THE PATENTING OF RECOMBINANT DNA RESEARCH INVENTIONS DEVELOPED UNDER DHEW SUPPORT:

An Analysis by the Director,
National Institutes of Health

November 1977

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

March 2, 1978

Dr. Robert M. Rosenzweig
Vice President for Public Affairs
Stanford University
Stanford, California 94305

Dear Dr. Rosenzweig:

Shortly after the release of the NIH Guidelines on Recombinant DNA Research in June 1976, you sent me a letter requesting that the National Institutes of Health review DHEW policies relating to the patenting of recombinant DNA research inventions. As you know, your letter prompted NIH to review current DHEW patent regulations governing existing institutional patent agreements and to consider how recombinant DNA research inventions should be handled under the terms of those agreements. Over the summer and fall of 1976, NIH solicited comments from a broad range of individuals and institutions on this matter.

An analysis of the comments received on the question of patenting recombinant DNA inventions was completed in December 1976, and was referred for review to the Federal Interagency Committee on Recombinant DNA Research. As you know, this Committee was convened by the Secretary of HEW, with the approval of the President, to address the extension of NIH Guidelines beyond NIH to the public and private sectors.

In an interim report to the Secretary in March 1977, the Committee recommended that legislation be developed to govern the conduct of recombinant DNA activities nationally. On the basis of those recommendations, an Administration bill was drafted and was introduced in Congress by Senator Edward M. Kennedy and Representative Paul G. Rogers. Congressional hearings were held, but no bills were enacted in the past session. It appears, however, that new bills will be considered shortly by the relevant congressional committees.

The Committee reviewed NIH patent policies with respect to recombinant DNA research in May, and the Public Health Service and the Office of the General Counsel completed a review of the report in December. The report, enclosed, provides an analysis of all comments received on this matter and of the Interagency Committee review of patent policy. On the basis of the findings contained in the report and my discussions with Dr. Julius Richmond, the Assistant Secretary for Health, and Peter Libassi, General Counsel for the Department, it is my recommendation that at least for the present, recombinant DNA research inventions developed under DHEW-NIH support should continue to be administered within current DHEW patent

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Contents

I. Introduction 1

II. Review of Issues and Comments Received in the Patenting of Recombinant DNA Inventions 3

III. Interagency Committee 10

IV. Summary Review and Analysis 13

APPENDICES 18

THE PATENTING OF RECOMBINANT DNA RESEARCH INVENTIONS DEVELOPED UNDER DHEW SUPPORT: An Analysis by the Director, National Institutes of Health, November 1977

I. Introduction

The need for the Department of Health, Education, and Welfare (DHEW) to establish a policy on the patenting of DHEW-supported inventions involving the use of recombinant DNA molecules has occasioned efforts to achieve a consensus of views from the public and private sectors. An account of these efforts, with relevant background and analysis, is presented here.

On June 23, 1976, the National Institutes of Health (NIH) released guidelines to govern the conduct of NIH-supported research on recombinant DNA molecules. In this research, "genes"--that is, deoxyribonucleic acid (DNA) molecules--from virtually any living organism can be transferred to single cells from certain completely unrelated organisms. These experiments depend on the ability to join genetic material of different sources and then to propagate the resulting hybrid elements in single bacterial and animal cells. The NIH Guidelines establish carefully controlled conditions for the conduct of experiments involving the insertion of such recombinant genes into organisms such as bacteria.

The guidelines were developed by a scientific advisory committee created by NIH in response to requests by many scientists engaged in this field of research. These scientists had previously called for a moratorium on certain kinds of experiments while appropriate guidelines were devised. In December 1975 the NIH Recombinant DNA Advisory Committee

Appendix I lists all individuals and groups whose views were solicited in the drafting of the present analysis. A copy of the letter soliciting their comments is also attached. All correspondence from the commentators will be published in the second of a series of volumes that document the public policy issues and the proceedings relating to NIH decisions on recombinant DNA research.

A review and analysis of comments received on the question of patenting recombinant DNA inventions was completed in December 1976 and referred to the Federal Interagency Committee on Recombinant DNA Research for their attention. Following the Committee review, the report was considered by the DHEW Office of the General Counsel, the Public Health Service, and the National Institutes of Health. The review, together with a brief report on related activities of the Interagency Committee, appears below.

II. Review of Issues and Comments Received in the Patenting of Recombinant DNA Inventions

A. Department of Health, Education, and Welfare Patent Policies

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 instituted mechanisms for administering patents on inventions (see Appendix II). The IPA provides the institution the first option to own all inventions made in performance of Department grants or contracts, subject to a number of conditions deemed necessary to protect the public interest. Some of the more important conditions are--

applications were filed from 1969 through the fall of 1974 under IPAs. Approximately $24 million is committed to the development of inventions on the basis of licenses granted under these patents. Meanwhile the Department has reviewed 178 petitions for ownership from institutions not having IPAs and has granted 162 of them. Approximately $53 million has been invested or committed to development under the licenses awarded through this mechanism. The commitment of private risk capital in these instances may be viewed as evidence that a licensable patent right is a primary factor in the successful transfer of results from Department-funded research to the public.

It indeed appears that the incentives provided by Department patent policy have encouraged the development of new technology and its transfer to the public--a clear benefit to the United States.

B. The Patenting of Recombinant DNA Research Inventions

1. Patenting and Disclosure of Information

In reviewing patent policies generally, the effect of the processing of patent applications on the rapid dissemination of scientific and safety information must be considered. Under U.S. law an inventor has a one-year period of grace after research results are published in which to file for a patent. In a number of foreign countries, however, valid protection requires that a patent application be filed prior to publication. If one publishes first, valid patent protection cannot be obtained. Thus it could be anticipated that the effect of allowing patents on recombinant DNA inventions would be to encourage U.S. inventors to file for

for the expedited processing of patents. The order and its subsequent review by the Interagency Committee is discussed in Section 3, devoted to the Interagency Committee review.

2. Exclusion of DNA Research Inventions from IPAs

The views of commentators were solicited on excluding recombinant DNA research inventions from IPAs, 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 IPAs. None of the commentators favored this option.

Alternatively, the IPA could require institutions filing patent applications for recombinant DNA research inventions to dedicate all issued patents to the public. No commentator voiced support for this.

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 assignee, could either dedicate the patent to the public or pursue licensing, with appropriate conditions attached. Some commentators supported this policy, including four members of the Recombinant Advisory Committee. Among the industrial representatives, one commentator found this option acceptable. Several commentators who attended the public hearing favored this policy option, and one suggested that royalties accrued by the Government should be used to

such as compliance with the NIH Guidelines, as a condition for granting an exclusive or a nonexclusive license.*

The commentators generally supported the inclusion of requirements in the IPAs which would extend the NIH Guidelines beyond NIH grantees and contractors to private industry.

Commentators from industry had reservations about mandatory compliance with the NIH Guidelines as a condition for obtaining licenses. Most found, however, that the use of the patent system for requiring compliance with the Guidelines would be acceptable. It was noted that the Guidelines would need to be modified for application to industry and that the development of a plan for their administration through the patent system would require considerable thought and care. A number of industrial commentators also pointed out that use of the patent system to achieve compliance with the Guidelines could only be a temporary measure, for legislation or some form of administrative regulation would ultimately be needed to cover recombinant DNA research activity in both the public and private sectors. The Federal Government,

* A nonexclusive license allows several licenses to be granted simultaneously for the development and marketing of one patentable invention. As noted in the relevant section of the patent agreement included in Appendix II, an institution must attempt to grant nonexclusive licenses. When the institution is unable to find a market for nonexclusive licenses, it may then grant an exclusive license. An exclusive license permits only one license to be granted for a limited time. A number of conditions are set forth in the patent agreement governing the granting of an exclusive license (see Appendix II). In an alternative approach to that mentioned above, the Department could review and approve exclusive licenses but not review nonexclusive licenses.

of the NIH Guidelines to govern research in these sectors and, if necessary, to recommend appropriate legislative or executive action. The Committee consists of all Federal Departments and agencies that support and conduct such research and all regulatory agencies that may have potential authority over it. (The members of the Committee are listed in Appendix III.)

After several months of work, the Interagency Committee agreed that legislation was required to ensure uniform standards to govern all recombinant DNA activities nationally. After detailed deliberations, the Committee agreed on a set of elements for proposed legislation. The agreed-upon elements and various alternatives reviewed by the Committee were presented in an Interim Report transmitted on March 15, 1977, to HEW Secretary Califano who had legislation developed along the lines recommended by the Committee. The Administration bill, drafted by the Department, was introduced into Congress, where it and several other bills dealing with recombinant DNA activities are pending.

B. Committee Review of Patent Policies

1. Commerce Department Order

The Department of Commerce published in the Federal Register on January 13, 1977, an order for the accelerated processing of patent applications for recombinant DNA inventions. In response to expressions of concern by members of Congress, HEW Secretary Califano requested Secretary of Commerce Juanita Kreps to withdraw the order pending review by the Interagency Committee. In a notice filed in the

All agencies voiced support for DHEW's policies governing Institutional Patent Agreements. Further, all except Justice believe that recombinant DNA research inventions should be handled no differently from other inventions under the terms of the IPAs. The Department of Justice believed that, in view of the great public interest in this research, ownership of any invention stemming from Government-sponsored research in the recombinant DNA field should be held by the U. S. Government.

IV. Summary Review and Analysis

From all the comments received, there was general support for Institutional Patent Agreements between the DHEW and grantee institutions. The agreements allow, through appropriate conditions, the disposition of inventions as a result of Department-supported research. Under the terms, there is a careful delineation of the rights and duties of grantees and of the Department. Detailed conditions are set forth for institutions to grant exclusive and nonexclusive licenses, and a set of conditions for the distribution of royalties is included. Either party may terminate the agreement upon 30 days notice.

Under the terms of the agreement, institutions must grant the Government a royalty-free nonexclusive license, under which any grantee or contractor of the Government operates. Under patent law, the use of patents for research purposes is not an infringement, and anyone may use the invention in research without paying royalties. In sum, DHEW Institutional Patent Agreements are perceived to strike a fair and equitable balance between public rights and private interests.

They were divided, however, on whether to achieve that goal through the use of patent agreements. Several commentators recommended Federal action to ensure uniform standards with appropriate monitoring. They noted that the implementation of the NIH Guidelines through licenses granted under patents is awkward at best and would be only a temporary solution.

The Interagency Committee members voiced strong support for Department policies governing Institutional Patent Agreements, and all except representatives of the Department of Justice believe that recombinant DNA research inventions should be considered within the existing terms of the Institutional Patent Agreement. It should be noted that the Justice Department opinions rested heavily on a draft bill orginally proposed by Senator Kennedy for the regulation of recombinant DNA research activities. Specifically, Justice referred to the patent sections of this draft bill that were based on the concept of Government ownership of recombinant DNA research inventions. In subsequent versions of Senator Kennedy's bill, however, all sections related to patents were eliminated.

The perceived need for extension of the Guidelines generated support among the commentators in the summer and fall of 1976 for the use of patents as a means of obtaining compliance. Legislation to ensure uniform standards and regulations nationally for all recombinant DNA activities in both the public and private sectors was considered in the First Session, 95th Congress. In the current session, legislation once again is being considered. Use of the Institutional Patent Agreement as a means of obtaining compliance with the NIH guidelines is not an adequate substitute for legislation.

will comply with the physical and biological containment standards set forth in the Guidelines in any production or use of recombinant DNA molecules under the license. If legislation is passed, these safety standards will be mandated by the law for all who conduct or support recombinant DNA research.

Appendix I

SAMPLE LETTER ON DHEW PATENT POLICY AS APPLIED TO RECOMBINANT DNA INVENTIONS; ADDRESSEES; RECOMBINANT DNA ADVISORY COMMITTEE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

September 8, 1976

Dear

I am writing to solicit your views on the question of patent applications in the area of recombinant DNA research activity. As you may know, Stanford University and the University of California have proceeded to file a patent application on a process for forming recombinant DNA. This invention was generated in performance of an NIH grant. A number of other Universities, including the University of Alabama, may also file patent applications on derivatives of recombinant DNA research. Notwithstanding Stanford's right to file under the terms of a prior agreement with the Department, they have solicited NIH's view on an appropriate plan for administration of this invention.

These patent activities, the certitude that other important inventions in this field are forthcoming, and the public's apprehension over control of recombinant DNA research compel inquiry into whether the Department's normal policy of allocating invention rights is consonant with the concerns about this research or whether special treatment would be more appropriate.

Invention rights are normally allocated in either of two ways under Department patent regulations--

First, if a University or other nonprofit institution seeks to enhance its technology transfer capability, the Department may enter into an Institutional Patent Agreement (IPA). This provides to the institution the first option to ownership in all inventions made in performance of Department research, subject to a number of conditions deemed necessary to protect the public interest. Some of the more important conditions are:

1. a royalty-free license permitting the Government and those functioning under Government direction to practice the invention,

2. a limit on the term of any exclusive license granted,

3. Department authority to withdraw specified grants from the agreement, and

As noted, Stanford has indicated some willingness to consider modification of their IPA as it relates to such research. There are a number of possible policy options, short of the present allocation of rights under the IPA, which could be considered for discussion with Stanford and as possible alternatives to the present allocation of rights made under all other IPA's. Some of these options are as follows:

1. Institutions could be discouraged from filing patent applications on inventions arising from recombinant DNA research. If this option were pursued, publication would be relied on to cut off all possible adverse patent claims.

2. Institutions could be asked to file patent applications on inventions arising from recombinant DNA research and to dedicate all issued patents to the public. This would, to a greater extent than 1., block adverse patent claims.

3. Institutions could be asked to assign all inventions made in performance of recombinant DNA research to the Department. The Department as assignee of the invention could either pursue the licensing of whatever patent applications were filed or dedicate issued patents to the public.

4. The Department could continue to permit institutions to exercise their first option to ownership under the IPA but require that all licensing of patented inventions be approved by the Department. The Department could set certain conditions for approval, such as compliance with the NIH guidelines on recombinant DNA research.

5. The Department could permit institutions to retain their first option as in 4., but approve only exclusive licenses. Here, as above, the Department could set out conditions to account for the special nature of recombinant DNA research, both in approved exclusive and nonexclusive licenses.

If it is determined that institutions with IPA's should be permitted to retain ownership of inventions arising from recombinant DNA research, I am concerned about the effect of the processing of patent applications on the dissemination of research information. Under United States law, an inventor has a one-year period of grace after research results are published in which to file in order to obtain a valid United States patent. However, valid protection in a number of foreign countries requires that a patent application be filed prior to publication. If one publishes first, valid patent protection cannot be obtained in such countries. Our patent people believe that any necessary patent applications can be handled expeditiously without an undue burden on disclosure. I am especially mindful of the concerns expressed at the

ADDRESSEES OF SAMPLE LETTER:
Members of the Advisory Committee to the Director, NIH, Past and Present; and
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1976

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Appendix II

INSTITUTIONAL PATENT AGREEMENT GOVERNING GRANTS AND AWARDS FROM THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

This Agreement, made and entered into this _____ day of _____, 19_____, by and between the United States of America, as represented by the Assistant Secretary (Health and Scientific Affairs) of the Department of Health, Education, and Welfare, hereinafter sometimes referred to as the Grantor, and _____ _____, hereinafter referred to as the Grantee.

WITNESSETH:

WHEREAS, the Regulations of the Department of Health, Education, and Welfare, covering inventions resulting from research grants, fellowship awards, and contracts for research (45 CFR Parts 6 and 8), provide in Secs. 8.1 through 8.5 that upon approval by the Assistant Secretary (Health and Scientific Affairs), the ownership and disposition of domestic and foreign rights to inventions arising out of activities assisted by grants and awards may be left to the Grantee pursuant to its approved established patent policy, with such modifications as may be agreed upon; and

WHEREAS, the Grantee is desirous of entering into an agreement whereby it has a first option to retain principal rights in and to administer inventions made in the course of or under research supported by grants and awards from the Department of Health, Education, and Welfare, pursuant to the aforesaid Regulations; and

WHEREAS, the Assistant Secretary (Health and Scientific Affairs) has reviewed the patent policy of the Grantee as set forth in _____ _____ _____, and its practices thereunder and has found them to be acceptable, subject to the provisions of this Agreement, and that said

application thereon. In such event, all rights in and to such invention, except rights in any foreign patent application filed by Grantee, shall be subject to disposition by the Grantor in accordance with its Regulations then in effect.

IV. Supplementary Patent Agreements

(a) The Grantee shall obtain patent agreements from all persons who perform any part of the work under a grant or award from the Department of Health, Education, and Welfare, exclusive of clerical and manual labor personnel, requiring that such persons promptly report and assign all subject inventions to Grantee or its approved patent management organization.

(b) The Grantee shall include the following provision in any contract it enters into involving research and/or development for which DHEW research grant or award funds are utilized.

"The Contractor hereby agrees to report fully and promptly to _____ (Grantee) any invention conceived or first actually reduced to practice in performance of this contract (hereinafter referred to as "such invention(s)", and to assign all right, title and interest in and to such invention to _____ (Grantee) or its designee.

"In addition, the Contractor agrees to furnish the following materials, disclosures and reports:

'(i) Upon request, such duly executed instruments (Prepared by the _____ (Grantee) or its designee) and such other papers as are deemed necessary to vest in the _____ (Grantee) or its designee the rights granted under this clause and to enable the _____ (Grantee) or its

(d) If the Grantee specifies that no U.S. patent application will be filed (or having specified that it intends to file, thereafter notifies the Grantor to the contrary), the Grantee shall promptly inform the Grantor of the date and identification of any known publication of subject invention made by or known to the Grantee or, where applicable, of any contemplated publication to be made by or known to the Grantee, and also the date subject invention or any embodiment thereof was first in public use or on sale in the United States and shall furnish such other information (and have executed such documents as provided in VIII(f) as may be required to enable the Grantor to make disposition of subject invention rights).

VI. Administration of Inventions on Which the Grantee Elects to File Patent Applications

(a) The Grantee shall require assignment to it of all right, title and interest in and to each subject invention on which it elects to file any patent application for administration by it in accordance with and subject to the terms and conditions herein set forth. Assignments from the inventor to the Grantee under U.S. patent applications shall be promptly obtained and recorded by the Grantee in the United States Patent Office, and copies of the recorded assignment shall be furnished to the Grantor.

(b) The Grantee shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license for governmental purposes and on behalf of any foreign government, pursuant to any existing or future treaty or agreement with the United States under each U.S. or foreign patent application it elects to file on a subject invention. The form of the license to be granted shall be as set forth in Exhibit "A" attached hereto, and by this reference made a part hereof. Any license issued by Grantee shall be made expressly subject to the license to the Government of the United States.

(c) The Grantee shall administer those subject inventions to which it elects to retain title in the public interest and

(f) If permitted by its patent policies and the terms of the grant or award under which an invention is made, the Grantee may share royalties received with the inventor(s), provided that the Grantee shall not pay the inventor(s) more than (1) fifty percent (50%) of the first $3,000 gross royalty paid under the patent, (2) twenty-five percent (25%) of the gross royalty income between $3,000 and $13,000, and (3) fifteen percent (15%) of the gross royalty in excess of $13,000. The balance of the royalty income after payment of expenses incident to the administration of all inventions assigned to it pursuant to the provisions of this Agreement shall be utilized for the support of educational and research pursuits.

(g) All licenses issued by the Grantee to other than the Government of the United States under any patent application or patent on a subject invention shall be subject to the conditions of this Agreement and shall specifically reserve to Grantor those rights specified in paragraph XII hereof. The Grantee shall, upon request, promptly furnish copies of any license agreements entered into by it to the Department.

VII. Patent Management Organizations

The Grantee shall not assign any subject invention to parties other than the Grantor in circumstances as set forth in this Agreement except it may assign rights in the invention to a nonprofit patent management organization, provided that the patent administration agreement between such organization and Grantee is approved by the Grantor. Any reference to a Grantee in this Agreement shall also include a patent management organization when applicable and an assignment to such an organization shall be subject to all the terms and conditions of this Agreement.

VIII. Patent Applications

(a) Grantee shall promptly furnish Grantor with a copy of each U.S. patent application filed in accordance with this Agreement specifying the filing date and the serial number. Grantee shall promptly notify Grantor of each foreign patent application filed, including filing date and serial number, and shall furnish a copy of each application upon request.

IX. Invention Reports and Certifications

Notwithstanding the provisions of this Agreement, the Grantee shall provide invention reports and certifications as may be required by the terms of any grant or award.

X. Disclosure and Publication

The Grantee shall not bar or prohibit publication of disclosures of inventions on which patent applications have been filed.

The Grantor shall have the right to publish and make disclosure of any information relating to any subject invention whenever deemed to be in the public interest, provided that upon request, reasonable opportunity shall be afforded the Grantee to file U.S. and foreign patent applications.

XI. Reports on Development and Commercial Use

The Grantee shall provide a written annual report to the Department on or before September 30 of each year covering the preceding year, ending June 30, regarding the development and commercial use that is being made or intended to be made of all subject inventions left for administration by the Grantee. Such reports shall include information regarding development, the date of first commercial sale, gross sales by licensees, gross royalties received by the Grantee, and such other data and information as the Department may specify.

XII. Additional Licenses

(a) The Grantee agrees that if it, or its licensee, has not taken effective steps within three years after a United States patent issues on a subject invention left for administration to the Grantee to bring that invention to the point of practical application, and has not made such invention available for licensing royalty-free or on terms that are reasonable in the circumstances, and cannot show cause why he should retain all right, title and interest for a further period of time, the Grantor shall have the right to require

made under grants or awards entered into during and subject to this Agreement will not be affected by such a termination except that in the event the Department terminates this Agreement because of a failure or refusal by Grantee to comply with its obligations under Articles V or VI of this Agreement, the Department shall have the right to require that the Grantee's entire right, title and interest in and to the particular invention with respect to which the breach occurred be assigned to the United States of America, as represented by the Secretary of the Department of Health, Education, and Welfare.

XV. Limitation

It is agreed and understood that this Agreement shall not apply to any grants or awards issued under statutes containing requirements for disposition of invention rights with which the provisions of this Agreement are inconsistent. It is further agreed, that any constituent agency of the Department of Health, Education, and Welfare may, with the approval of the Assistant Secretary (Health and Scientific Affairs), provide as a condition of any grant or award that this Agreement shall not apply thereto. It is also agreed that any constituent agency of the Department of Health, Education, and Welfare may provide, subject to approval by the Assistant Secretary (Health and Scientific Affairs), that this Agreement shall apply to specific research contracts.

IN WITNESS WHEREOF, each of the parties hereto

EXHIBIT "A"

LICENSE TO THE UNITED STATES GOVERNMENT

WHEREAS, _____ (Inventor), of _____, has invented _____ (Invention), and filed a patent application thereon in _____ (Country) +++, bearing Serial No. _____, filing date _____; and

WHEREAS, the invention was made in the course of research supported by grant(s) from the Department of Health, Education, and Welfare; and

WHEREAS, the United States Government is entitled to certain rights in and to said invention and application by reason of the terms of said grant(s); and

WHEREAS, the _____ (Institution), hereinafter called the "Licensor" has acquired by assignment from the inventor the entire right, title, and interest of the inventor to such invention;

NOW, THEREFORE:

1. The Licensor, in consideration of the premises and other good and valuable consideration, hereby grants and conveys to the United States Government a royalty-free, nonexclusive and irrevocable license for governmental purposes and on behalf of any foreign government pursuant to any existing or future treaty or agreement with the United States under the aforesaid patent application, and any and all divisions or continuations, and in any and all patents or reissues which may be granted thereon during the full term or terms thereof. As used herein, "governmental purpose" means the right of the Government of the United States (including any agency thereof, state or

Appendix III

INTERAGENCY COMMITTEE ON RECOMBINANT DNA RESEARCH
JUNE 1977

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domestic municipal government) to practice and have practiced (made or have made, used or have used, sold or have sold) throughout the world by or on behalf of the Government of the United States.

2. The Licensor covenants and warrants that he has the right to grant the foregoing license, and that any assignment or license which he may make of the invention or the said patent applications or patents thereon, shall expressly be made subject to this license.

3. The Licensor agrees that the Government shall not be estopped at any time to contest the enforceability, validity, scope of, or title to, any patent or patent application herein licensed.

_____
(Institution)

_____
(Signature)

_____
(Print or type name)

Date _____

_____
(Official Title)

CERTIFICATE

I, _____, certify that I am the _____ of the Institution named as Licensor herein; that _____, who signed this License on behalf of the Institution is _____ of said Institution; and that said License was duly signed for and in behalf of said Institution by authority of its governing body, and is within the scope of its corporate powers.

has executed this Agreement as of the day and year first above written.

UNITED STATES OF AMERICA

By_____

Title_____

_____
(GRANTEE)

(Corporate Seal) By_____

Title_____

CERTIFICATE

I, _____, certify that I am the Secretary of _____ named above; that _____, who signed this Agreement on behalf of said corporation was then _____ of said corporation; and that this Agreement was duly signed for and in behalf of said corporation by authority of its governing body and is within the scope of its corporate powers.

Witness my hand and the seal of said corporation this _____ day of _____, 19_____.

(Corporate Seal) By_____

(1) assignment of said patent to the United States, as represented by the Grantor; (2) cancellation of any outstanding exclusive licenses under said patent; or (3) the granting of licenses under said patent to an applicant on a nonexclusive, royalty-free basis or on terms that are reasonable in the circumstances.

(b) The Grantor reserves the right to license or to require the licensing of other persons under any U.S. patent or U.S. patent application filed by the Grantee on a subject invention on a royalty-free basis or on terms that are reasonable in the circumstances, upon a determination by the Assistant Secretary (Health and Scientific Affairs) that the invention is required for public use by governmental regulations, that the public health, safety, or welfare requires the issuance of such license(s), or that the public interest would otherwise suffer unless such license(s) were granted. The Grantee and its licensees shall be given written notice of any proposed determination pursuant to this subparagraph not less than thirty (30) days prior to the effective date of such determination, and that if requested, shall be granted a hearing before the determination is issued and otherwise made effective.

XIII. Inventions by Federal Employees

Notwithstanding any provision contained in this Agreement, inventions made by Federal employees, or by Federal employees jointly with others, shall be subject to disposition under provisions of Executive Orders, Governmental and Department Regulations applicable to Federal employees.

XIV. Termination

This Agreement may be terminated by either party for convenience upon thirty (30) days written notice. Disposition of rights in, and administration of inventions

(b) Upon request, Grantee shall fully advise the Grantor concerning all steps and actions taken during the prosecution of any patent application covering a subject invention and shall, upon request, furnish copies of any final actions, amendments, petitions, motions, appeals or other papers relating to the prosecution of said application.

(c) Upon request, the Grantee shall promptly furnish to the Grantor an irrevocable power of attorney granting the right to inspect and make copies of any patent application covering a subject invention or any of the final actions, amendments, petitions, motions, appeals, or other papers relating to the prosecution of said application.

(d) The Grantee shall include the following statement in the first paragraph of the specification following the abstract of any patent application filed on a subject invention:

> "The invention described herein was made in the course of work under a grant or award from the Department of Health, Education, and Welfare."

(e) The Grantee shall not abandon any U.S. patent application filed on a subject invention without first offering to transfer all rights in and to such application to the Grantor not less than forty-five (45) days prior to the date a reply to the Patent Office action is due. If the Grantor does not request assignment within thirty (30) days of receipt of this offer, the Grantee may permit the application to go abandoned.

(f) If the Grantee elects to file no patent application or to abandon prosecution of a U.S. patent application on a subject invention, he shall, upon request, execute instruments or require the execution of instruments (prepared by the Grantor) and such other papers as are deemed necessary to vest in the Grantor all right, title and interest in the subject invention to enable the Grantor to apply for and prosecute patent applications in any country.

shall, except as provided in paragraph (d) below, make them available through licensing on a nonexclusive, royalty-free or reasonable royalty basis to qualified applicants.

(d) The Grantee may license a subject invention on an exclusive basis if it determines that nonexclusive licensing will not be effective in bringing such inventions to the commercial market in a satisfactory manner. Exclusive licenses should be issued only after reasonable efforts have been made to license on a nonexclusive basis, or where the grantee has determined that an exclusive license is necessary as an incentive for development of the invention or where market conditions are such as to require licensing on an exclusive basis. Any exclusive license issued by Grantee under a U.S. patent or patent application shall be for a limited period of time and such period shall not, unless otherwise approved by the Assistant Secretary (Health and Scientific Affairs), exceed three years from the date of the first commercial sale in the United States of America of a product or process embodying the invention, or eight years from the date of the exclusive license, whichever occurs first, provided that the licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to approval of the Grantor. Upon expiration of the period of exclusivity or any extension thereof, licenses shall be offered to all qualified applicants at a reasonable royalty rate not in excess of the exclusive license royalty rate.

(e) Any license granted by the Grantee to other than the Government of the United States under any patent application or patent on a subject invention shall include adequate safeguards against unreasonable royalty and repressive practices. Royalties shall not, in any event, be in excess of normal trade practice. Such license shall also provide that all sales to the U.S. Government shall be royalty free.

designee to apply for and prosecute any patent application, in any country, covering such invention.

'(ii) Interim reports on the first anniversary of this contract where extended or renewed and every year thereafter listing all such inventions made during the period whether or not previously reported or certifying that no inventions were conceived or first actually reduced to practice during the applicable period.

'(iii) Prior to final settlement of this contract, a final report listing all such inventions, including all those previously listed in interim reports, or certifying that no inventions were conceived or first actually reduced to practice under the contract.'"

V. Report of Invention

(a) The Grantee shall submit a written invention report to the Grantor of each subject invention promptly after conception or first actual reduction to practice.

(b) Such invention report shall be furnished directly to the Grantor in addition to any other requirement under any grant or award for the submission of progress or financial reports, and whether or not reference to subject invention has been made in any progress or other report furnished to the Grantor; such report shall include description of such invention, appropriately illustrated by a simple sketch or diagram, to permit the invention to be understood and evaluated, and such other information as Grantor may require.

(c) The report shall specify whether or not Grantee intends to file a U.S. patent application or any foreign patent application on the invention. Notice of an election not to file a U.S. patent application shall be given Grantor not less than ninety (90) days prior to the date a statutory bar becomes effective.

policy provides for administration by the Grantee of patents in the public interest and is consistent with the stated objectives of the President's Statement and Memorandum of Government Patent Policy, issued October 10, 1963;

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

I. Scope of Agreement

This Agreement shall define the rights of the parties hereto regarding disposition of title to inventions made in the course of or under research supported by grants and awards from the Department of Health, Education, and Welfare, which are subject to the Department Patent Regulations and are issued after the date hereof.

II. Definitions

(a) The term "subject invention" as used in this Agreement means any process, machine, manufacture, composition of matter or design, or any new or useful improvement thereof, and any variety of plant which is or may be patentable under the Patent Laws of the United States made in the course of or under research supported by grants and awards from the Department of Health, Education, and Welfare.

(b) The term "made" when used in relation to any invention or discovery means its conception or first actual reduction to practice.

III. Disposition of Principal Rights to Subject Inventions

The Grantee shall have the right to elect to file patent application in the United States and in foreign countries on any subject invention and to administer such invention pursuant to the provisions of this Agreement. Grantee shall notify Grantor at the time each subject invention is reported to Grantor as required by paragraph V hereof, if it intends to file patent application(s) on and to administer the invention. If Grantee does not elect to file a U.S. patent application on and to administer a subject invention, it shall notify Grantor in sufficient time to permit Grantor to file a U.S. patent

RECOMBINANT DNA MOLECULE PROGRAM ADVISORY COMMITTEE

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WHO RECEIVED A COPY OF THE SAMPLE LETTER

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Director's Advisory Committee meeting in February that there be a rapid dissemination of research and safety results in recombinant DNA research. I would especially welcome your thoughts on this matter. What experience, if any, have you or your colleagues or institution had with patent claims in this regard? I would especially appreciate your views on Department patent policy as it relates to the suggested policy options I have outlined above. I intend also to solicit advice on this matter from other interested parties in the scientific community and public and private sectors.

Thank you very much for your consideration of this most important matter. In order that we might be able to respond to Stanford in a timely fashion, I would appreciate your comments by October 1.

Sincerely yours,

/s/

Donald S. Fredrickson, M.D.
Director

4. the right of the Department to regain ownership due to public interest considerations or the institution's failure to take effective steps to commercialize the invention.

Stanford and the University of Alabama each hold one of the 65 IPA's now being administered by the Department.

Second, under grants and contracts with institutions having no identified technology transfer capability, the Department utilizes a provision deferring determination of ownership until an invention has been made. Under the deferred determination provision, an innovating institution may petition the Department for ownership of an invention after it is identified. In the past, approximately 90 percent of all such petitions have been granted on the basis of a satisfactory institution plan for development or licensing, subject, however, the conditions similar to those contained in the Department's IPA's.

The Department's normal policy of allocating invention rights is designed to facilitate the transfer of technology from the bench to the marketplace, by assuring that the innovating institution has the right to convey those intellectual property rights necessary to induce industrial investment and continued development of inventions generated with Department support. Only the IPA policy, however, assures a management focal point in the innovating institution which is trained to solicit and establish timely rights in intellectual property prior to invention.

We have been advised by the Department Patent Branch that 167 patent applications were filed from 1969 through the fall of 1974 under IPA's. Approximately $24 million is committed to the development of inventions on the basis of licenses granted under these patent applications. Meanwhile, we are advised that the Department, under the deferred determination provision, has granted 162 of the institutions' 178 petitions for ownership. Approximately $53 million was invested or committed to development under the licenses awarded. The commitment of private risk capital in these instances is viewed as evidence that a licensable patent right is a primary factor in the successful transfer of Department research results to industry and the marketplace.

It indeed appears that the incentives provided by Department patent policy have encouraged the development of new technology in general and afforded patent protection for some inventions to the economic benefit of the United States.

The control of DNA research envisioned by the guidelines, however, requires a delicate balance between need for rapid exchange of information unhampered by undue concern for patent rights and a potential for achieving uniformity in safety practices through conditions of licensure under patent agreements.

Appendices

I. Sample Letter on DHEW Patent Policy as Applied to Recombinant DNA Inventions; Addressees; Recombinant DNA Advisory Committee

II. Institutional Patent Agreement Governing Grants and Awards from the Department of Health, Education, and Welfare

III. Interagency Committee on Recombinant DNA Research, June 1977

However, in the absence of legislation, a condition in the IPAs to require assurances of compliance with the safety standards in the NIH guidelines is warranted.

This leaves the residual question whether the subject of the patentable processes (recombinant DNA techniques) is of such a peculiar nature that financial return to the inventors should be denied. This argument, too, 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 when partially or wholly developed with public funds. Such inventions include vaccines for rubella and rabies, treatments for herpes infections of the eye, treatments for uremia, and prostaglandins--compounds that may have a number of possible medical uses. The argument that commercial development based on patent protection has or will assure maximum benefits of these inventions 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 recommended, 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 each agreement should be amended to ensure that the licensees

A number of commentators disagreed with the action of Stanford and the University of California in seeking to patent such inventions. Specifically, several commentators believed that those universities were ill-advised to seek patents when contributions to research advancement in this area were shared by a number of institutions and investigators. These are important considerations in the determination of patent rights. However, the appropriate forums for adjudicating rights to patent inventions are the U.S. Patent and Trademark Office and the courts. The Patent Office reviews all patent applications to determine whether the claims for the new inventions are attributable solely to the claimant. The NIH recognizes its responsibility to provide the Patent Office with all relevant research information on recombinant DNA, in order that review of claims can proceed with full knowledge of prior research results in this area.

The commentators did not believe patents to be an impediment to the free flow of information. There may be special problems posed by the Freedom of Information Act which will influence the administration of patents in the future. For the present, however, it would appear that the Act and the patent agreement do not necessarily conflict. The commentators supported the IPAs and urged that recombinant DNA research inventions not be excluded from them.

When the Guidelines were released in June, a key public issue was their extension to the rest of the public and private sectors. All commentators whose views were solicited in 1976 agreed that there must be standards to govern the conduct of recombinant DNA research and that the NIH Guidelines could provide the standards for such research nationally.

Federal Register on March 9, 1977, Commerce announced suspension of the order (except for applications relating to safety of research in this field, which would continue to receive expedited processing).

At a meeting held on March 29, the Committee reviewed the order and documents prepared by the Commerce Department explaining in detail the underlying policies. The majority of Committee members were favorably disposed to the reinstatement of the Commerce Department order because: (1) accelerated processing involves no change in patent policies, merely a speeding up of the procedures; (2) it motivates compliance with the safety standards of the NIH Guidelines by nongovernmentally funded domestic investigators during the period while national legislation is being considered; and (3) it encourages compliance with a set of recognized safety standards by foreign investigators who may not yet be subject to comparable standards in their own countries. The views of the Committee were transmitted to the Secretary for his review in April 1977. The Secretary has taken no action, pending enactment of legislation.

2. Institutional Patent Agreements

An analysis of the HEW Institutional Patent Agreements was referred to the Committee for review. A number of the agency representatives referred the analysis to their patent counsels. Among the relevant agencies that commented were the National Science Foundation, the Defense Department, the Department of Agriculture, the Energy Research and Development Administration, and the Department of Justice.

it was stated, has a broader responsibility for enforcing safety regulations--and such enforcement should not be limited to NIH employees and awardees.

Generally, those commentators who had attended the public hearing in February 1976 also expressed reservations about requiring compliance through the patent system. A number pointed out the difficulty in exercising regulatory controls through the patent process. They urged that regulation might better be carried out by a Government agency responsible for all recombinant DNA research. One commentator noted that the universities do not have the capability to monitor their licensees for compliance with the Guidelines and that, necessarily, such responsibility would have to rest with the Federal Government. Another commentator, however, believed that the enforcement of compliance by licensees should rest with the universities holding the patents. The rationale for this view was that the Government has not assumed the primary role of enforcer in other patent circumstances and that an exception should not be created for recombinant DNA research.

III. Interagency Committee

A. Mandate of the Interagency Committee

The Secretary of HEW, with the approval of the President, established in October 1976 an Interagency Committee on Recombinant DNA Research chaired by the Director of the NIH. The Committee was chartered to review the nature and scope of Federal and private-sector activities related to recombinant DNA research, to determine the applicability

finance more recombinant DNA research. It may be noted, however, that institutional patent agreements contain clauses defining rates for royalty return to the investigator and to the institution (see Appendix II). The conditions set for royalties provide flexibility for the institution or the inventor to use accrued royalties in support of continued research.

3. Extension of the NIH Guidelines Through the Department Patent System

In light of the control of recombinant DNA research envisioned by the NIH Guidelines, there is a potential for achieving uniformity in safety practices through conditions of licensure under patent agreements. Thus the general views of all commentators were also solicited on the possibility of incorporating requirements for adherence to the NIH Guidelines in the IPAs.*

Possible means to accomplish these ends include the following:

Institutions would retain the right to file patent applications for recombinant DNA research, but all licenses would have to be reviewed and approved by the Department of Health, Education, and Welfare. The Department would be free to set standards,

*This action was proposed prior to the creation of the Interagency Committee, which recommended in March 1977 that legislation be passed to regulate all recombinant DNA activities nationally. Legislation was subsequently proposed by the Administration and is currently pending before the Congress.

patents before publication in order to protect their interests abroad. DHEW and Patent Office counsels believe that any necessary patent applications can be handled expeditiously without undue delays in publication.

The NIH Recombinant DNA Advisory Committee places high priority on the rapid dissemination of results in recombinant DNA research. Members of the committee believed, however, that patenting would not create an undue delay or impede the operations of the committee in disseminating research and safety information. Other commentators who participated in the public hearing on the guidelines also concluded that patenting would not create an undue delay. Commentators from industry stated that patents expedite the disclosure of research results. Several noted that lack of patents would discourage the free flow of information because industry would seek to protect innovations through trade secrets.

One commentator, however, suggested that recombinant DNA research patents might be specially expedited by the U.S. Patent Office, as in the case of patents in the field of environmental protection. This recommendation was forwarded to the U.S. Patent Office for comment. Another suggestion was that foreign rights be waived in an emergency, in order to release important safety information quickly. (In Germany and Japan, there is a grace period of 6 months after publication in which to file for patent protection.) This recommendation was forwarded to the U.S. Patent Office for comment. The Commerce Department did issue an order

(1) a royalty-free license permitting the Government and those functioning under Government direction to use the invention,

(2) a limit on the term of any exclusive license granted ("exclusive" = permission to grant only one license for a limited time),

(3) authority to withdraw specified grants from the Institutional Patent Agreements,

(4) a right of the Department to regain ownership if the institution breaches the terms of the IPA or fails to take effective steps to commercialize the invention, and

(5) a right to disclose the invention to the public after a U.S. patent application has been filed.

Stanford and the University of California each hold one of the 72 IPAs now being administered by the Department.

For those institutions that have not entered into a patent agreement with the Department, determination of ownership is deferred until an invention has been made, at which time an institution may petition the Department for ownership of 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 development or licensing.

The IPA provides a mechanism to facilitate the conversion of new knowledge from the research laboratory to marketable products, by assuring that the institution where the discovery is made can grant licenses for continued development of inventions generated with Department support. The Department Patent Branch reports that 167 patent

proposed guidelines to the Director of NIH which were reviewed at a public hearing in February 1976. As released on June 23, 1976, these guidelines had been revised in light of a number of suggestions presented by the public commentators. Accompanying the release was a Director's Decision document addressing the issues raised at the public hearing and in subsequent correspondence.

The NIH Guidelines were published in the Federal Register on July 7, 1976, for further public comment. In response to suggestions of public commentators, NIH also undertook an environmental impact assessment of recombinant DNA research and filed a Draft Environmental Impact Statement in the Federal Register on September 9, also for public comment.

In June, shortly before the release of the Guidelines, 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.

agreements with the universities. Each agreement, however, will be amended to permit the institution to grant a license under patents secured on any such invention only if the licensee provides assurance of compliance with the physical and biological containment standards set forth in the Guidelines in any production or use of recombinant DNA molecules under the license. In my view, the requirements set for NIH grantees and contractors will thus be honored by licensees as well.

Accordingly, Stanford may proceed to file recombinant DNA research patent applications. You should know that Federal patent policies are under extensive review by the Executive Branch and the Congress, and that this may lead to actions affecting the administration of institutional patent agreements generally and other conditions for recombinant DNA research inventions specifically. For the present, however, recombinant DNA research inventions should not be handled differently under current institutional patent agreements, except for the requirement that licencees agree to comply with containment standards set forth in the NIH Guidelines.

I regret the long period of time required to review patent policies involving recombinant DNA research, but the complexity of the issues necessitated an extended analysis. Your letter stimulated a thorough and much needed policy review. I appreciate your interest and patience.

Sincerely yours,

Donald S. Fredrickson

Donald S. Fredrickson, M.D.
Director

Enclosure