THE UNIVERSITY OF WISCONSIN MADISON 53706

CENTRAL UNIVERSITY SERVICES OFFICE OF THE BUSINESS MANAGER A. W. PETERSON OFFICE BUILDING

May 5, 1969

Mr. Howard Bremer Wisconsin Alumni Research Foundation 506 North Walnut Street Madison, Wisconsin 53705

Dear Mr. Bremer:

As discussed during our telephone conversation on Friday, we have reviewed the patent policy of the Public Health Service with regard to research grants such as those awarded for the research of Dr. De Luca.

Both the applications for such grants and statements of grant award set forth the condition that the grantee accept the obligation to comply with Public Health Service Research Project Grant Regulations in effect at the time of the award. The recent Public Health Service patent policy is set forth on the enclosures. The first enclosure is a copy of page 19 from <u>Grants for Research Projects Guide to Operating</u> <u>Procedures</u>, USDHEW, PHS, which was effective July 1, 1965. The second enclosure is a copy of pages 4 and 5 from <u>Public Health Service Grants</u> for Research Policy Statement, USDHEW, PHS, revised July 1, 1967.

We trust that the above information and enclosures will be helpful in arriving at the answer to the questions that were asked.

Sincerely,

George 7. Evenson

George F. Everson Business Manager

GFE/slm Encl - 2 cc: Mr. Len Van Ess SECTION D - PATENTS AND INVENTIONS

525. PUBLIC HEALTH SERVICE PATENT POLICY

Department of Health, Education, and Welfare regulations (45 C.F.R., Parts 6 and 8) provide as a condition that all inventions arising out of the activities ass<u>isted</u> by Public Health Service grants and awards shall be promptly and fully reported to the Surgeon General. In respect to inventions reported, the institution and the principal investigator must either: (a) refer the inventions to the Surgeon General for determination, in accordance with Department patent regulations, of the ownership and manner of disposition of all rights therein and whether patent protection on such inventions shall be sought, and, if so, the manner of obtaining, administering, and disposing of the patents in the public interest; or (b) where the institution has a separate formal patent agreement with the Surgeon General covering inventions deriving from Public Health Service support, make a determination of ownership and disposition in accordance with its policies as approved or as modified by such agreement. In no event, shall patent applications be filed on inventions reported under (a) above, without prior written consent of the Surgeon General.

Progress reports or publications may not substitute for formal reports of invention.

526. AMENDED PATENT AGREEMENT (Exhibit 9)

In the following instances, Public Health Service procedure requires the completion of an amended patent agreement:

- A. Where the institution proposes to subcontract with a commercial organization for a portion of the research to be conducted under the grant.
- B. Where the investigator proposes to submit compounds to be synthesized and/or developed with Public Health Service support to a commercial company for screening purposes.

Before an award is made the Institute or Division will furnish amended patent agreement forms to the applicant. The agreement when signed and returned becomes a part of the terms and conditions of the award.

PUBLIC HEALTH SERVICE GRANTS FOR RESEARCH PROJECTS A Guide to Operating Procedures

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GRANTEE RESPONSIBILITIES

In applying for a research grant the grantee agrees to administer the grant in accordance with the regulations and policies governing the research grants program of the Public Health Service in effect at the time of award. Where a grantee has a policy not covered by the Public Health Service or where the grantee policy is more restrictive than Public Health Service policy, the grantee policy prevails. Administration of a grant-supported research project is a joint undertaking by the grantee and the principal investigator. The grantee assumes responsibility for fiscal and administrative management and fulfillment of any special conditions which may be prescribed for the conduct of the research. The principal investigator and the grantee institution share responsibility for the conduct of the research and for using grant funds prudently for the purposes set forth in the application and Notice of Grant Awarded. When the grantee is an individual not affiliated with an institution, bonding is required as an assurance of financial responsibility.

Civil Rights

Public Health Service grants and awards must be administered in conformance with the Civil Rights Act of 1964; the regulation (45 CFR, Part 80) issued pursuant thereto by the Department of Health, Education, and Welfare; and the grantee's Assurance of Compliance (Form HEW-441), on file with the Public Health Service.

Patents and Inventions

Policy

In accordance with Department of Health, Education, and Welfare Regulations (45 CFR Subtitle A, Parts 6 and 8), all inventions made in the course of or under any Public Health Service grant shall be promptly and fully reported to the Assistant Secretary (Health and Scientific Affairs), Department of Health, Education, and Welfare.

The grantee institution and the principal investigator shall neither have nor make any commitments or obligations which conflict with the requirements of this policy.

Determination

Determination as to ownership and disposition of invention rights, including whether a patent application shall be filed, and if so, the manner of obtaining, administering, and disposing of rights under any patent application or patent which may issue shall be made either:

- a. by the Assistant Secretary (Health and Scientific Affairs) whose decision shall be considered as final, or
- b. where the institution has a separate formal institutional agreement with the Public Health Service or the Department, by the grantee institution in accordance with such agreement.

Patent applications shall not be filed on inventions under (a) above without prior written consent of the Assistant Secretary (Health and Scientific Affairs) or his representative. Any patent application filed by the grantee on an invention made in the course of or under a Public Health Service grant shall include the following statement in the first paragraph of the specification:

"The invention described herein was made in the course of, or under, a grant from the U.S. Public Health Service, Department of Health, Education, and Welfare."

Reports and Other Requirements

A complete written disclosure of each invention in the form specified by the Assistant Secretary (Health and Scientific Affairs) shall be made by the grantee

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