

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 line or microbial isolate or cloned genetic material) listed in Appendix 1; and

WHEREAS, COMPANY wishes to obtain a license from USDA to use the monoclonal antibodies produced by the (hybridoma cell line or microbial isolate or cloned genetic material) for (description of commercial products); and

WHEREAS, COMPANY represents that it has the facilities, personnel and expertise to produce the (monoclonal antibodies or antigens or assays) and is willing to expend reasonable efforts and resources, including contracting with third parties, to produce the (monoclonal antibodies or antigens or assays or diagnostic test kits) 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.

OR

1.1 Licensed Materials means the microbial isolate, 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.

OR

1.1 Licensed Materials means the cloned genetic material, 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.

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 Affiliate(s) means any company, corporation, partnership, or other entity controlled by, controlling, or under common control with COMPANY, directly or indirectly, where control means the ownership of at least fifty percent (50%) of the voting stock or other ownership interest of an entity. For purposes of this Agreement, all references to COMPANY shall be deemed to include its Affiliates.

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

1.6 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. The rights granted include the right to transfer the Licensed

Materials to a third party (e.g., toll manufacturer) for the sole purpose of producing monoclonal antibodies, antigens, assays or diagnostic test kits, on behalf of COMPANY.

ARTICLE III
RESERVATION OF RIGHTS (RESERVED) & EXPORT CONTROL

COMPANY acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. Government or written assurances by COMPANY that it shall not export these items to foreign countries without prior approval of this agency. USDA neither represents that a license is or is not required or that, if required, it shall be issued.

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) or microbial isolate(s) or cloned genetic material(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 7.2 below, 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 or microbial isolate or cloned genetic material) 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 Licensed 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 to USDA under this Article IV shall be payable in United States dollars using **Pay.gov** at <https://pay.gov/public/form/start/76123725>. **Pay.gov** accepts payments from a U.S. bank (up to U.S. \$99,999,999.99 per transaction) or using a credit card (up to U.S. \$24,999.99 for all transactions on the same day using the same credit card). Please refer to License No. (XXXX-XXX) when submitting payments. 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. 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 Product 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 COMPANY is required to execute fully this Agreement and submit a fully executed original to USDA. If USDA does not receive the fully executed original within sixty (60) days from the date of USDA's signature on the Agreement, then the terms and conditions of this Agreement shall be withdrawn from further consideration by COMPANY and the Agreement shall

be null and void. At its sole discretion, USDA may extend the sixty (60) day execution period, any such extensions must be provided in writing.

7.2 This Agreement shall commence on the Effective Date and, unless sooner terminated as provided under Article VII, shall expire at the end of the Licensed Term. Subject to Paragraph 7.3, 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 above. Payment of the license renewal fee shall be due thirty (30) days prior to the end of the Licensed Term.

7.3 This Agreement may be terminated by USDA, subject to the provisions of Paragraphs 7.4 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.

7.4 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.

7.5 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.

7.6 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 LICENSED 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 and maintenance fees and royalties, shall be delivered either: (a) in person; (b) by electronic mail (Email); (c) by first class mail, postage prepaid; (d) by registered or certified mail, postage prepaid, return receipt requested; or (e) by national or international commercial overnight courier, all fees prepaid, that guarantees next day delivery and provides a receipt. Such notices, reports, and payments shall be addressed as follows:

For Agreement Notices and Requests to Amend License Agreement:

If to USDA:

If to COMPANY:

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

Email: license@ars.usda.gov

Email: _____

For Financial Notices and Payments:

If to USDA:

If to COMPANY:

Business Licensing Officer
USDA, ARS, Office of Technology Transfer
5601 Sunnyside Avenue, 4-1159
Beltsville, MD 20705-5131
Email: license@ars.usda.gov

Email: _____

ARTICLE XII
MISCELLANEOUS PROVISIONS

12.1 This Agreement shall not be assigned or otherwise transferred (including transfer by legal process or by operation of law, or any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court), except to COMPANY’s Affiliate(s), without the prior written consent of USDA. The parties agree that the identity of the parties is material to the formation of this Agreement and that the obligations under this Agreement are non-delegable. If USDA approves such proposed assignment, COMPANY shall pay USDA, as an additional royalty, one percent (1%) of the fair market value of any consideration received by COMPANY for any assignment of this Agreement within sixty (60) days assignment. In no event shall COMPANY assign or transfer this Agreement to a party not a citizen or resident of the United States of America.

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 These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive Order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive Orders and statutory provisions are incorporated into this Agreement and are controlling.

12.8 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

Name: _____
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)

or

Docket No. B (XXXX.XX)- the microbial isolate named (Name/Code) for use in (description of the invention)

or

Docket No. B (XXXX.XX)- the cloned genetic material identified as (Name/Code) for use in (description of the invention)