Instructions for Ready-To-Sign Agreement

“Recombinant Dicer can generate siRNAs from large dsRNAs in vitro”

STANFORD DOCKET S02-028

1. Please insert the following information into the agreement:
   • Opening paragraph: today’s date, your company’s name, state of incorporation and primary address.
   • Section 17: the appropriate company contact information for Notices.

2. Have the appropriate officer of the company sign duplicate copies of the agreement.

3. Return two signed copies of the agreement with a check for the license issue royalty ($15,000) to:
   Office of Technology Licensing
   1705 El Camino Real
   Palo Alto, CA 94306-1106
   Attention: Director

4. OTL will sign both agreements, keep one for OTL’s records and return the other original to the address and contact noted on the agreement. If you need an invoice to pay the issue fee, OTL will generate an invoice. Once the payment for the upfront fee is received by OTL, the Biological Materials will be provided.

5. If you have any questions about completing the agreement, please contact (650) 723-0651. The favorable licensing royalties included in this Ready-To-Sign agreement apply only if no negotiation is required. If you would like to negotiate changes to the Ready-To-Sign agreement there will be an increase in licensing royalties of at least $2,000 upfront and $1,000 per year.
AGREEMENT

This agreement ("Agreement") effective as of __________________ ("Effective Date") between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("STANFORD"), a body having corporate powers under the laws of the State of California, and __________________ ("LICENSEE"), a __________________ corporation having a principal place of business at ___________________. STANFORD and LICENSEE agree as follows:

1. BACKGROUND

1.1 STANFORD has an assignment of “Recombinant Dicer can generate siRNAs from large dsRNAs in vitro” from the laboratory of Dr. James Ferrell ("Invention"), as described in Stanford Docket S02-028, and any Licensed Patent, as hereinafter defined, which may issue to such Invention. The Invention includes Biological Materials as hereinafter defined.

1.2 STANFORD desires to have the Invention perfected and marketed at the earliest possible time in order that products resulting therefrom may be available for public use and benefit.

1.3 LICENSEE desires a license under said Invention and Licensed Patent to develop, manufacture, use, and sell Licensed Product in the Licensed Field of Use.

1.4 The Invention was made in the course of research supported by the National Institutes of Health.

2. DEFINITIONS

2.1 “Licensed Patent” means any Letters Patent issued upon STANFORD’s U.S. Patent Applications, Serial Numbers 60/337704 and 60/400655, any foreign patents corresponding thereto, and/or any divisions, continuations, or reissue thereof.

2.2 “Biological Materials” means the materials listed in Exhibit A and provided to LICENSEE pursuant to this Agreement.

2.3 “Licensed Product” means any product or part thereof in the Licensed Field of Use, the manufacture, use, or sale of which:

   (a) Is covered by a valid claim of an issued, unexpired Licensed Patent directed to the Invention. A claim of an issued, unexpired Licensed Patent shall be presumed to be valid unless and until it has been held to be invalid by a final judgment of a court of competent jurisdiction from which no appeal can be or is taken;

   (b) Is covered by any claim being prosecuted in a pending application directed to the Invention; or
(c) Is derived from, contains or made using Biological Materials.

2.4 “Net Sales” means the gross revenue derived by LICENSEE from Licensed Product, less the following items but only insofar as they actually pertain to the disposition of such Licensed Product by LICENSEE, are included in such gross revenue, and are separately billed:

(a) Import, export, excise and sales taxes, and custom duties;
(b) Costs of insurance, packing, and transportation from the place of manufacture to the customer’s premises or point of installation;
(c) Costs of installation at the place of use
(d) Credit for returns, allowances, or trades; and
(e) Customary trade, quantity, or cash discounts to brokers, agents or distributors.

2.5 “Licensed Field of Use” means reagent sales for research purposes. The Field of Use specifically excludes use of Biological Materials which requires regulatory approval, including any in vitro and in vivo diagnostic or therapeutic applications, and any in vivo use for whatever purpose.

2.6 “Licensed Territory” means worldwide.

3. GRANT

3.1 STANFORD hereby grants and LICENSEE hereby accepts a license in the Licensed Field of Use to make, use, and sell Licensed Product in the Licensed Territory.

3.2 Said license is nonexclusive in the Licensed Field of Use for a term commencing as of the Effective Date and ending on the expiration of the last to expire of Licensed Patent.

3.3 STANFORD retains title to all Biological Materials.

4. GOVERNMENT RIGHTS

This Agreement is subject to all of the terms and conditions of Title 35 United States Code Paragraphs 200 through 204, and LICENSEE agrees to take all reasonable action necessary on its part as LICENSEE to enable STANFORD to satisfy its obligation thereunder relating to Invention.

5. DILIGENCE

5.1 As an inducement to STANFORD to enter into this Agreement, LICENSEE agrees to use all reasonable efforts and diligence to proceed with the development, manufacture, and sale or lease of Licensed Product and to diligently develop markets for the Licensed Product. Unless LICENSEE has a Licensed Product available for commercial sale prior to eighteen (18) months from the Effective
Date and notifies STANFORD of this first commercial sale, LICENSEE agrees that STANFORD may terminate this Agreement. STANFORD may terminate this Agreement if LICENSEE has not sold Licensed Product for any six (6) month period after LICENSEE’s first commercial sale of Licensed Product.

5.2 Progress Report – LICENSEE acknowledges that diligent development of Licensed Product is of utmost importance to STANFORD. On or before September 1st of each year until LICENSEE markets a Licensed Product, LICENSEE shall make a written annual report to STANFORD covering the preceding year ending June 30, regarding the progress of LICENSEE toward commercialization of Licensed Product. Such report shall include, as a minimum, information (e.g., summary of work completed, key scientific discoveries, summary of work in progress, current schedule of anticipated events or milestones and market plans for introduction of Licensed Product) sufficient to enable STANFORD to satisfy reporting requirements of the U.S. Government and for STANFORD to ascertain progress by LICENSEE toward meeting the diligence requirements of this Article 5.

6. ROYALTIES

6.1 Issue Royalty – LICENSEE agrees to pay to STANFORD a noncreditable, nonrefundable license issue royalty of Fifteen Thousand Dollars ($15,000) upon signing this Agreement. Upon receipt of payment, STANFORD shall send Biological Materials to LICENSEE. LICENSEE shall not transfer Biological Materials to any third party without prior written consent from STANFORD.

6.2 License Maintenance - Beginning with the first anniversary of the Effective Date and each anniversary thereafter, LICENSEE also shall pay to STANFORD a license maintenance royalty of Ten Thousand Dollars ($10,000). Said yearly royalty payments are nonrefundable, but they are creditable against earned royalties to the extent provided in Section 6.4.

6.3 Earned Royalty - In addition, LICENSEE shall pay STANFORD earned royalties of Five Percent (5%) on Net Sales of Licensed Products.

6.4 Creditable payments under this Agreement shall be an offset to LICENSEE up to 100% against each earned royalty payment that LICENSEE would be required to pay in the subsequent twelve (12) months pursuant to Section 6.3.

6.5 LICENSEE shall be obligated to pay royalties on all Licensed Product that are either sold or produced under the license granted in Article 3, regardless of whether such Licensed Product are produced prior to the Effective Date of this Agreement or sold after the expiration of the Licensed Patent.

6.6 The royalty on sales in currencies other than U.S. Dollars shall be calculated using the appropriate foreign exchange rate for such currency quoted by the Bank of America (San Francisco) foreign exchange desk, on the close of business on the last banking day of each calendar quarter. Royalty payments to STANFORD shall be in U.S. Dollars. All non-U.S. taxes related to royalty payments shall be paid by LICENSEE and are not deductible from the payments due STANFORD.
7. ROYALTY REPORTS, PAYMENTS, AND ACCOUNTING

7.1 Earned Royalty Payment and Report - Beginning with the first sale of a Licensed Product, LICENSEE shall make written reports (even if there are no sales) and earned royalty payments to STANFORD within thirty (30) days after the end of each calendar half-year. This report shall state the number, description, and aggregate Net Sales of Licensed Product during such completed calendar half-year, and resulting calculation pursuant to Section 6.3 of earned royalty payment due STANFORD for such completed calendar half-year. LICENSEE will also report Net Sales of Licensed Product and identity of any single company or institution, excluding academic and other not-for-profit institutions, that exceeds $5,000 in quarterly purchases. Concurrent with the making of each such report, LICENSEE shall include payment due STANFORD of royalties for the half year covered by such report. Once LICENSEE’s sales exceed $200,000 per half year, LICENSEE agrees the earned royalty report and payment schedule will be due quarterly.

7.2 Termination Report - LICENSEE also agrees to make a written report to STANFORD within ninety (90) days after the expiration of the license pursuant to Section 3.2. LICENSEE shall continue to make reports pursuant to the provisions of this Section 7.2 concerning royalties payable in accordance with Article 6 in connection with the sale of Licensed Product after expiration of the license, until such time as all such Licensed Product produced under the license have been sold or destroyed. Concurrent with the submittal of each post-termination report, LICENSEE shall pay STANFORD all applicable royalties.

7.3 Accounting - LICENSEE agrees to keep and maintain records for a period of three (3) years showing the manufacture, sale, use, and other disposition of products sold or otherwise disposed of under the license herein granted. Such records will include general ledger records showing cash receipts and expenses, and records which include production records, customers, serial numbers, and related information in sufficient detail to enable the royalties payable hereunder by LICENSEE to be determined. LICENSEE further agrees to permit its books and records to be examined by STANFORD from time to time to the extent necessary to verify reports provided for in Sections 7.1 and 7.2. Such examination is to be made by STANFORD or its designee, at the expense of STANFORD, except in the event that the results of the audit reveal an underreporting of royalties due STANFORD of five percent (5%) or more, in which event the audit costs shall be paid by LICENSEE.

8. NEGATION OF WARRANTIES

8.1 Nothing in this Agreement is or shall be construed as:

(a) A warranty or representation by STANFORD as to the validity or scope of any Licensed Patent;

(b) A warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents, copyrights, and
other rights of third parties;

(c) An obligation to bring or prosecute actions or suits against third parties for infringement;

(d) Granting by implication, estoppel, or otherwise any licenses or rights under patents or other rights of STANFORD or other persons other than Licensed Patent, regardless of whether such patents or other rights are dominant or subordinate to any Licensed Patent; or

(e) An obligation to furnish any technology other than the Biological Materials.

8.2 Except as expressly set forth in this Agreement, STANFORD MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS, OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.

9. INDEMNITY

9.1 LICENSEE agrees to indemnify, hold harmless, and defend STANFORD and Stanford Hospitals and Clinics, and their respective trustees, officers, employees, students, and agents against any and all claims for death, illness, personal injury, property damage, and improper business practices arising out of the manufacture, use, sale, or other disposition of Invention, Licensed Patent, Licensed Product, or Biological Materials by LICENSEE, or their customers.

9.2 STANFORD shall not be liable for any indirect, special, consequential or other damages whatsoever, whether grounded in tort (including negligence), strict liability, contract, or otherwise. STANFORD shall not have any responsibilities or liabilities whatsoever with respect to Licensed Product.

9.3 LICENSEE shall at all times comply, through insurance or self-insurance, with all statutory workers’ compensation and employers’ liability requirements covering any and all employees with respect to activities performed under this Agreement.

9.4 In addition to the foregoing, LICENSEE shall maintain, during the term of this Agreement, Comprehensive General Liability Insurance, including Product Liability Insurance, with a reputable and financially secure insurance carrier to cover the activities of LICENSEE. Such insurance shall provide minimum limits of liability of One Million Dollars ($1,000,000) and shall include STANFORD and Stanford Hospitals and Clinics, and their respective their trustees, directors, officers, employees, students, and agents as additional insureds. Such insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement and will be placed with carriers with ratings of at least A- as rated by A.M. Best. Within fifteen (15) days of the Effective Date of this Agreement, LICENSEE shall furnish a Certificate of Insurance evidencing primary coverage and additional insured requirements and
requiring thirty (30) days prior written notice of cancellation or material change to STANFORD. LICENSEE shall advise STANFORD, in writing, that it maintains excess liability coverage (following form) over primary insurance for at least the minimum limits set forth above. All such insurance of LICENSEE shall be primary coverage; insurance of STANFORD and Stanford Hospitals and Clinics shall be excess and noncontributory.

10. MARKING

Prior to the issuance of patents on the Invention, LICENSEE agrees to mark Licensed Product (or their containers or labels) made, sold, or otherwise disposed of by it under the license granted in this Agreement with the words “Patent Pending,” and following the issuance of one or more patents, with the numbers of the Licensed Patent. A Limited Label License must also accompany the product as a product insert sheet or printed with the product information that is received as part of the product (see Exhibit B).

11. STANFORD NAMES AND MARKS

LICENSEE agrees not to identify STANFORD in any promotional advertising or other promotional materials to be disseminated to the public or any portion thereof or to use the name of any STANFORD faculty member, employee, or student, or any trademark, service mark, trade name, or symbol of STANFORD or Stanford Hospitals and Clinics, or any that is associated with any of them, without STANFORD’s prior written consent. Any use of STANFORD’s name shall be limited to statements of fact and shall not imply endorsement of LICENSEE’s products or services.

12. INFRINGEMENT BY OTHERS: PROTECTION OF PATENTS

LICENSEE shall promptly inform STANFORD of any suspected infringement of any Licensed Patent by a third party.

13. SUBLICENSING

LICENSEE may not grant sublicenses.

14. TERMINATION

14.1 LICENSEE may terminate this Agreement by giving STANFORD notice in writing at least thirty (30) days in advance of the effective date of termination selected by LICENSEE.

14.2 STANFORD may terminate this Agreement if LICENSEE:

(a) Is in default in payment of royalty or providing of reports;
(b) Is not diligently developing and commercializing Licensed Product;
(c) Is in breach of any provision hereof; or
(d) Provides any false report;
and LICENSEE fails to remedy any such default, lack of diligence, breach, or false report within thirty (30) days after written notice thereof by STANFORD.

14.3 Surviving any termination or expiration are:

(a) LICENSEE’s obligation to pay royalties accrued or accruable;

(b) Any cause of action or claim of LICENSEE or STANFORD, accrued or to accrue, because of any breach or default by the other party; and

(c) The provisions of Section 6.5, Articles 7, 8, and 9, and any other provisions that by their nature are intended to survive.

14.4 Concurrent with notice of termination by either LICENSEE or STANFORD or expiration, LICENSEE shall destroy all Biological Materials and Licensed Products in its possession, and shall provide written evidence of said destruction.

15. ASSIGNMENT

This Agreement may not be assigned.

16. ARBITRATION

16.1 Any controversy arising under or related to this Agreement, and any disputed claim by either party against the other under this Agreement excluding any dispute relating to patent validity or infringement arising under this Agreement, shall be settled by arbitration in accordance with the Licensing Agreement Arbitration Rules of the American Arbitration Association.

16.2 Upon request by either party, arbitration will be by a third party arbitrator mutually agreed upon in writing by LICENSEE and STANFORD within thirty (30) days of such arbitration request. Judgment upon the award rendered by the arbitrator shall be final and nonappealable and may be entered in any court having jurisdiction thereof.

16.3 The parties shall be entitled to discovery in like manner as if the arbitration were a civil suit in the California Superior Court. The arbitrator may limit the scope, time, and/or issues involved in discovery.

16.4 Any arbitration shall be held at Stanford, California unless the parties hereto mutually agree in writing to another place.

17. NOTICES

All notices under this Agreement shall be deemed to have been fully given when done in writing and addressed as follows:
All general notices to LICENSEE should be sent to:


All financial invoices to LICENSEE (i.e., accounting contact) should be e-mailed to:


All progress report invoices to LICENSEE (i.e., technical contact) should be e-mailed to:


All general notices to STANFORD should be e-mailed or mailed to:

Office of Technology Licensing
1705 El Camino Real
Palo Alto, CA 94306
info@otlmail.stanford.edu

All payments to STANFORD should be mailed to:

Stanford University
Office of Technology Licensing
Department #44439
P.O. Box 44000
San Francisco, CA 94144-4439

All progress reports to STANFORD should be e-mailed or mailed to:

Office of Technology Licensing
1705 El Camino Real
Palo Alto, CA 94306
info@otlmail.stanford.edu

Either party may change its address upon written notice to the other party.

18. WAIVER

None of the terms of this Agreement can be waived except by the written consent of the party waiving compliance.
19. APPLICABLE LAW

This Agreement shall be governed by the laws of the State of California applicable to agreements negotiated, executed, and performed wholly within California.

20. ELECTRONIC COPY

The parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

Signature ______________________________
Name ________________________________
Title ________________________________
Date ________________________________

LICENSEE

Signature ______________________________
Name ________________________________
Title ________________________________
Date ________________________________
EXHIBIT A

r-Dicer Bacmid

HTC-Vector encoding r-Dicer

Virus for r-Dicer production
Limited Label License

This product is covered by several patent applications owned by Stanford University.

The purchase of this product conveys to the buyer the limited, non-exclusive, non-transferable right (without the right to resell, repackage, or further sublicense) under these patent rights to perform the siRNA production methods claimed in those patent applications for research purposes solely in conjunction with this product. No other license is granted to the buyer whether expressly, by implication, by estoppel or otherwise. In particular, the purchase of this product does not include nor carry any right or license to use or otherwise exploit this product for commercial purposes, which may include, without limitation, the right to use the product or components of the product for provision of services to a third party, generation of commercial databases for sale to third parties, or clinical diagnostics or therapeutics.

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