263-2827

December 20, 1977

Mr. Norman J. Latker
Patent Counsel
Department of Health, Education
and Welfare
Washington, D.C. 20201

Dear Mr. Latker:

RE: Institutional Patent Agreement, DHEW - University of Wisconsin

The above-referenced agreement provides that this Foundation, as a designee of the University of Wisconsin, may when the facts support it grant a limited term exclusive license to inventions which were made at the University of Wisconsin where the research support, either in whole or in part, came from DHEW. The term of exclusivity provided is for three years from date of first commercial sale or eight years from date of license, whichever shall first occur. The agreement also provides that upon proper showing these terms may be extended by the DHEW.

This is a formal request for the extension of the exclusive period for two inventions which are currently the subject of license negotiation between WARF and several companies.

The first of these inventions has been reported to you under the grant #HEW GMO 7215-01. It is concerned with frost protection for plants through the prior spray inoculation with an organism identified as M232A. In August 1977, we invited the representatives from fifteen U.S. companies, each of which was known to be involved with agricultural chemical operations, to attend a seminar in Madison. Eight companies sent representatives to that seminar and four of these have indicated continuing interest in being licensed to undertake the substantial development work remaining to be done provided such license can

be exclusive. In subsequent meetings with three of these companies, we have been advised that the three years from date of first marketing is not an adequate time in which it could expect to recover the substantial costs which will be incurred if the product is brought to market. A major part of such cost will be the investment made in information needed by the government regulatory agencies before approval can be secured for widespread use of the process. We are convinced, through these discussions, that a limited term exclusive license will have to be provided and sincerely believe that the risks to be undertaken are sufficient to justify an extention of the term of exclusivity which we are at present able to provide. We, therefore, request permission to offer a license providing exclusivity for a period of five years from date of first commercial sale or ten years from date of license agreement, except that in calculating the ten years the time delay which is the result of the approval process of any U.S. federal regulatory agency should be tolled, thus extending the possible total elapsed time.

The second invention under consideration, which has been reported to you under the grant designation PHS HL 06314, concerns the use of primed leukocyte cells for typing the antigen character of human tissue. This technique has, to date, been recognized by only one or two of the world's related laboratories and these are in academic institutions. The licensee which we have identified, namely Biotest-Serum-Institut, a German company, is, we believe, the best company to develop and provide the reagent materials and devices necessary for this test. Unquestionably, it will take a long time to establish, at the working level, a recognition and dependence upon this test, even though we at WARF believe it will eventually become a standard procedure for any medical situation in which tissue is transplanted from one human to another. We are convinced that a three year exclusive period from date of first commercial sale will be inadequate to insure that the Biotest-Serum-Institut will be able to at least recover the expenditures which will be required for it to develop the inventions and initiate a commercial program based on this technology. We would like permission, therefore, to also extend the term of exclusivity in a licensing arrangement with Biotest under the U.S. patents involved to five years from date of first commercial sale or ten years from date of license agreement, whichever is longer, with the provision that the time delay necessitated by the approval process of any U.S. federal regulatory agency will be tolled in computing the exclusive periods.

Very truly yours,

Marvin D. Woerpel
Director of Licensing

MDW:cm