DRAFT Agreement B.

Collaborative Research Agreement

This Agreement, effective _____, 1986, is by and between _____ and the _____ (hereinafter referred to as _____, National Institutes of Health (NIH), a component agency of the Department of Health and Human Services (DHHS).

1. During the term of this Agreement, _____ will provide through the _____ salary and salary dependent charges for a postdoctoral research worker (the _____ postdoctoral research fellow), who will work on the project for _____ as a Guest Worker at NIH, miscellaneous supplies and expense items in the amount of $_____ for the first year and for the second year commencing October 1, 1987, $_____.

2. The Principal Investigator for the study is Dr. _____. The Principal Investigator is responsible for performing the work described in the research protocol attached at Tab A. In the event the Principal Investigator becomes unable to complete the protocol for any reason, _____ and _____ may mutually agree to a substitute Principal Investigator, in which event this Agreement shall continue in full force and effect. If _____ and _____ cannot agree on a substitute, this Agreement shall immediately terminate.

DRAFT Agreement B.

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3. The _____ postdoctoral research fellow and not more than one other _____ employee at any one time, may work as Guest Workers with the Principal Investigator and may have a reasonable use of research facilities, including laboratory space and equipment, at no charge, as may from time to time be agreed by the Principal Investigator and the appropriate _____ manager.

4. The collaborative research shall be conducted in accordance with the attached research protocol entitled "_____ _____."

5. The Principal Investigator and the postdoctoral research fellow will visit _____ corporate bioscience group once each year. _____ will pay for the accommodations, subsistence, and travel for the postdoctoral research fellow and the Principal Investigator, to the extent permitted by Federal Regulations at 45 CFR 73.735-507(b).

6. Regular monitoring of the research project will be conducted by biannual progress reports prepared jointly by the Principal Investigator and the postdoctoral research fellow, and by biannual meetings between staff from _____ and those directly involved in the research project.

7. Confidentiality of Information

shall treat all data and information relating to the collaborative research program either: (a) submitted in writing by _____

to and suitably indicated or marked as confidential, as trade secrets or commercial or financial information within the exception to the disclosure mandate of the Freedom of Information Act (5 U.S.C. 552(b)(4)), unless otherwise determined by NIH or DHHS FOIA officials or a court of competent jurisdiction. further agrees that such data and information may be disseminated within , but only to the extent necessary to permit performance of obligations under this Agreement. The obligations and restrictions provided in this paragraph shall not apply to whatever portion of such data and information (a) may be in the public domain at the time of disclosure to by _____ or at the time it is derived by and/or _____ in the course of the research program, or after such disclosure or derivation, is made part of the public domain by _____ or a third party not affiliated with or employed by NIAID who is legally in possession of this data or information and is under no obligation to _____ or to to maintain such information confidential; (b) is lawfully made available to by a third party who is not affiliated with or employed by _____ and is under no obligation to _____ to maintain the same confidentiality; or (c) was already known to NIAID at the time of the disclosure to by _____.

8. _____ agrees to cooperate with NIAID in facilitating and creating useful publications in the area of research related to the development of pertussis vaccines, so long as such publications do not result in the disclosure of trade secrets or commercial or financial information treated as priviledged or confidential by under paragraph 7. In order to protect _____ confidential information, agrees to give _____ at least 30 days to review any proposed article resulting from the collaborative research and will not submit any such article for publication prior to obtaining _____ approval. That approval may be withheld only if _____ reasonably determines that the article contains confidential information as defined in paragraph 7. of this Agreement.

9. In accordance with Executive Order 10096, the Department of Health and Human Services (DHHS), the parent agency of . shall have title to any invention developed under this Agreement by employees or by Guest Researchers or Guest Workers. In the event a patent application is filed on such inventions by the DHHS, the DHHS and the . agree to grant to _____ an irrevocable, nonexclusive, royalty-bearing license to make, use, and sell the invention for a period of five (5) years from the date of first commercial sale, or eight (8) years from the date of this license, whichever occurs first, in accordance with the terms and conditions contained in the DHHS Standard Exclusive License

Agreement, (a copy of which is attached hereto and made a part of this agreement attached at Tab B) provided that _____ complies with the requirements of 37 CFR Part 404 (especially §§ 404.5 and 404.8).

10. In the event the and the DHHS determine that no inventions have arisen from the research or that no patent applications will be filed, _____ shall be free to use all information and materials including biological materials, generated or developed during the course of the research, so long as this does not interfere with the use of such information and materials.

11. In the event of any dispute between and _____ arising out this Agreement, which dispute cannot be settled by consultation and discussion between the parties, said dispute shall be referred to the DHHS Assistant Secretary for Health for resolution.

12. The term of this Agreement shall be two (2) years from the date of execution of the Agreement unless extended by written agreement of the parties. This Agreement may be terminated by either party upon 30 days prior written notice and thereafter the parties have no further obligation to supply materials or conduct research. All other rights and obligations set forth herein which vest prior to the termination, shall survive any termination of the Agreement.

13. No indemnification for damages is intended or provided under this Agreement. Each party shall be liable for any damages it incurs as a result of its activities under this Agreement.

14. This Agreement, including any questions concerning its validity or effect, or performance hereunder, or its operation, interpretation of construction, shall be governed and determined in accordance with Federal law.

Date: _____ ___ ___ _____

DRAFT AGREEMENT C.

DRAFT AGREEMENT D

EXHIBIT C.

LICENSE AGREEMENT

Effective _____, 1987, the Director of XYZ Center, X Agency, as the representative of the United States of America (hereafter LICENSOR), a

, agree as follows:

ARTICLE I

BACKGROUND

1.00 The United States of America is the owner by assignment recorded iin the United States Patent and Trademark Office at Reel { } Frame { } on { } (U. S. Patent Application No.) of the entire right, title and interest to the products and methods, described and claimed in the LICENSED PATENT, which pertain to the use of { }

1.01 Under the authority of Section ___ of Public Law 99-502, United States Code section _____, LICENSOR has custody of the products and methods described and claimed in, and the right to issue licenses under the LICENSED PATENT.

1.02 LICENSOR desires the products and methods, claimed and described in the LICENSED PATENT, be brought to THE POINT OF PRACTICAL APPLICATION in the shortest possible time and made available to the public, thereby serving the public interest and

broadening the potential supply base for LICENSOR and other Government agencies.

1.03 LICENSEE desires to obtain an exclusive license under the LICENSED PATENTS for the purpose of developing { }

ARTICLE II

DEFINITIONS

2.00 Terms in this agreement (other than names of parties and Article headings) which are set forth in upper case letters have the meanings established for such terms in the succeeding paragraphs of this ARTICLE II.

2.01 LICENSED PATENTS means United States Patent Application No._____, and U.S. Patent No. _____ issued _____, and such other foreign patent and patent applications as may be derived from the aforesaid U.S. Patent Application including any and all divisions, continuations, continuations in part, reissues, renewals or extensions thereof. Exhibit A shall be updated from time-to-time by LICENSOR as additional patents based on the patent application identified in Article I, Section 1.00 are issued (if any).

2.02 LICENSED PRODUCTS means any and all machines, articles of manufacture, products made by a process or compositions of matter as defined by the claims of the LICENSED PATENTS.

2.03 LICENSED METHODS means any and all products and methods, uses or processes which employ methods as claimed in the LICENSED PATENTS.

2.04 ROYALTY-BASE PRODUCTS means any and all products which are employed to practice the LICENSED PRODUCTS AND/OR METHODS.

2.05 LICENSED AREA means the United States of America, its territories and possessions and any other country in which a PATENT corresponding to the licensed U.S. patent has been filed and licensed.

2.06 LICENSOR'S REPRESENTATIVE means the General Counsel, XYZ Center.

2.07 THE POINT OF PRACTICAL APPLICATION means to develop the products and methods described and claimed in the LICENSED PATENTS under such conditions as to establish that the products and methods are being utilized and that their benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms within { } years of the date of this Agreement, and to continue during the term of this Agreement to make the benefits of the products and methods reasonably accessible to the public.

2.08 NET SALES means the amount billed or invoiced on sales of any ROYALTY-BASE PRODUCTS or, in the event of disposal of any ROYALTY-BASE PRODUCTS other than as scrap prior to its shipment from its place of manufacture or other than by sales, the amount

license granted herein be converted to a nonexclusive license under the provisions of ARTICLE VIII, paragraph 8. 02, of this Agreement, LICENSEE shall pay royalties in accordance with the first sentence of this paragraph at the rate of { } percent.

4.01 Except for year 19___, specified in 2.01 above. In case the royalties paid do not aggregate a minimum of Five Thousand dollars ($5,000) for each calendar year during the life of this Agreement beginning with the second year in which sales subject to such royalties are made, the LICENSEE will within sixty (60) days of the end of such year make up the deficiency of the royalties actually paid to such minimum sum. The minimum sum owed for the first year in which sales subject to such royalties are made will be prorated based on the month in which the first such sale is made.

4.02 Royalties shall be payable in United States dollars, paid by check to XYZ Center, and mailed to LICENSOR'S REPRESENTATIVE.

4.03 Upon the execution of this Agreement, LICENSEE is to be credited for royalties, if any, in the year 19___.

4.04 LICENSEE shall pay royalties accrued for sales made subject to such royalties to include sales by its sublicensees not later than sixty (60) days after each calendar half year ending June 30th and December 31st. LICENSEE shall submit with its payment the written report required in ARTICLE V, paragraph 5.01, of this Agreement. If no royalties are due, the report shall so state. Sales shall be considered to be made, for

purposes of this paragraph and paragraph 4.01 above, when billed out, except that upon any termination of this Agreement, all shipments made on or prior to the day of such termination which have not been billed out prior thereto shall be considered as sold (and therefore subject to royalty). Royalties paid on sales of ROYALTY-BASE PRODUCTS which are not accepted by the customer shall be credited to LICENSEE.

4.05 LICENSEE shall pay within thirty (30) days from any termination of this Agreement royalties (including minimum royalties) accrued or accruable for payment at the time of any such termination.

4.06 Royalty payments not received by LICENSOR by the due date shall be subject to interest charges computed at ten percent (10%) per annum.

4.07 Transfer of ROYALTY-BASE PRODUCTS between LICENSEE and sublicensees shall not be deemed sales and shall not be included in computing NET SALES.

4.08 No royalty shall be payable under this Agreement for direct sales of ROYALTY-BASE PRODUCTS by LICENSEE or its sublicensees to the United States Government or any of its agencies for governmental purposes.

ARTICLE V

REPORTS AND RECORDS

5.00 LICENSEE shall provide written annual progress reports

LICENSEE, or, at the option and expense of LICENSEE, by a certified public accountant appointed by LICENSOR.

ARTICLE VI

SUBLICENSING RIGHTS

6.00 LICENSEE shall have the right under the LICENSED PATENTS to grant sublicenses to others at royalty rates not less than those required to be paid by the first sentence of paragraph 4.00, ARTICLE IV, of this Agreement, subject to the provisions of this Agreement and to the submission to, and approval by LICENSOR'S REPRESENTATIVE, which approval shall not be unreasonably withheld. Any sublicense shall make reference to this Agreement including those rights retained by LICENSOR. A copy of any sublicense shall be furnished to LICENSOR'S REPRESENTATIVE promptly after its execution.

6.01 Royalties paid by a sublicensee to include any minimum royalties shall be shared equally by LICENSEE and LICENSOR.

6.02 Termination or conversion under ARTICLE VIII, paragraph 8.02, or any of the provisions of ARTICLE X of the license granted to LICENSEE in this Agreement shall terminate all sublicenses which may have been granted by LICENSEE, provided that any sublicenses may elect to continue its sublicense by advising LICENSOR in writing, within sixty (60) days of the sublicensee's receipt of written notice of such termination or conversion, of its election, and of its agreement to assume in respect to LICENSOR all the obligations (including obligations

for payment) contained in its sublicensing agreement with LICENSEE. Any sublicense granted by LICENSEE shall contain provisions corresponding to those of this paragraph respecting termination or conversion and the conditions of continuance of sublicenses.

6.03 LICENSOR reserves the right to require LICENSEE to grant sublicenses to responsible applicants on reasonable terms to the extent that the LICENSED PATENTS are required for public use by government regulations or when necessary to fulfill public health, welfare, or safety needs. Any decision by LICENSOR to require such a sublicense may be appealed by LICENSEE under the procedures set forth in ARTICLE XI.

ARTICLE VII

LICENSEE PERFORMANCE

7.00 LICENSEE shall expend reasonable efforts and resources to carry out the development and marketing of the licensed invention and to bring the products and methods, described and claimed in the LICENSED PATENTS, to THE POINT OF PRACTICAL APPLICATION.

7.01 After bringing the products and methods, described and claimed in the LICENSED PATENTS, to THE POINT OF PRACTICAL APPLICATION in the LICENSED AREA, LICENSEE agrees to make LICENSED PRODUCTS AND METHODS available to the public on reasonable terms during the term of this Agreement. LICENSEE shall promptly report discontinuance of its making the benefits of the products and methods reasonably accessible to the public.

7.02 Failure to comply with the terms of this ARTICLE shall be cause for modification or termination of this Agreement in accordance with the provisions of ARTICLE X below.

ARTICLE VIII

PATENT ENFORCEMENT

8.00 LICENSOR and LICENSEE shall notify each other promptly in writing of any infringement of the LICENSED PATENTS which becomes known to either of them. LICENSEE shall notify LICENSOR promptly of any action taken in accordance with this ARTICLE VIII to eliminate such infringement.

8.01 While and as long as its license under this Agreement remains exclusive, LICENSEE is authorized pursuant to the provisions of Chapter 29 of TITLE 35, United States Code, or other statutes:

a. To bring suit in its own name or, if required by law, jointly with LICENSOR, at its own expense and on its own behalf, for infringement of the LICENSED PATENTS;

b. In any such suit, to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and

c. To settle any claim or suit for infringement of the LICENSED PATENTS by granting the infringing party a sublicense under the provisions of ARTICLE VI of this Agreement. Any royalties received by LICENSEE pursuant to such a sublicense

shall be shared with LICENSOR in accordance with ARTICLE VI, paragraph 6.01.

8.02 In the event LICENSOR shall bring to the attention of LICENSEE any unlicensed infringement of the LICENSED PATENTS, and LICENSEE shall not, within six months,

a. Secure cessation of the infringement, or

b. Enter suit against the infringer, or

c. Provide LICENSOR with evidence of the pendency of a bona fide negotiation for the acceptance by the infringer of a sublicense under the LICENSED PATENTS,

the license herein granted to LICENSEE shall forthwith become nonexclusive, and LICENSOR shall thereafter have the right to sue for the infringement at LICENSOR's own expense, and to collect for its own use all damages, profits, and awards of whatever nature recoverable for such infringement.

8.03 LICENSOR and LICENSEE mutually agree to furnish technical and other necessary assistance to each other in conducting any litigation necessary to enforce the LICENSED PATENTS against others. Expenses for such assistance will be paid by the party requesting such assistance.

ARTICLE IX

RESERVATION OF RIGHTS

9.00 The license granted in ARTICLE III of this Agreement shall

be subject to the irrevocable, royalty-free right of the Government of the United States to practice and have practiced the products and methods described and claimed in the LICENSED PATENTS on behalf of the United States.

ARTICLE X

TERM AND TERMINATION

10.00 The term of this Agreement begins with its effective date as set forth in the heading paragraph located above. ARTICLE I and, unless sooner terminated or otherwise modified as provided for in this ARTICLE X, shall run, as to each of the LICENSED PATENTS, for the full life of such patent. The life of the LICENSED PATENTS shall also include any term of extension, if any, as provided for by Title 35, Chapter 14, United States Code.

10.01 The LICENSOR may modify or terminate this license, in whole or in part, if:

a. LICENSEE or any of its sublicenses fails to meet the obligations set forth in ARTICLE VII above;

b. The LICENSOR determines that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of this Agreement and such requirements are not reasonably satisfied by the LICENSEE;

c. The LICENSEE has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this Agreement;

a. LICENSEE's obligation to supply a terminal report as specified in ARTICLE V, paragraph 5.02, of this Agreement.

b. LICENSOR's right to receive or recover and LICENSEE's obligation to pay royalties (including minimum royalties) accrued or accruable for payment at the time of any termination as specified in ARTICLE IV, paragraph 4.04, of this Agreement.

c. LICENSEE's obligation to maintain records and LICENSOR's right to conduct a final audit as provided in ARTICLE V of this Agreement.

d. Licenses, releases, and agreements of nonassertion running in favor of customers or transferees of LICENSEE in respect to ROYALTY-BASE PRODUCTS sold or transferred by LICENSEE prior to any termination and on which royalties shall have been paid as provided in ARTICLE IV of this Agreement.

e. Any cause of action or claim of LICENSOR accrued or to accrue, because of any breach or default by LICENSEE.

10.04 In the event of termination of this Agreement or conversion of the license granted hereunder, any sublicense of record granted pursuant to this Agreement may, at sublicensee's option, be converted to a license directly between sublicensee and LICENSOR in accordance with the provisions of ARTICLE VI herein.

ARTICLE XI

GENERAL

d. The LICENSEE commits a substantial breach of a covenant or agreement contained in this Agreement;

e. The LICENSEE defaults in making any payment or report required by this Agreement;

f. The LICENSEE is adjudged a bankrupt or has its assets placed in the hands of a receiver or makes any assignment or other accommodation for the benefit of creditors;

g. The LICENSEE or any of its sublicenses misuses the LICENSED PATENTS.

10.02 Prior to any modification or termination of this Agreement, LICENSOR shall furnish LICENSEE and any sublicenses of record a written notice of intention to modify or terminate, and the LICENSEE and any notified sublicensee shall be allowed thirty (30) days after the date of such notice to remedy any breach or default of any covenant or agreement of this Agreement or to show cause why this Agreement should not be modified or terminated.

10.03 The word "termination" and cognate words, such as "term" and "terminate," used in this ARTICLE X and elsewhere in this Agreement are to be read, except where the contrary is specifically indicated, as omitting from their effect the following rights and obligations, all of which survive any termination to the degree necessary to permit their complete fulfillment or discharge:

11.00 This Agreement shall extend to any reissued patent which may be derived from the LICENSED PATENTS, provided that LICENSOR has custody of the rights thereto and is able to grant a license without incurring liability to third parties; this Agreement shall not apply to the rights to any other invention, patent, or patent application.

11.01 This Agreement shall not be transferred or assigned by LICENSEE to any party other than to a successor or assignee of the entire business interest of LICENSEE relating to ROYALTY-BASE PRODUCTS without the approval of LICENSOR'S REPRESENTATIVE.

11.02 This Agreement does not confer any immunity from or defenses under the antitrust laws, the laws and regulations pertaining to or administered by the Food and Drug Administration, or the export laws nor does it confer immunity from a charge of patent misuse. Furthermore, LICENSEE's or sublicensee's acquisition and exercise of rights hereunder are not immunized from the operation of any state or Federal law by reason of the source of the grant. This Agreement does not constitute an endorsement by LICENSOR of any LICENSED METHODS OR ROYALTY-BASE PRODUCTS and LICENSEE shall not state or imply in any medium that such endorsement exists as the result of this Agreement.

11.03 LICENSOR makes no warranty, express or implied, regarding the patentability or validity of the LICENSED PATENTS and no representations whatsoever with regard to the scope of the

LICENSED PATENTS or that the LICENSED PATENTS may be exploited without infringing other patents.

11.04 LICENSOR agrees to maintain the LICENSED PATENTS in force during the term of this Agreement by paying, when due, the fees required by 35 United States Code section 41(b).

11.05 LICENSOR assumes no liability resulting from LICENSEE's exercise of its rights under this Agreement or from LICENSOR's exercise of its rights under this Agreement, including modification or termination thereof.

11.06 LICENSEE agrees that ROYALTY-BASE PRODUCTS used, sold or otherwise disposed of in the LICENSED AREA by LICENSEE and its sublicensees will be manufactured substantially in the United States.

11.07 The decision of LICENSOR'S REPRESENTATIVE on any requirement, dispute, interpretation, modification, or termination of this Agreement shall be reduced to writing and a copy mailed or otherwise furnished to LICENSEE. Such decision shall be final, Provided, that LICENSEE may, within thirty (30) days of receiving notice of such decision, submit a written appeal through LICENSOR'S REPRESENTATIVE to {_____
_____}, which appeal shall set forth in detail the decision being appealed and the basis of the appeal and may include appropriate supporting materials. Implementation of such decision shall be stayed pending a final resolution of such appeal. Pending such final

resolution, LICENSEE shall proceed diligently with the performance of its obligations under this Agreement.

11.08 The partities shall notify each other of any changes in name, address, or business status, and any notice, payment or report required to e given under the provisions of this Agreement shall be considered duly given if mailed by first class mail, postage prepaid and addressed as follows:

a. If to LICENSOR: General Counsel
XYZ Center

b. If to LICENSEE:

11.09 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the United States as interpreted and applied by the Federal courts in the District of Columbia, United States of America.

11.10 This Agreement constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

IN WITNESS THEREOF, each of the parties hereto has caused this Agreement to be executed in duplicate originals by its duly authorized officers or representatives.

FOR LICENSOR;

WITNESS	Director, XYZ Center X Agency
DATE	DATE

FOR LICENSEE:

LICENSE AGREEMENT D. DRAFT AGREEMENT D.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

This Agreement, made and entered into this _____ day of _____, 19__, by and between the United States of America, as represented by the Assistant Secretary for Health of the Department of Health and Human Services, hereinafter referred to as the DEPARTMENT, and _____

_____,

hereinafter referred to as the LICENSEE,

WITNESSETH: That whereas the Department is the owner of the entire right, title, and interest in and to United States Patent Number _____, issued _____, and entitled _____

_____

_____;

and

WHEREAS, the Regulations of the Department covering licenses to practice inventions covered by patents and pending patent applications owned by the United States Government, as represented by the Department, provide in 45 C.F.R., Section 6.3 that where it appears that the public interest will be served, the Assistant Secretary for Health may issue licenses providing for limited exclusivity and the payment of royalties to the Department; and

WHEREAS, the Licensee is desirous of obtaining an exclusive license under said patent for the manufacture, use, and sale of the inventions depicted therein throughout the United States, its territories, possessions and dependencies, and the issuance of such a license has been determined to be in the public interest, in order to more adequately and quickly develop the aforesaid invention of the patent for the widest use by the general public; and

WHEREAS, the Licensee has tendered the required sum of two hundred and fifty dollars ($250.00) to the Government to partially reimburse the Government for administrative costs incurred in the issuance of this license and the further processing required during its term;

WHEREAS, the Assistant Secretary for Health has reviewed the request for this license submitted by the Licensee and has determined that extensive development and testing requiring substantial investment of private risk capital in the invention covered by the above patent is needed to bring this invention to the point of practical application, and that the granting of this license is consistent with Section 6.3 of the Department patent regulations,

NOW, THEREFORE, in consideration of the foregoing premises and in consideration of the public interest, and for other good and valuable considerations, the parties hereto agree as follows:

1. DEFINITIONS

Patent Rights - "Patent Rights" means said United States Patent Number _____ and any reissue of such patent, and the invention described therein.

Improvements - "Improvements" means betterment of the processes, intermediates, or the products which are defined by the claims of the above-cited United States patent developed by the Department or party obligated to assign such developments to the Department.

Product - "Product" means any device, material, or subtance which is within the scope of Patent Rights, or which is synthesized by a process within the scope of Patent Rights or employing an intermediate within the scope of Patent Rights.

2. LICENSE

The Department hereby grants and Licensee hereby accepts an exclusive and revocable license under the Patent Rights to make, have made, use, and vend Products, and to use processes coming within the scope of the Patent Rights in the United States of America, its territories, dependencies and possessions, subject to the conditions and limitations hereinafter set forth until _____ years after the first commercial sale of Product by Licensee, or _____ years from the date of this license, whichever occurs first, provided that 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 the approval of the Department. Any request for such an extension shall be considered on its merits upon written request and justification, it being understood that upon expiration of the period of exclusivity or any extension thereof, the Licensee thereafter for the remaining life of the patent shall have a nonexclusive license. The Licensee shall have the privilege of granting sublicenses with respect to all Patent Rights, or assigning such rights, subject to all the conditions of this Agreement, after

furnishing the Department with a copy of the proposed sublicense or assignment thirty (30) days prior to its execution and receiving no reasonable objection thereto. Such sublicense or assignment shall not be revoked by the Department except under the terms of Paragraph 11 hereof.

3. RESERVATION OF RIGHTS

The license granted in Paragraph 2 above is subject to the reservation by the Department of an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of such invention throughout the world by or on behalf of the United States or any foreign government pursuant to any existing or future treaty.

4. OPTION ON IMPROVEMENTS

The Department will disclose each Improvement to Licensee pursuant to Paragraph 8 hereof. The Licensee may elect, by written notice to the Department within three (3) months after being notified of an Improvement, to file a United States patent application and have said Improvement included as a part of Patent Rights under this Agreement at no increase in royalty. If Licensee does not elect to have an Improvement included as a part of Patent Rights, Licensee and the Department shall have no further obligations hereunder, each to the other, with respect to said Improvement.

5. GOVERNMENT FUNCTIONS - PERFORMANCE

a. The Licensee agrees that development and testing of the invention disclosed in the aforesaid patent or application and marketing of all products under this license will be in accordance with all laws and regulations applicable thereto. This license shall not be construed as restricting any of the rights or powers of the United States to exercise its normal governmental functions in the control of the manufacture, sale, distribution, or consumption of any product within the scope of this license under all pertinent Federal laws or regulations which may now or hereafter be in force.

b. In the event of the exploitation of the Patent Rights outside the United States, Licensee shall comply with all applicable laws and regulations of the United States, including particularly the export control regulations, foreign assets control regulations and transaction control regulations. The license granted herein shall not be construed as exempting Licensee from any of such laws or regulations of the United States.

6. PATENT FILING, PROSECUTION AND MAINTENANCE

The Licensee shall bear the expense of all prosecution of any United States patent applications on Improvements which Licensee has elected to include as part of Patent Rights.

Licensee shall not abandon any patent application on an Improvement, without first offering to transfer prosecution of such application to the Department not less than forty-five (45) days prior to the date a reply to a Patent Office action is due. If the Government does not request a power of attorney to continue prosecution within thirty (30) days of receipt of this offer, the Licensee may permit the application to go abandoned. The Licensee shall, upon request, grant a power of attorney authorizing the Department to inspect and make copies of any documents in the Patent Office pertaining to the prosecution of United States patent applications on any Improvements.

7. DISCLOSURE

The Department shall, upon execution of this Agreement, disclose to Licensee all information, know-how and data relating to Patent Rights, Products, methods for manufacturing Products and formulations containing Products in its possession or under its control, and the Department shall from time to time disclose to Licensee such additional information, know-how and data as it shall acquire or control, all to the extent the Department shall have the right to disclose such information, know-how and data for use by Licensee hereunder without restriction or obligation other than as set forth in this Agreement. The Department shall have the right to publish and make disclosure of any information relating to any subject matter or invention pertaining to the Patent Rights or Improvements, whenever deemed to be in the public interest, provided compliance with Article 4 above of this Agreement has been effected.

8. REPORTS

Licensee shall provide written annual reports to the Department commencing one year from the date of this Agreement regarding the development and commercial use that is being made and is intended to be made of the invention, including the amount of money expended in such development and such other non-proprietary data and information as the Department may

PRODUCTS, METHODS FOR MANUFACTURING PRODUCTS AND FORM [illegible]

specify. No further annual reports will be required after notification of the first commercial sale of any product embodying the invention unless otherwise requested by the Department.

9. PATENT MARKING

Licensee agrees that it will take all reasonable steps to assure that all packages or containers in which Products are sold by it pursuant to the license herein granted will bear an appropriate legal notice with respect to the patent included in Patent Rights, under which patent the Product is sold. The Department will from time to time supply Licensee the necessary information to be contained in such notices.

10. DEPARTMENT REPRESENTATION OR WARRANTY

a. Warranty - The Department does not warrant that this Product is capable of commercial exploitation, or that the practice by the Licensee of the invention licenses hereunder will be free from any infringement or charges of infringement of any patent or patents. The Department assumes no liability whatsoever that may result from the exercise of the license. The Department, in granting this license, does not represent or warrant the validity of any patent, nor does the Department undertake to prosecute or defend any suit brought by or against the Licensee, or indemnify it for the infringement or enforcement of any patent, nor do the parties hereto waive any rights they may have under the anti-trust laws.

b. Non-Use of Names - This license shall not be construed or in any way be represented as constituting the endorsement by the Government of any product manufactured by the Licensee within the scope of this license, or of the therapeutic utility or safety of any such product.

Licensee shall not use the name of the Government, nor any adaptation of the name of the Government, in any advertising, promotional or sales literature without prior written consent obtained from the Government (as represented by the Assistant Secretary for Health, Department of Health and Human Services) in each case.

11. REVOCATION OF EXCLUSIVE LICENSE

a. The Department reserves the right to revoke the exclusive license granted under Paragraph 2 of this Agreement and/or grant licenses to an applicant on a nonexclusive basis, royalty-free or on terms that are

warranty for validity of any patent, nor does the Department undertake to

reasonable under the circumstances if (1) the Licensee or its sublicensees fail to comply with any of the provisions of this Agreement, (2) the Department determines that the public health, safety or welfare requires such action, or (3) within three years after the issue date of this license agreement, the Licensee or its sublicensees have not only failed to bring the invention to the point of practical application, but have also failed to make the invention available for licensing royalty-free or on terms that are reasonable in the circumstances.

Licensee shall be given written notice of any proposed determination pursuant to the provisions of this paragraph not less than thirty (30) days prior to the effective date of such determination and, if it requests, shall be granted a hearing before any such determination is put into effect.

In the event the written notice proposes to revoke the exclusive license on the ground that the Licensee or its sublicensees have failed to comply with any of the provisions of this Agreement (pursuant to clause (1) of this subparagraph), such notice shall not be effective unless, within a period of ninety (90) days (or such longer period as the officer executing this Agreement on behalf of the Department, or his successor, may authorize in writing) from its receipt, the Licensee or its sublicensees shall have failed to cure the asserted noncompliance.

b. If the exclusive license is revoked pursuant to the provisions of subparagraph "a(2)" or "a(3)" above, the Licensee shall have a nonexclusive license under the Patent Rights until expiration thereof. A nonexclusive license obtained pursuant to the terms of this subparagraph shall be revocable if the Licensee, three years after a patent issues on the invention, has failed to bring the invention to the point of practical application.

12. OTHER LICENSEES

In the event that this license becomes nonexclusive, the Department agrees that with respect to licenses to others, if the Department should during the period of this License Agreement grant a license to any person, firm or corporation under more favorable terms, except as to the royalty paid, than those hereby granted to Licensee, the Department will promptly notify Licensee and advise Licensee concerning the differences, in terms between such more favorable license and this License Agreement. Licensee

shall, at Licensee's election, be entitled to the benefit of such more favorable terms as of the date upon which such more favorable license shall become effective.

13. TERMINATION OF AGREEMENT

Licensee shall have the right to terminate this Agreement at any time by giving six (6) months prior written notice to the Department to that effect. From and after the effective date of any termination of this Agreement, neither the Licensee nor the Department shall have further rights, powers, privileges, licenses, obligations or liabilities under any of the provisions of this Agreement.

14. DISPUTES

All disputes concerning the interpretation or application of this License Agreement which are not disposed of by mutual agreement shall be decided by the officer executing this license on behalf of the Government, or his successor, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Licensee. His decision shall be final and conclusive, except on questions of law, unless within thirty (30) days from the date of receipt of such copy the Licensee mails or otherwise furnishes to him a written appeal addressed to the Secretary, Department of Health and Human Services. The decision of the Secretary, or his duly authorized representative for the determination of such appeals, shall be final and conclusive, except on questions of law, unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with appeals under this clause, the Licensee shall be afforded an opportunity to be heard and to offer evidence in support of its appeal.

15. NOTICES

Any report or notice to be given hereunder shall be sent to the following respective addressees:

For the Department:

Assistant Secretary for Health
Department of Health and Human Services
Washington, D. C. 20201

For the Licensee:

_____

_____

_____

16. COVENANT AGAINST CONTINGENT FEES

The Licensee warrants that no person or selling agency has been employed or retained to solicit or secure this license upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Licensee for the purpose of securing business. For breach or violation of this warrant, the Department shall have the right to annul this license without liability.

17. OFFICIAL NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this license or to any benefit that may arise therefrom, but this provision shall not be considered to extend to this license if granted to a corporation for its general benefit.

18. COMPLETE AGREEMENT

This Agreement sets forth the entire understanding between the parties as to the subject matter, and the provisions cannot be modified or changed without the written consent of both parties.

IN WITNESS WHEREOF, the parties hereto have executed this instrument in triplicate by proper persons thereunto duly authorized of the day and year hereinabove written.

UNITED STATES OF AMERICA

By:_____ Date:_____

Title: Assistant Secretary for Health,
Department of Health and Human Services

_____

By:_____ Date:_____

Type Name:_____

Title:_____

ATTACHMENT III.

UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

2 NOV 1987

MEMORANDUM FOR Douglas A. Riggs
General Counsel

FROM: Robert Ortner
Under Secretary for Economic Affairs

SUBJECT: Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986

In your memorandum of February 11, 1987, you reviewed this Department's Employee Standards of Conduct for the purposes of the Federal Technology Transfer Act of 1986, and concluded that "our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time." My office is now beginning to prepare materials for use in the Department's laboratories that will establish guidelines for employees in situations likely to arise under the Act. The purpose of this memorandum is to ask you to assign a member of your staff to work with Norm Latker, Director, Office of Federal Technology Management, in the preparation of these guidelines.

These guidelines would address problems that might arise in the course of this Department's implementation of the Act. Some examples of specific questions that should be discussed include:

- Could a Federal employee/inventor accept compensation as a consultant from a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor or co-inventor accept compensation for giving technical advice to a private firm on developing an invention that these employees made under a cooperative agreement with the laboratory?
- Could a Federal employee/inventor invest or become a stockholder in a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor become an officer in a firm which is licensing that employee's invention from the Federal government?

- Could a Federal employee/inventor remain an employee and become an officer in a firm which, as a result of a cooperative agreement, has been granted in advance a patent license for all that employee's inventions arising under the agreement?

- Would a Federal employee/inventor who obtains a license from the government to use his or her own invention receive 15 percent of the royalties back from the government that he or she paid to the government for the right to use the invention?

- What restrictions are there on a former employee of a Federal laboratory negotiating a cooperative R&D agreement with that Federal laboratory?

- Under what circumstances can an employee of a laboratory leave the laboratory and become an employee of a company which has a cooperative agreement with the laboratory?

UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity, Technology and Innovation
Washington, D.C. 20230
(202) 377-1984

08 DEC 1987

Honorable Robert E. Windom, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Windom:

This is in addition to my November 2, 1987 response to Mr. Randall's July 17, 1987 inquiry, copies of the exchange enclosed. Since my response I understand that you have delegated the authority to enter into cooperative R&D and licensing agreements to your PHS Agencies, Centers and Institutes in accordance with Executive Order 12591 and the Federal Technology Transfer Act of 1986 (FTTA). As you know that delegation inherently carries with it the responsibility by delegatees to determine whether or not it is appropriate to pursue intellectual property protection. (See Section 1(b)(1)(B) of Executive Order 12591). Accordingly, when dealing with hybridomas which was the subject of the Randall inquiry the delegatees will need to determine the appropriate means for managing this type of technology.

The decision whether to file a patent on a hybridoma should rest on whether the patent will include broad claims on the use of the class of hybridomas of which the specific hybridoma is an example. If the patent would cover only the specific hybridoma then filing of a patent is widely believed not warranted by technology managers.

Even though patents are usually not filed on hybridomas, the actual physical hybridomas are being licensed by the university community on an exclusive basis to private sector distributors when wide and easy access is deemed desirable. We strongly support the university initiative as being entirely consistent with the Administration's policy to enhance commercialization of Federally-funded research results.

I urge you to advise the delegatees of the authorities under the FTTA and Executive Order 12591 that they are able to pursue the same course undertaken by universities in the licensing of hybridomas created in their laboratories. In light of the fact that a delegatee determines not to pursue patent protection, licensing the physical hybridomas is not subject to the procedures of 37 CFR 404 since the hybridoma is not a "patentable invention" under 37 CFR 404 3(a).

In addition, consistency suggests that your grant and contract managers make clear through PHS funding arrangements that the current university licensing practice of hybridomas (and for that matter any other tangible property resulting from Federally-funded research) is in accordance with Administration policy (see Section 1(b)(6) of Executive Order 12591). This seems important since I have been advised by the university community that they are unsure what the DHHS position is on this matter.

Sincerely,

D. Bruce Merrifield

Enclosures

cc: Mr. Leroy Randall (DHHS)

EA/PTI/FTM/Norman Latker/rh 12-2-87
bc: Dr. Merrifield
Niels Reimers (Stanford University)
Roger Ditzel (University of California)
George Dummer/John Preston (MIT)
Chron
Read

UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity, Technology and Innovation
Washington, D.C. 20230
(202) 377-1984

NOV 2 1987

Mr. Leroy Randall
Chief, Patents Branch
U.S. Department of Health & Human Services
Westwood Building, Room 5A03
5333 Westbard Avenue
Bethesda, MD 20912

Dear Mr. Randall:

Thank you for your letter of July 17, regarding the trade secret licensing of hybridomas. For purposes of discussion I would characterize the subject as the licensing of tangible property resulting from federally-funded research. The fact that such property may be licensed exclusively does not necessarily mean that we are dealing with trade secrets. Most investigators producing such property publish articles which teach how the property was made which eliminates the need to discuss this as a "trade secret" issue.

The issue of licensing tangible property resulting from Federally-funded research is of great concern to the Department of Commerce. In light of your inquiry, I have asked my staff to look into undertaking the development of a policy statement. After that review, I will be back in contact with you.

Sincerely,

(Signed)
D. B. Merrifield

D. Bruce Merrifield

cc: Dr. Robert E. Windom, AS, HHS (w/cc of incoming)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

c/o National Institutes of Health
Westwood Building, Room 5A03
Bethesda, Maryland 20912
(301) 496-7056

July 17, 1987

Dr. Bruce Merrifield
Assistant Secretary for Productivity,
Technology and Innovation
Department of Commerce
14th Street and Constitution Avenue
Room 4824
Washington, D.C. 20230

Re: Trade Secret Licensing of Hybridomas

Dear Dr. Merrifield:

This refers to the enclosed copy of a letter dated June 17, 1987 from Dr. Ed Pandolfino of Hybritech suggesting that the Government license hybridomas as trade secrets, without filing patent applications, and to our telephone conversation of July 14, 1987 discussing this proposal.

I would appreciate your review of the suggestion from Dr. Pandolfino, and your opinion as to its merit, particularly in view of the publication requirements of the Department of Commerce regulations covering the exclusive or partially exclusive licensing of Government owned inventions (37 CFR 404). Our procedure before exclusive or partially exclusive licensing could provide for publication and an opportunity for filing written objections, if a need exists for such publication.

Before we get into the details of this type of licensing, I would appreciate your review of the merit of the basic idea.

Thanks for your cooperation.

Sincerely,

Leroy B. Randall
Chief, Patent Branch

cc: Mr. D. Grinstead, HHS
Dr. Philip Chen, NIH

RECEIVED

SEP 0 2

D BRUCE MERRIFIELD

LR

Hybritech INCORPORATED

1987 JUL -7 PM 2:15

June 17, 1987

Robert E. Windom, M.D.
Assistant Secretary for Health
Room 716G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Windom:

I am writing to offer a suggestion which could greatly facilitate the transfer of clinically useful government-owned technology to the biomedical industry.

During the last five years, I have been involved in licensing technology for two different biotechnology companies. One consistently frustrating aspect of my work has been the difficulty of licensing technology (particularly hybridomas) from federal institutions. Numerous investigators at NIH and CDC have developed monoclonal antibodies and other technology which could be incorporated into commercial products. The primary difficulty in making this technology available to U.S. industry appears to stem from the current federal licensing policy.

As I understand it, technology developed at government institutions cannot usually be licensed unless a decision to file a patent application has been made. In the case of most hybridomas and many other biologicals, this may not be appropriate.

Most universities and companies involved in making hybridomas have come to the conclusion that patent cliams which are restricted to a specific hybridoma are of very limited value. Patent prosecution is expensive, and requires that the hybridoma be made publically available. One must also reveal exactly how the hybridoma was generated. It is usually not difficult for someone else to produce an equivalent hybridoma which does not infringe the restricted patent claims. Also, the public availablility of the hybridoma creates the risk that others will use it without obtaining a license. Such infringement could be very difficult to detect and prove.

In light of this, many organizations active in this field (both companies and universities) often choose to protect hybridomas as they would protect trade secrets or know-how. That is, access to the hybridoma is restricted.

The hybridomas can still be made available to researchers by having them sign a 'research use only' agreement. If the organization wishes to have the hybridoma used commercially, a license agreement (very similar to a patent license) can

11095 Torreyana Road • P.O. Box 9006 • San Diego, California 92121-1104
619 455-6700 • TELEX 697126 • FAX 619 453-4124 • CABLE HYBR

be executed. This agreement typically specifies fees, royalties and limits on the licensee's rights. In most cases, the licensee is specifically precluded from transferring the hybridoma to any third parties. This sort of agreement has been common in the industry since the late 1970's and has worked quite well.

My suggestion is that a new policy be instituted which permits the licensing of government-owned hybridomas (and other biologicals) in the absence of a patent applicaton. This policy could work as described below:

1. Given a specific set of criteria, a determination would be made at a regional level that a particular hybridoma would be best treated as 'know-how' or a 'trade secret'.

2. Once that determination is made, the regional institution would be free to license the hybridoma using a standard license agreement.

3. The income from such licenses would have to be shared according to current federal policy. Hopefully, some of the revenues would remain in the institution as an incentive to future technology transfer and, perhaps, to supply funds for prosecution of patents on other types of technology.

This system would allow the biomedical industry much more efficient access to government technology of potential clinical value. It would also bring additional funds to the regional institutions without the expense associated with a patent application. The use of standard criteria and a standard license agreement means that very little administrative time would be required.

Under the current system, many valuable hybridomas are simply not made available either because they are not considered patentable or because the institution does not wish to bear the costs of patent prosecution. This situation is frustrating not only to the companies which would like to use these hybridomas, but also the investigators who would like to see their developments put to clinical use.

I hope that you will give this proposal serious consideration. I believe that a policy can be developed which is consistent with the charters of the institutions and in the best interest of the public.

Best regards,

Ed Pandolfino, Ph.D.
Licensing Manager

ERP:MG

cc: Dr. Lowell Hermison

application. The use of standard criteria and [illegible] patent

JAN 26 1988

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE NATIONAL TECHNICAL INFORMATION SERVICE
AND
THE U.S. PUBLIC HEALTH SERVICE

WHEREAS, the Public Health Service (PHS) sponsors research on new and useful products and processes which have potential application in the private and public sectors; and

WHEREAS, PHS may receive certain valuable patent or other forms of intellectual property rights in the United States and foreign countries covering such products and processes; and

WHEREAS, PHS has the authority pursuant to 35 U.S.C. 207 and 15 U.S.C. 3710 to transfer the custody of such rights to another Federal agency; and

WHEREAS, the National Technical Information Service (NTIS) has the authority pursuant to 35 U.S.C. 207 and 15 U.S.C. 3710 to receive by transfer custody of such rights from another Federal agency, to obtain and maintain patents or other forms of protection in the U.S. and foreign countries and to grant licenses in accordance with the regulations set forth in 37 C.F.R. Chapter IV as amended, thereunder to receive fees, royalties or other revenues therefrom, and to take all other suitable and necessary steps to protect and administer such rights; and

WHEREAS, PHS and NTIS desire that the results of Federally-sponsored research and development be perfected, marketed, and

practiced so that such results are made readily available for widest possible utilization in the shortest time possible for the benefit of the public and to increase U.S. economic activity and competitiveness; and

WHEREAS, PHS and NTIS desire to promote the use, by qualified private or public sector entities, of Government-owned U.S. and foreign patent properties in the custody of PHS or NTIS and, with respect to those foreign patent properties, to protect overseas markets for U.S. industry and to promote U.S. trade objectives; and

WHEREAS, PHS and NTIS desire to advance the objectives of the Technology Transfer Act of 1986 (P.L. 99-502), including the provision of appropriate recognition and incentives to Government researchers and other Government employees who contribute substantially to technical developments or to the transfer of technology to the private or public sectors.

NOW THEREFORE, in consideration of the foregoing, PHS and NTIS agree as set forth below.

ARTICLE I

Definitions

1.1 U.S. shall mean the United States of America.

1.2 PHS shall mean the U.S. Public Health Service, a primary operating unit of the U.S. Department of Health and Human Services, as well as any PHS organization to whom licensing authority under 15 U.S.C. 3710a(a)(2) has been delegated.

1.3 For the purpose of this agreement, PHS Agencies shall mean the National Institutes of Health, the Food and Drug Administration, the Health Resources and Services Administration, the Centers for Disease Control, and the Alcohol, Drug Abuse and Mental Health Administration.

1.4 NTIS shall mean the National Technical Information Service, a primary operating unit of the U.S. Department of Commerce.

1.5 Government shall mean the Federal Government of the U.S.

1.6 Patent property shall mean a patent or pending patent application, whether U.S. or foreign, owned in whole or in part by the Government as represented by an agency of the Government.

1.7 Custody shall mean the responsibility of an agency on behalf of the Government for administration and management, including power of attorney for matters relating to patent

prosecution, of the right, title, or interest in a patent property owned in whole or in part by the Government.

1.8 Addendum shall mean the addendum to this agreement which outlines the financial procedures and obligations of PHS and NTIS pursuant to implementation of this Memorandum of Understanding (MOU).

ARTICLE II

Scope of Agreement

2.1 This MOU sets forth, as its primary objective, the basic terms, conditions and procedures under which the custody of selected patent properties owned by the Government and in the custody of PHS shall be transferred to NTIS for the purpose of obtaining and maintaining foreign patents, whether the patent property is a U.S. or foreign patent or patent application, and granting domestic and foreign licenses under such patent properties. It does not require that the custody of every patent property in the custody of PHS be transferred to NTIS.

2.2 This MOU sets forth the basic procedures for the granting of incentive awards from funds collected in Fiscal Year 1987 to qualified PHS personnel pursuant to the authority of 15 U.S.C. 3710.

2.3 This MOU also provides a broad, conceptual framework for PHS and NTIS to undertake cooperative technology transfer efforts, not limited to the scope of Paragraph 2.1 and 2.2, within which framework other forms of services or agreements covering the disposition of Government proprietary rights, laboratory technology, equipment, facilities, and other resources might be developed to advance PHS and NTIS technology transfer objectives.

ARTICLE III

Licensing

3.1 NTIS and PHS agree to use their best efforts to locate and secure licensees under PHS patent properties in the custody of NTIS.

3.2 PHS may select and recommend to NTIS those newly created patent properties which PHS believes have good potential for licensing and commercial development. PHS may also stipulate that NTIS promote licensing of certain properties. PHS shall forward copies of such patent properties to NTIS within a week of filing for the patent. PHS may also identify specific or general conditions or special provisions which NTIS will endeavor to implement to the extent permitted by pertinent statutes and regulations in the administration and licensing of the subject patent property.

3.3 NTIS shall routinely bring all PHS patent properties forwarded to NTIS to the attention of the public through general announcements and publications. NTIS shall also review newly created patent properties forwarded to NTIS by PHS and PHS recommendations pursuant to Paragraphs 3.2 and select those patent properties most likely to benefit from specific and targeted attempts by NTIS to promote the licensing of such patent properties as, for example, by direct contact with organizations with a high probability of licensing interest.

3.4 NTIS shall have the authority to negotiate and execute license agreements under PHS patent properties in the custody of NTIS. NTIS agrees that the terms and conditions of such license agreements shall be consistent with Federal licensing regulations and policies and with other such conditions, instructions, or considerations which PHS may make known to NTIS pursuant to Paragraph 3.2, above.

3.5 NTIS shall provide the Assistant Secretary or his designee the opportunity, if desired, to participate in NTIS' license negotiations with interested parties and in decisions as to whether to grant exclusive, partially exclusive, or nonexclusive licenses. NTIS shall implement such decisions unless they are not in accordance with pertinent statutes, regulations, or Department of Commerce policy.

3.6 PHS agrees to make its inventors, other knowledgeable technical staff, patent attorneys, and agents available to NTIS and prospective licensees and licensees of PHS patent properties for reasonable periods of consultation. Furthermore, PHS may invite NTIS to participate in preliminary discussions within PHS, or to be represented on advisory groups, concerned with the planning, development, and conduct of activities that may result in patentable properties. The purpose of such consultations shall be to assist in the transfer of the technology embodied in such patent properties for the benefit of the U.S. public.

3.7 Licenses under PHS patent properties in the custody of NTIS normally shall require the payment to NTIS of fees, royalties, or such other consideration as NTIS may determine is in the public interest.

ARTICLE IV

Custody Transfers, Foreign Patent Filing and Patent Protection

4.1 PHS normally shall initiate the filing of patent applications in the U.S. on inventions which PHS selects and in which PHS retains an assignment of rights. When custody of such patent applications is transferred to NTIS pursuant to Paragraph 4.2, PHS normally shall continue to prosecute such patent applications. PHS shall, upon request of NTIS, provide NTIS with

a copy of the prosecution file of such patent applications to facilitate foreign patenting and licensing. NTIS may, from time to time and at the request of PHS, assume an active role in the prosecution of such domestic patent applications to facilitate licensing.

4.2 At some time during the course of licensing activities described in Article III, NTIS may request the transfer of the custody of such patent properties from PHS to NTIS. PHS shall transfer custody of such requested patent properties to NTIS pursuant to the authorities cited herein unless it is determined by PHS that it does not wish to make such transfer due to unusual circumstances necessitating alternative licensing arrangements. Unlicensed PHS patent properties previously transferred into the custody of NTIS may be transferred back to PHS upon written request from PHS at such time and under such conditions as PHS and NTIS mutually agree are in the public interest. In the event that patent properties are transferred back to PHS or a custody transfer is denied to NTIS, NTIS shall be reimbursed for expenses incurred by NTIS for work performed on such patent properties.

4.3 PHS shall stipulate which eligible patent properties NTIS shall seek to be patented abroad and in which countries such protection should be sought. NTIS shall review these patent properties for foreign patent filing based upon potential licensability and shall notify PHS in each instance when PHS

[illegible] transferred into the

stipulations regarding foreign filing can not be followed by NTIS for whatever reason, or when NTIS does not choose to exercise the Government's option within the legal period for option exercise. Such notification will be provided at least 30 days before the expiration of such option time period in order to enable PHS to consider acting on its own to obtain foreign protection. In the event NTIS chooses to file, it shall notify PHS and the employee-inventor within such period.

4.4 At the direction of PHS, NTIS shall take all reasonable and necessary steps, including the payment of maintenance fees and taxes, to procure and maintain patent protection in foreign countries on patent properties selected pursuant to Paragraph 4.3. PHS will be responsible for paying all related costs. NTIS may contract with private firms for professional services concerning the filing, prosecution and maintenance of such patent properties. PHS agrees to make its technical and patent attorney staff and PHS contract patent attorneys reasonably available for consultation with NTIS and NTIS' contractors in support of foreign patent prosecution of such patent properties.

4.5 NTIS may discontinue the prosecution or defense of any patent property in its custody covering a PHS invention, decline to pay the maintenance fees for a patent property, or otherwise abandon a patent property when, after consultation with PHS, it appears to be in the public interest to do so, or when funds

therefor are unavailable to NTIS. Thirty days before taking such action, NTIS shall inform PHS in writing of its intentions. PHS may request NTIS to reconsider its intentions, and may reacquire custody of such patent property for the purpose of continuing prosecution, of paying maintenance fees, or otherwise assume responsibility for such patent property.

ARTICLE V

Financial Considerations and Reports

5.1 NTIS shall be responsible for the collection of fees and royalties and other income from licenses under PHS patent properties in the custody of NTIS or, as mutually agreed upon, for fees, royalties, or other income from other forms of services or agreements executed and administered by NTIS and covering the disposition of PHS proprietary rights, laboratory technology, equipment, facilities, and other resources.

5.2 NTIS shall be responsible for handling and accounting for fees, royalties or other income collected pursuant to Paragraph 5.1, above, in accordance with customary and accepted Government accounting procedures and regulations.

5.3 For funds collected in FY 1987, NTIS shall make payments to PHS employees, the precise amount of which and the form of payment of which shall be determined by PHS, in compliance with

the mandate and authorities of 15 U.S.C. 3710 as indicated in Article VI below. In subsequent years, PHS will distribute payments to employees.

5.4 NTIS shall retain a portion of fees, royalties or other income collected pursuant to Paragraph 5.1 or shall otherwise be directly compensated by PHS to offset the cost of NTIS performing services for PHS under this MOU. The specific amounts of such fees and royalties retained or otherwise paid to NTIS by PHS shall be established annually by mutual agreement as provided in the Addendum each year.

5.5 PHS will be responsible for paying the cost of obtaining and maintaining U.S. and foreign patent properties. If NTIS acts as its agent for any of the activities under this agreement, PHS agrees that NTIS may retain license income to cover their cost.

5.6 NTIS shall report to PHS 45 days after the end of each Government fiscal year on:

- the domestic and foreign licensing and the new and abandoned foreign patent properties transferred to NTIS under Paragraph 4.2 during that fiscal year.

- such other information as PHS may request on the disposition of such patent properties. PHS shall indicate if any

information forwarded to PHS is considered confidential information not releasable under the Freedom of Information Act. PHS assures that such indicated information shall be treated as confidential and shall only be released to those PHS personnel who shall treat such information as confidential.

- the total of fees, royalties and other income collected for each PHS Agency from each licensed PHS patent property in the custody of NTIS by individual inventor pursuant to the requirements of Section 14(a)(1)(A)(i) of the Stevenson-Wydler Act, as amended. This report will also be prepared 45 days after the middle of the fiscal year. The end-of-year report will also identify the portion of royalties and other income pursuant to that act for which these inventors are eligible for payment.

- the other forms of services or agreements executed and administered and fees paid to NTIS and covering the disposition of PHS proprietary rights or laboratory technology and know how.

5.6 For funds collected in FY 1987, the balance of fees, royalties and other income collected by NTIS pursuant to Paragraph 5.1 which is in excess of the payments paid or due to PHS employees under Paragraph 5.3 and Article VI, below, and of that

portion of such fees, royalties and other income retained by or paid to NTIS under Paragraph 5.4 and as described in the Addendum, shall be forwarded to the appropriate PHS agencies. In subsequent years, all income in excess of that to be retained by NTIS per the Addendum shall be forwarded to the individual PHS agencies, with those agencies making the payments due to employees.

ARTICLE VI

Payments to Employees

6.1 For funds collected in FY 1987, PHS will review the end-of-year report referred to in Paragraph 5.6, above, and will notify NTIS within 45 days whether PHS employees have been properly identified as eligible for payment of a portion of royalties and other income pursuant to the requirements of Section 14(a)(1)(A)(i) of the Stevenson-Wydler Act, as amended. If PHS desires to authorize payments (a) in addition to the statutory minimum of 15 percent of royalties or other income received from the licensing of Government-owned patent properties, or (b) in the form of incentive cash awards authorized by Section 13 of the Stevenson-Wydler Act, as amended, such additional payments will be made by NTIS from monies made available and forwarded to NTIS, with authorization and related instructions, by PHS. NTIS will make such payments within 45 days of the receipt of the information from PHS.

6.2 The time, place and manner of presentation of 1987 awards to PHS personnel under this-Article shall be jointly determined by NTIS and PHS.

6.3 At the end of each subsequent fiscal year, payments described in section 6.1 will be made by PHS agencies.

ARTICLE VII

General

7.1 This MOU is effective as of the date of signing by the Director, NTIS, and will remain in effect until such time as it may be terminated in accordance with Paragraph 7.3 below.

7.2 This MOU does not require that the custody of every PHS patent property be transferred to NTIS.

7.3 Specific provisions of this MOU may be revised, amended, or terminated by mutual written agreement among the signatories to this MOU or by their respective designees.

7.4 PHS or NTIS may terminate this MOU at the end of any Government fiscal year upon written notice to the opposite party not less than one year prior to the end of such fiscal year. Termination of this MOU will not reconvey to PHS custody of PHS patent properties acquired by NTIS prior to the date of

termination of this MOU unless specifically provided pursuant to Paragraph 4.2.

7.4 In the event that the Office of Federal Patent Licensing, now part of NTIS in the Department of Commerce, is privatized, this agreement will be subject to renegotiation. This includes the issue of returning to PHS patents previously transferred to the Department of Commerce.

7.5 The Addendum to this MOU shall be reviewed and updated annually. Should the revisions to the Addendum to this MOU not be mutually agreed upon by the signatories to this agreement at least 90 days prior to the start of any Government fiscal year, the Addendum from the prior fiscal year shall remain in effect until such time as a revised Addendum is mutually agreed upon.

U.S. Public Health Service
200 Independence Avenue, S.W.
Washington, D.C. 20201

BY: _____ 2/3/88
Assistant Secretary for Health Date

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161

BY: _____ 2/10/88
Director Date
National Technical Information Service

MEMORANDUM OF UNDERSTANDING
BETWEEN NTIS AND PHS

ADDENDUM FOR FY 1987, 1988

In FY 1988, NTIS will retain the equivalent of 85 percent of gross execution and minimum annual fees (hereafter referred to as fee income) to cover the cost of NTIS labor and overhead associated with PHS activities. Should NTIS receive an FY 1988 appropriation, a share of those monies proportionate to the level of activity NTIS has expended on behalf of PHS shall be used to offset the proposed retention of fees by NTIS. Should the appropriation exceed that amount, the increment will be used to offset PHS foreign patent filing costs.

NTIS will provide PHS with a report on the size and composition of the staff devoted to PHS activities, and a summary report on those activities, broken down by PHS agency, and on labor and overhead costs. This report will be submitted forty-five days after the end of the fiscal year and will be used to adjust the annual charges in the subsequent year, if necessary.

U.S. Public Health Service
200 Independence Avenue, S.W.
Washington, DC 20201

BY: _____ 2/3/88
Assistant Secretary for Health — Date

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161

BY: Joseph F. Caponio 2/10/88
Director — Date
National Technical Information Service

TO: NORM LATICEK
Tel: 738-0213
FAX: 738-0212

FROM JOE ALLEN
DOC
Tel: 377-8100
FAX: 377-0432

UNITED STATES DEPARTMENT OF COMMERCE
Associate Under Secretary for
Economic Affairs
Washington, D.C. 20230
(202) 377-3709

7 MAR 1988

Mr. Rick Summerour
Chairman Joint DAR/CAAC SubcommitteeOn
Patents/Technical Data/Computer Software
SAF-AQCS, Pentagon, Room FC323
Washington, D.C. 20330-1000

Dear Mr. Summerour:

At your request, I am writing to explain my concerns with the proposed modifications to the existing patent regulations of the Federal Acquisition Regulation (FAR) found in Parts 27 and 52 of 48 CFR. The proposed modifications currently being considered by the Civilian Agency Acquisition Council (CAAC) have been designated by CAAC Case 85-33/DAR Case 85-56, Commerce Patent Regulation, P.L. 98-620.

The areas the Department of Commerce has the greatest concern about were reflected in a letter sent to Mr. Stephen Mournighan dated July 22, 1987 (copy enclosed) from this Office. The latest revisions of the proposed FAR patent regulations have addressed many of the objections set forth in that letter. However, the proposed regulations still fail to address our policy concerns. We are concerned not only with the citation of Executive Order 12591, but with its application to the proposed patent regulations. Section 1(b)(4) of the Order states:

"(b) The head of each Executive department and agency shall, within overall funding allocations and to the extent permitted by law:

(1)...
(2)...
(3)...
(4) promote the commercialization, in accord with Memorandum to the Heads of Executive Departments and Agencies of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government;"

We believe the mandate of the Order coupled with the Paperwork Reduction Act of 1980 (Pub. L. 96-511), justifies the use of our short form patent clause and the deletion of the long-form clause (52.227-12) providing for title-in-the contractor for contractors other than small business and nonprofit organizations.

We also believe that, even if a policy decision is made to use the existing two title-in-the-contractor clauses, the intermingling of provisions in the FAR effecting small businesses and nonprofit organizations - as the regulations now exist-with those affecting other entities is undesirable and confusing. Having two distinct sections--one for universities and small businesses and another section for others--will be much less burdensome on contractors and Government procurement officials. The concerns expressed in this letter and the attachment have been outstanding for some time. An early resolution of them at the DAR and CAAC Councils is long overdue. Our strong suggestion to resolve this matter is to request an urgent opinion on these matters from OMB's Office of Federal Procurement Policy.

Sincerely,

Joseph P. Allen
Director, Federal Technology
Management Division

Enclosure

cc: Mike Gerich
Tom Zack

UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity, Technology and Innovation
Washington, D.C. 20230
(202) 377-1984

22 JUL 1987

Mr. Stephen Mournighan
Director, Office of Policy, MA-42
U. S. Department of Energy
1000 Independence Avenue, S.W.
Washington, D.C. 20585

Dear Steve,

This responds to your request for us to review and comment on the proposed revision to the Federal Acquisition Regulation (FAR) Subpart 27.3. We did not participate in the drafting of this revision because we felt at the time that development was premature since our Final Regulation was not yet published in the Federal Register. We were awaiting completion of negotiations on the Regulations with the Department of Energy.

We note that the draft regulation is based on the Department of Commerce's Interim Final Regulations dated July 14, 1986 and not on our Final Regulations which appeared in the Federal Register on March 18, 1987. The proposed revision to the FAR should be based on the Department of Commerce's March 18 Final Regulations because the Final Regulation is in certain areas different from the Interim Regulations. We are enclosing a list of specific comments on the draft FAR Subpart and clauses.

In addition, Executive Order 12591 of April 10, 1987 should be considered in any proposed revision to the FAR. For example, we note that in light of subparagraph 1(b)(4) of the Executive Order, we do not believe that a separate title-in-the-contractor clause is justified for contractors other than small business and nonprofit organizations. We recommend deletion of the long-form clause numbered 52.227.12.

Based on the foregoing, we strongly recommend that the DAR subcommittee reconvene to further consider this proposed revision.

Sincerely,

Norman J. Latker
Director, Office of Federal
Technology Management

Enclosure

cc: Eugene Stevens, III (AF/JACP)