DEC 2 1968

Dear Dr. Harrington:

Thank you for your letter of November 22, 1968, returning copies of the Institutional Patent Agreement which have been signed on behalf of the University of Wisconsin.

I have signed the Agreement on behalf of the Department, effective as of December 1, 1968, and am returning one fully executed copy herewith.

Your interest in the Department's patent program is appreciated.

Sincerely yours,

Philip R. Lee, M.D.
Assistant Secretary for
Health and Scientific Affairs

Fred Harvey Harrington, Ph.D.
President
University of Wisconsin
Madison, Wisconsin 53706

Enclosure

CBBROWN/dka
cc: Inv. Off.

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

This Agreement made and entered into this 1st day of December, 1968, 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 The Regents of the University of Wisconsin, 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 the University's letters dated April 18, 1967 and September 25, 1968 and the enclosures thereto, and its practices thereunder, and has found them to be acceptable, subject to the provisions of this Agreement, and that said 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 heretc 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 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 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.

(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 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 practices. Such license shall also provide that all sales to the U.S. Government shall be royalty free.

(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.

(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.

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

App B (waiver)

(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 (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.

(U.S. Govt)

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

UNITED STATES OF AMERICA

By _____

Title Assistant Secretary for Health and Scientific Affairs

(Corporate Seal)

THE REGENTS OF
THE UNIVERSITY OF WISCONSIN

By _____
Fred Harvey Harrington

Title President of the University of Wisconsin

CERTIFICATE

I, Clarke Smith, certify that I am the Secretary of The Regents of the University of Wisconsin, named above; that Fred Harvey Harrington, who signed this Agreement on behalf of said corporation, was then President of the University of Wisconsin ~~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 22nd day of November, 1968.

(Corporate Seal)

By _____
Clarke Smith, Secretary

(October 1968)

LICENSE TO THE UNITED STATES GOVERNMENT

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.

WHEREAS, _____ (Inventor), has invented _____ and filed a patent

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.

(Invention) (Country) 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 _____ (Institution)

WHEREAS, the United States Government [illegible] certain rights in and to said [illegible] reason of the terms of said grant(s), and (Signature)

WHEREAS, the _____ (Institution) (Print or type name) hereinafter called the "Licensor" has acquired by assignment from ~~the inventor~~ the entire ~~right, title, and interest of~~ the inventor to such invention; Date (Official Title)

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, non-exclusive and irrevocable license for governmental purposes on behalf of any foreign government purpose, 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.

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.

As used [illegible] the Government [illegible] thereof, state or [illegible] 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.

October 1968
October 1968