior also served, I think at the time they made that statement~~ their opinion at a later date. -- ~~[illegible]~~ Would you give me the date again, please?

Mr. Sturges. Well, the letter was in reply to the request for comment on the draft IPA which makes it 1976

and probably October.

Mr. Latker. I can give no response other than belief that ~~Well, at any rate I have no response.~~ I am not familiar with the memorandum that you are talking about. Interior's comment was contrary to the clear majority opinion no matter when it was made. ~~I think~~ Interior commented favorably in moving with the IPA. Again, my recollection indicates that

Mr. Sturges. Well, some of the agencies commented from two or more branches or units. I just wondered whether your working group had found any merit in this point raised by the Office of the Solicitor.

Mr. Latker. Well, obviously we did not feel that it reflected the majority view.

You want me to proceed with the statement?

Chairman Nelson. Yes.

Mr. Latker. No. 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.

Mr. Sturges. Let me interrupt with your item 3. Your list of institutions and non-profit organizations holding IPAs administered by HEW shows by our count 71 of them and does not include the University of California, yet the report of NIH on the patenting of DNA inventions developed under HEW's report released in March says there are 72 IPA holders and the University of California, is it one of them.

Mr. Latker. No. The University of California has no IPA.

Mr. Sturges. Has it had one under the current one?

Mr. Latker. They were one of the original 18 that were eliminted in 1968 and replaced by the uniform agreement of 1970.

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

Mr. Sturges. May I pose a question here about the example? You have submitted as your item 7 a copy of an agreement between the University of Rochester and a patent management organization's research corporation made in March, 1953. It provides the research corporation will pay the inventor up to 15 percent of the proceeds of his patent. The University of Rochester is to determine the exact percentage and from what is left, the research corporation will subtract the amounts it needs to be reimbursed for such expenses as applying for and prosecuting patent applications, litigation and extraordinary commercial development of the remainder -- 50 percent to the University of Rochester and 50 percent is retained

Why should the patent manager get such a big slice of the pie?

Mr. Latker. Well, the whole area, it is contingent ~~contingent~~

The one reaching the market must pay the patent manager for all the effort and experience put into the losers.

on success. The patent management organization takes a very large risk in filing statistics, (and these are rough) indicate that a maximum of the one in ten inventions ultimately is commercialized. The 50-50 split after taking care of the inventor has been in existence much longer than the IPA program at HEW. I believe it goes back as far as the establishment of a research corporation which might be traced back to 1914. The split has been acceptable to the universities for many years, which presumes that they recognize there is a very high inherent risk on the part of the patent managers of ever making expenses.

Mr. Sturges. Well, the agreement is 25 years old so if it still being observed it shows the universities approach to distribution of royalties but it should be noted that the HEW institutional patent agreement allows the inventor to be paid up to 50 percent of the first $3,000 gross royalties and the scale slides down to 15 percent. With that kind of scale permitted in the IPA it raises the question do universities go along with the Univer'sty of Rochester kind of split more than not, do you know?

Mr. Latker. Yes, in fact, the scale in the HEW agreement was intended to assure that we would not be impinging on the outstanding agreements with Research Corporation. It is slightly higher than the 15 percent return to the inventor

with the clear intent of insuring that we would not be involved in eliminating the Research Corporation agreements.

Mr. Sturges. I see. Thank you.

Mr. Latker. I had already read the 4th question. No. 5: A list of approved patent management organizations, if any, not presently having an agreement with an IPA holder. Now, I do not know whether I misunderstood your question here.

Mr. Sturges. No, the question was, was there any standing group.

Mr. Latker. 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 Section 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.

Mr. Chairman, I will not take the time to read the list of universities.

Chairman Nelson. They will appear in the record at this point.

xxx lay in

(The list of universities follows:)

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

Mr. Latker. 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.

Mr. Sturges. How large a number do you think it is -- 100 or 200?

Mr. Latker. I would say between 100 and 200. (Later review indicated 67 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 licenseees 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 than 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 three to four inventions held by universities is eventually licensed, and of those licensed, approximately one of every nine to ten inventions held by universities reaches commercial utilization.

Of course, the six of nine to ten 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.

I understand you have a copy of that.

Mr. Sturges. Yes, I do.

Mr. Latker. No. 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.

Mr. Sturges. Did they all respond as required?

Mr. Latker. I am sorry, I did not check that out to Sept 30 but we, prior to September 30, about three months prior thereto a reminder to IPA holders that their we send out an indication that, you know, your reports will be due September 30, and most of the universities are very prompt and do report. But, as indicated, however, whether this includes the entire listing I am not quite sure because I did not check that.

No. 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. Sturges has copies of 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.

I would add that the National Commission requested public statements through ~~the~~ a Federal Register ~~item~~ notice, to which they received ~~something like~~ approximately 250 letters on that subject, and their report is a distillation of the 250 responses.

Mr. Sturges. Mr. Latker, can you tell us about the processing of deferred determinations, that is requests for retention of patent rights by universities coming to HEW after the invention had been made; that is schools not holding IPAs?

It is our understanding processing stopped sometime ago and we would be interested in the details.

Mr. Latker. Well, there is a delay, and backlog of ~~case-by-case~~ reviews in the department, ~~and this is~~ why would be conjecture on my part, ~~why there is a delay~~ although there is a study ~~going on at this point.~~ on Department patent policy being conducted.

Mr. Sturges. There is a what?

Mr. Latker. A study of ~~the higher~~ our patent policy of the department going on, so one could assume that the delay is part of the study or caused by the study.

Mr. Sturges. At what level within the department?

Mr. Latker. General Counsel.

Mr. Sturges. Can you tell us how many applications for rights might be involved?

Mr. Latker. There is a backlog ~~of~~ de in General Counsel's office of between 25 and 30 cases.

Mr. Sturges. Between 25 and 30?

Mr. Latker. Yes.

Mr. Sturges. When did the processing stop?

Mr. Latker. August, 1977.

Mr. Sturges. August of 1977?

Mr. Latker. Yes.

Mr. Sturges. So we are nine months into a period of delay on processing these determinations?

Mr. Latker. Yes.

Mr. Sturges. Has there been any comparable restraint imposed on IPA holders in any way?

Mr. Latker. No.

Mr. Sturges. Mr. Latker, in May of 1977 you testified in the House before the Subcommittee on Science Research and Technology of the House Committee on Science and Technology. You attached some examples of inventions licensed by universities which reached or were near reaching the market place and in your prepared statement you said:

"As you will note, there are a number of pharmaceutical products on this list. We knew of no comparable situations at the time of the GAO report in ~~1978.~~ 1968. I would conjecture this number will increase in subsequent years due to the opportunity of the pharmaceutical industry to capitalize on positive leads from the non-profit sector which could result in ~~production~~ reduction of the industry's escalating R&D costs by eliminating the

number of blind leads.

"The rise in successful development of university generated inventions is also considered significant when noting the steady decline ~~of~~ in introduction of new drug entities in 1959. This slide might also be attributed to the increased cost of drug development. ~~This should lead to increased cost of drug development.~~ In this context it is apparent that the existence of a licensable patent right is probably a primary factor in the successful transfer of the university innovation to the industry and marketplace, and failure to protect such right may affect the transfer of a major health innovation."

Comment: This sentence was misquoted from the testimony before the Thornton Committee. I have corrected it.

That is the end of the quotation. That seems to be a prediction or suggestion that the cost of developing deadend drugs, or those that do not make it to the marketplace should be transferred from the private to the public sector.

Is that what you had in mind?

Mr. Latker. No, not at all. In fact, it is just the opposite. The ability of the universities to license and there are many ~~are some~~ examples of this, with a comparison to an ~~or the~~ inability at one time to license indicates in the latter situation that potential drugs lie ~~and the falling of the land into the public domain~~ ~~is resulted in drugs lying~~ dormant for many years until the government perceives some ~~the~~ pressure ~~of some sort and~~ to involve itself ~~themselves~~ in the development of the drug. In most such situations, Federal funds never become available.

Mr. Sturges. I am sorry, but I am not following your answer. The statement seems to say that, or at least to imply that, in your statement in May of 1977, you said that

campus discoveries are playing a larger role.

Mr. Latker. Right, as long as there ~~is~~ are licensing rights available.

Mr. Sturges. As long as the rights are available?

Mr. Latker. Yes.

Mr. Sturges. Well, does the current institutional patent agreement facilitiate then the development of new drugs that are transferred to the marketplace?

Mr. Latker. Yes.

Mr. Sturges. Do you see more of this occurring?

Mr. Latker. Yes.

Mr. Sturges. Why?

Mr. Latker. Because of the availability of ~~the~~ necessary rights ~~prior to the~~ at a time when the ~~that it was clear to~~ industrial developers needs to commit capital ~~that~~ when those rights were not available ~~and~~ the universities ~~were soccer balls~~ were not considered to be fertile grounds for ~~basic results that might accrue as~~ therapeutic leads ~~to~~ for industrial developers.

Mr. Sturges. Well, has the same attention been paid in the past to the drug development of the campuses as is being paid now?

Do you think it is simply a matter or the rights or are the rights perhaps stimulating greater increase in making drug discoveries on campus?

Mr. Latker. I do not think I follow your question.

Mr. Sturges. Well, could universities have been as

big a factor in the 1960's as discoverers of new drugs as you appear to think they can be now?

Mr. Latker. Well, the whole essence of the 1968 GAO report which I have attached to this presentation indicated that when GAO went out into the university sector and interviewed a number of investigators, they found that the investors were stuck with hundreds of potential therapeutic agents on their shelves, and they advised the GAO that they were unable to make any interface with industry on the basis that industry would not utilize risk capital without some assurance of property protection.

Mr. Sturges. Well, of course, there was a huge backlog of chemical entities from the 1950's and early 1960's that people wished to have screened and certainly, the cancer area was one in which peopled hoped for drugs showing a promise but a year ago in May in your statement you said you would conjecture that this number will increase in subsequent years due to the opportunity of the pharmaceutical industry to capitalize on positive leads from the non-profit sector. That made it sound as if you thought the pharmaceutical industry might be doing less of its own R&D.

Mr. Latker. I did not mean that at all. I think it suggests the opposite; that the HEW with some limited exceptions only sponsors basic research and then ordinarily stops at the point where the compound at most possibly may have shown

some indication of potential [redacted] in humans, [redacted]. That is where our resources and cooperation stops.

At that point it was always presumed that the drug industry would step in and do what you consider the developmental work which is the collection of the necessary clinical data to clear through the Food and Drug Administration. With more positive leads it was perceived industry would invest more in R+D especially development.

I would emphasize that we do have some programs such as cancer chemotherapy that you mentioned in which we do have funding that takes drugs past the point of showing a potential therapeutic value.

Mr. Sturges. Let me go back to page 7 of your statement and your number 7 on that page where you note from a cursory review of your files it appears the number of licenses granted to inventors or associates of inventors is quite small, if any.

There is nothing in the HEW patent agreement to prevent such a license being issued, is there?

Mr. Latker. No.

Mr. Sturges. It is interesting that the National Science Foundation IPA as far as I know does have such a provision and that the government wide IPA in its draft form had such a provision which was deleted from the final. Can you tell us from your recollection of the subcommittee's actio in working on that proposal why it was not knocked out?

Mr. Latker. Well, first I think that the NSF provision does not preclude the grant of licenses to inventor:

or inventor-associated companies. It merely requires that when those individuals are involved ~~that~~ there will be a clearance at NSF.

I have no indication that there has ever been a denial on the part of NSF to permit a university to license such an organization, ~~and~~ As to your comment about that provision showing up in our first draft, if it did, I would suggest that ~~just~~ ~~your asking~~ you ask Jesse Lasken, and served as who is from NSF, ~~was~~ our draftsman, I believe ~~and~~ he was combining the provisions of the HEW and the NSF agreement, ~~This is just conjecture, I think you might get it from NSF when they get up here. We are combining all the features of the HEW and the NSF agreement~~ in order to arrive at a uniform agreement.

The membership at a later date determined that the NSF clause was unnecessary.

Mr. Sturges. Well, could we explore that further? Why is it unnecessary? The draft as I recall indicated that agency approval would be required for such a license.

Mr. Latker. Well, we felt that the information on whether there would be a conflict ~~between the~~ -- I am speaking for the subcommittee now in that I was Chairman and we did things by majority rule -- ~~all the information on conflict~~ was in the hands of the university, ~~and~~ We felt ~~that transmitting~~ that conflict questions were properly in the hands of the university as opposed to the federal government who probably

would not be in as good a position to make a determination as to whether to license an inventor or an inventor-associated organization, on the basis of lack of appropriate information.

Mr. Sturges. Well, the upshot at any rate with respect to the HEW agreement that there is no barrier, no bar to licensing.

Mr. Latker. That is not exactly correct because I would point out that the overall HEW grant policy statement provides that every university shall have a conflict of interest provision in its own policy, accordingly they are required to include, or have an ability to identify, conflict of interest at the university level as required by the HEW grant policy statement. Conflicts are not limited to patents. It is supposed to be a university-wide type of capability, patents or otherwise.

Again, the decision to drop the clause was based on the concept that the university is established and required to take care of this problem.

Mr. Sturges. Does your agency accept as a statement on conflict of interest the 1962 or 1963 at least 15 year old statement by the American Council on Education and American Association of University Professors?

Mr. Latker. I think you are way out of my area. I could not possibly comment on that.

Mr. Sturges. At any rate in terms of grants, there

is as far as you know, some kind of requirement?

Mr. Latker. Yes, there is a requirement [redacted] conflict of interest.

Mr. Sturges. I have no further questions.

Chairman Nelson. Thank you very much, Mr. Latker. Our next witness is Mr. Charles H. Herz, General Counsel, National Science Foundation accompanied by Mr. Jesse Lasken, Assistant to the General Counsel.

If you gentlemen will identify yourselves for our reporter, you may proceed.

STATEMENT OF:

CHARLES H. HERZ,

GENERAL COUNSEL, NATIONAL SCIENCE FOUNDATION, ACCOMPANIED BY JESSE LASKEN, ASSISTANT TO THE GENERAL COUNSEL.

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Mr. Herz. I am Charles Herz, General Counsel of the National Science Foundation. I am very fortunate to have with me, Mr. Jesse Lasken at the committee's request. Mr. Lasken has a great deal more experience and learning than I in this area. He was present at the creation of the proposed standard institutional patent agreements and I think it will be very helpful to the committee and he has also spent many years on the various agency groups and has a great knowledge of the subject.

We appreciate very much your invitation to testify

APPENDIX B

Issues upon which the University Patent Policy Ad Hoc Subcommittee Voted:

(a) Should the Subcommittee treat "public institutions" differently from industrial concerns?

This, of course, was the major issue under consideration, and the report reflects the majority view that special policies should be utilized for public institutions.

(b) Should the Institutional Agreement approach be utilized as the mechanism for providing special treatment to public institutions?

The Subcommittee was unanimously in favor of the Institutional Patent Agreement espoused by the report.

(c) Should universities and other nonprofit institutions be afforded the same treatment?

As reflected by the report, the majority of the Subcommittee felt that since universities and other nonprofit institutions both required industrial aid in bringing their inventive results to the marketplace, the proposal should treat them equally. However, two members of the Subcommittee felt differently. It was their opinion that the line between nonprofit and profit organizations has clouded in recent years, with many nonprofits actually functioning as profit-making organizations. Further, since nonprofit organizations have no educational mission, none of the royalty returns could be utilized for that purpose. They also wondered whether those organizations were strongly motivated to utilize royalty receipts for research purposes. The majority of the Subcommittee felt that these concerns could be resolved on a case-by-case basis at the time a nonprofit organization was negotiating for an Institutional Patent Agreement. Any agreement negotiated could, of course, set forth the manner in which royalty receipts could be utilized.

(d) Should the Institutional Patent Agreement be limited to designated "fields of technology"?

As reflected by the report, the majority of the Subcommittee did not believe the Institutional Patent Agreement should be so limited. However, four members of the Subcommittee felt that the Agreement should be limited to those inventions falling within technological areas

in which the institution had a demonstrated expertise. The majority felt that such a condition would make a determination of ownership impossible until the invention was identified, since only at that time could it be determined what field of technology it arose in. Further, the majority felt that the "fields of technology" could not be defined with any accuracy, which could result in prolonged argument as to whether an invention fell within or out of a particular field.

(e) Should the results of the survey of agency practices and statistics conducted by the Subcommittee be included in the report?

The majority of the Subcommittee felt that the survey should be included. (See Footnote 2 in the Text of the Report.) However, it was also agreed that no comments would be made regarding the survey, due to the numerous differing interpretations that could be attached to the statistics. Under any circumstances, no comparable figures are available regarding industry generated inventions.

(f) Should an interagency panel have the responsibility for reviewing and approving Institutional Patent Agreements for purposes of uniformity?

The Subcommittee was unanimously in favor of an interagency panel review of requests for Institutional Patent Agreements, which will serve to achieve uniform treatment of individual institutions throughout the Government.

(g) Should any distinction be made between inventions arising from grants or contracts?

The Subcommittee unanimously agreed that there should be no distinction made between grants and contracts, since the inventions that arise from either instrument would in most instances require industrial aid in completing development and bringing the invention to the marketplace. Further, the Subcommittee determined that there was no clear definition of grant or contract acceptable or utilized by all the agencies. This position is reflected in the report by failure to make a distinction between grants and contracts.

(h) Should the Institutional Patent Agreement be included under 1(a) and/or 1(c) of the Presidential Policy Statement?

The Subcommittee unanimously agreed that the Institutional Patent Agreement should be justified under the "exceptional circumstances" language of Paragraph 1(a) or under the "special situation" provision of Paragraph 1(c) of the President's Statement.