

BIOLOGICAL MATERIALS LICENSE AGREEMENT

This Agreement is entered into between the U.S. Government, as represented by the U.S. Department of Agriculture, Agricultural Research Service (hereinafter referred to as "USDA") and (company name), a (state) corporation having offices at (street address, city, and state) (hereinafter referred to as "COMPANY").

WHEREAS, USDA has performed research to develop the hybridoma cell listed in Appendix 1; and

WHEREAS, COMPANY wishes to obtain a license from USDA to use the monoclonal antibodies produced by the hybridoma cell for (description of commercial products); and

WHEREAS, COMPANY represents that it has the facilities, personnel and expertise to produce the monoclonal antibodies and is willing to expend reasonable efforts and resources to produce the monoclonal antibodies for commercial production and sales;

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and obligations hereinafter set forth, USDA and COMPANY, intending to be legally bound, agree as follows:

ARTICLE I DEFINITIONS

1.1 Licensed Materials means the hybridoma cell line, listed in Appendix 1 attached hereto and incorporated by reference into this Agreement, as further described in a full written description provided to USDA by the inventor, including all progeny, subclones and derivatives thereof, and any and all monoclonal antibody preparations of any kind, including but not limited to ascites fluids, purified antibodies, enzyme conjugated antibodies, or fluorescent conjugate antibodies which are derived from the hybridoma cell line.

1.2 Licensed Products means any and all (specific description of commercial products to be sold by licensee; e.g., monoclonal antibodies, biological control formulations, diagnostic test kits, vaccine and testing reagents, assays, reagents, test kits) which incorporate Licensed Materials for use in the detection of (description of intended commercial use).

1.3 Net Sales means the gross sales of Licensed Products by COMPANY to an independent third party less the sum of the following:

- (a) discounts, in amounts customary in the trade, for quantity purchases, cash payments, wholesalers, and distributors;
- (b) amounts repaid or credited by reason of rejection or returns; and

- (c) any freight or other transportation costs, insurance, duties, tariffs and sales and excise taxes based directly on sales or turnover or delivery of material produced under this Agreement.

No deductions shall be made for commissions paid to sales persons or agents or for the cost of collections. Licensed Products produced by COMPANY for its own use shall be included for the purposes of computing Net Sales, except such Licensed Products used for non-revenue producing activity such as promotional items or market trials. Licensed Products shall be considered sold when billed or invoiced.

1.4 Effective Date means the later date on which this Agreement is executed by a party to the Agreement.

1.5 Licensed Term means a period of five (5) years beginning on the Effective Date.

[Additional definitions may be included, as needed based upon COMPANY's business plan submitted to USDA pursuant to 35 U.S.C. 209(f)].

ARTICLE II
GRANT

2.1 USDA grants to COMPANY, subject to the terms and conditions herein, a nonexclusive license to make, have made, and use the Licensed Materials to make, have made, use and sell Licensed Products for the term of this Agreement. The rights granted herein do not include the right to grant sublicenses. COMPANY shall retain control over the Licensed Materials and shall not distribute them to third parties without the prior written consent of USDA, except as specifically provided in this Article II.

2.2 USDA shall provide COMPANY with samples of the Licensed Materials upon receipt of payment of the license execution fee, as provided under Paragraph 4.1 below. Upon reasonable notice to USDA by COMPANY and subject to availability, USDA shall replace Licensed Materials in the event of their unintentional loss or destruction.

ARTICLE III
RESERVATION OF RIGHTS
[RESERVED]

ARTICLE IV
FEES, ROYALTIES, AND PAYMENTS

4.1 Upon execution of this Agreement, COMPANY shall pay to USDA a license execution fee of _____ Thousand Dollars (\$X,XXX.XX) for the hybridoma cell line(s) identified in Appendix 1, no part of which shall be refunded for any reason. Payment of such fee shall be due within thirty (30) days of the Effective Date. In accordance with Paragraph 7.1, this Agreement may be automatically renewed for additional five (5) year periods upon payment of a license renewal fee in the amount of _____ Thousand Dollars (\$X,XXX.XX) for each

hybridoma cell line identified in Appendix 1, no part of which shall be refunded for any reason. Payment shall be due thirty (30) days prior to the end of the License Term.

4.2 COMPANY shall be responsible for costs associated with shipping and handling of the Licensed Materials.

4.3 COMPANY shall pay USDA royalties of _____ percent (X%) on the Net Sales of Licensed Products by COMPANY. Royalties shall be due and payable upon submission of each royalty report, in accordance with the provisions of Paragraph 5.1 below.

4.4 All payments due USDA under this Article IV shall be payable in United States dollars for the account of USDA/Agricultural Research Service, License No. (XXXX-XXX). All checks and bank drafts shall be drawn on United States banks. A late payment of a license fee or royalty shall automatically raise said fee or royalty by an amount equal to one percent (1%) of the amount due for each month beyond the due date of such late payment. Conversion of foreign currency to United States dollars shall be made on the last business day of the applicable reporting period for the purchase of United States dollar bank wire transfers for settlement of such payment obligations. Any and all loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion of other currency to United States dollars shall be paid entirely by COMPANY.

ARTICLE V REPORTS AND RECORDS

5.1 COMPANY shall submit to USDA within sixty (60) days of the end of each calendar year a report setting forth for the preceding twelve (12) month period the amount of Licensed Products made, used, or sold or otherwise disposed of by COMPANY, the Net Sales thereof and the royalties due pursuant to Paragraph 4.3 above. The report shall include an itemized accounting of the number of units of Licensed Products sold, price per unit, and each deduction taken from the gross sales for the purpose of calculating Net Sales. A written report shall be due for each reporting period whether or not any royalties are due to USDA.

5.2 COMPANY shall keep accurate and complete records as are required for the determination of royalties owed to USDA pursuant to this Agreement. Such records shall be retained for at least three (3) years following a given reporting period. Upon reasonable notice and at the expense of USDA, such records shall be available during normal business hours for inspection by an accountant selected by USDA and approved by COMPANY for the sole purpose of verifying reports and payments hereunder. Such accountant shall not disclose to USDA any information other than information relating to the accuracy of reports and payments made under this Agreement.

ARTICLE VI LICENSEE PERFORMANCE

6.1 COMPANY shall offer Licensed Products for sale within _____ (#) year(s) of the Effective Date of this Agreement unless this period is extended by mutual agreement of the parties.

6.2 Licensed Products sold or otherwise disposed of in the United States by COMPANY shall be manufactured substantially in the United States.

6.3 COMPANY shall notify USDA in writing within fifteen (15) days after the first commercial sale of Licensed Product by COMPANY.

6.4 After the first sale of Licensed Products in the United States, COMPANY shall keep Licensed Products reasonably available to the United States public during the term of this Agreement.

[Additional diligence requirements may be included, as needed based upon COMPANY's business plan submitted to USDA pursuant to 35 U.S.C. 209(f)].

ARTICLE VII DURATION, MODIFICATION, AND TERMINATION

7.1 This Agreement shall commence on the Effective Date and, unless sooner terminated as provided under Article VII, shall expire at the end of the License Term. Subject to Paragraph 7.2, the term may be extended for additional five (5) year periods upon mutual agreement of the parties and the payment of a license renewal fee in accordance with Paragraph 4.1. Payment of the license renewal fee shall be due thirty (30) days prior to the end of the License Term.

7.2 This Agreement may be terminated by USDA, subject to the provisions of Paragraphs 7.3 and 12.4 below, if it is determined that any one of the following has occurred:

- (a) COMPANY fails to meet the obligations set forth in Article VI above;
- (b) COMPANY has willfully made a false statement or willfully omitted a material fact in the license application or in any report required by this Agreement; or
- (c) COMPANY commits a substantial breach of a covenant or agreement contained in this Agreement.

7.3 Prior to termination of this Agreement, USDA shall furnish COMPANY a written notice of intention to terminate, and COMPANY 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 terminated.

7.4 COMPANY may terminate this Agreement at any time upon ninety (90) days written notice to USDA. Such notice shall include an explanation of the reasons for termination.

7.5 Upon termination or expiration of this Agreement, all sums due to USDA pursuant to Article IV hereunder shall become immediately payable, and COMPANY shall return all Licensed Materials to USDA, or provide written certification of their destruction. In all other

respects, the rights and obligations of the parties hereto concerning the Licensed Materials included shall cease as of the effective date of such termination or expiration. COMPANY may, however, sell all Licensed Products completed and in inventory provided that royalties are paid on any such sales in accordance with the provisions of Article IV.

ARTICLE VIII
PATENT ENFORCEMENT
[RESERVED]

ARTICLE IX
MARKING AND NON-USE OF NAMES

9.1 COMPANY is encouraged to publish the results of any research projects using the Licensed Materials or Licensed Products. Such research publications shall acknowledge the source of the Licensed Materials and shall make reference to relevant USDA research publications, if applicable.

9.2 COMPANY shall not use the name of the U.S. Government, the name of any department or agency of the U.S. Government, the name of any U.S. Government employee, or any adaptation of the above in any promotional activity without prior written approval from USDA.

ARTICLE X
REPRESENTATIONS AND WARRANTIES

10.1 USDA MAKES NO WARRANTIES AS TO THE MERCHANTABILITY OR FITNESS OF THE LICENSED MATERIALS OR THE LICENSED PRODUCTS FOR ANY PARTICULAR PURPOSE, OR THAT THE BIOLOGICAL MATERIALS OR LICENSED PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES, OR ANY OTHER WARRANTIES EXPRESS OR IMPLIED.

10.2 COMPANY shall indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through COMPANY's use of the Licensed Materials or Licensed Products. COMPANY further agrees that it shall not by its action bring the United States Government into any lawsuit involving the Licensed Materials or Licensed Products.

ARTICLE XI
NOTICES

Written notices and reports required to be given under this Agreement, and submission of license execution fees, minimum annual royalties, and royalties, shall be mailed by first class mail, postage prepaid and addressed as follows:

If to USDA:

If to COMPANY:

Assistant Administrator
USDA, ARS, Office of Technology Transfer
5601 Sunnyside Avenue, 4-1159
Beltsville, MD 20705-5131

ARTICLE XII
MISCELLANEOUS PROVISIONS

12.1 This Agreement shall not be transferred or assigned by COMPANY to any party other than to a successor or assignee of the entire business interest of COMPANY relating to the Licensed Materials, but in no event shall COMPANY assign or transfer this Agreement to a party not a citizen or resident of the United States of America. COMPANY shall notify USDA in writing prior to any such transfer or assignment.

12.2 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.

12.3 Neither party may waive or release any of its rights or interest in this Agreement except in writing. The failure of a party to assert a right hereunder or to insist on compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

12.4 The parties shall make every reasonable effort to resolve amicably any dispute concerning a question of fact arising under this Agreement. In accordance with the requirements of 37 CFR 404.11, USDA has established an administrative procedure for resolving disputes not settled amicably between the parties. Any such disputes shall be decided by the Assistant Administrator, Office of Technology Transfer, Agricultural Research Service (ARS), who shall reduce such decision to writing and mail or otherwise furnish a copy thereof to COMPANY. Any decision of the Assistant Administrator, ARS, whether it be a question of fact, or to modify or terminate this Agreement, may be appealed to the Administrator, ARS, whose decision shall be administratively final and conclusive. This shall not preclude COMPANY from taking additional legal action once all administrative avenues have been exhausted. Pending final decision of a dispute hereunder, COMPANY shall proceed diligently with the performance of its obligations under this Agreement.

12.5 The acquisition and use of rights pursuant to this license shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

12.6 The provisions of this Agreement are severable, and the illegality or invalidity of any provision of this Agreement shall not impair, affect, or invalidate any other provisions of this Agreement.

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

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives.

FOR THE UNITED STATES DEPARTMENT OF AGRICULTURE:

Signature

Date

MOJDEH BAHAR
Assistant Administrator, Agricultural Research Service

FOR (COMPANY NAME):

Signature

Date

Name: _____

Title: _____

APPENDIX 1

Docket No. B (XXXX.XX)- the hybridoma cell line (Name/Code) which produces monoclonal antibodies for (description of the invention)