

TAXES (8.5) ADDED TO V.G

September 1989

VERSION 7
(FINAL VERSION)

LICENSE AGREEMENT

Effective as of _____ THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, a body having corporate powers under the laws of the State of California (STANFORD), and _____ a _____ corporation having a principal place of business at _____ (LICENSEE)

agree as follows:

1. BACKGROUND

1.1—In the course of fundamental research programs at the University of California and STANFORD (Universities), inventions were conceived jointly which relate to engineering biologically functional replicons possessing desired genetic properties of parent DNA molecules. These research programs were supported by the National Science Foundation, the American Cancer Society, and the National Institutes of Health of the Department of Health, Education and Welfare, now Health and Human Services (HHS). These agencies and the Universities agreed that the intellectual property rights resulting from these inventions (and licensed through this Agreement) would be administered pursuant and subject to the terms of STANFORD's Institutional Patent Agreement (IPA) with HHS.

1.2—The Universities have agreed that Stanford will manage the securing of patent rights and licensing in the public interest, and that any net income arising therefrom will be shared between the Universities, and designated to be used for educational and research purposes.

1.3—By assignment of the inventions from the inventors, STANFORD is the owner of certain U.S. Patent rights and desires to grant licenses under those rights to licensees for development of products and processes for public use and benefit.

1.4—LICENSEE desires to develop processes and methods and marketable products for public use and benefit by using Licensed Patent Rights, and it will follow good safety practices in such development work.

2. DEFINITIONS

2.1—Licensed Patent Rights means U.S. Patent No. 4,237,224, issued December 2, 1980, U.S. Patent No. 4,468,464, issued August 28, 1984, and U.S. Patent No. 4,740,470, issued April 26, 1988 and any reissues or extensions thereof.

2.2—Ultimate Consumer means that person or entity whose use of the product results in its destruction or loss of activity and/or loss of value.

2.3—Licensed Product(s) means materials (including organisms) which, in the course of manufacture, use, or sale would, in the absence of this license, infringe one or more claims of Licensed Patent Rights which have not been held invalid by a court from which no appeal may be taken.

Four categories of *Licensed Products* are designated:

End Products (Paragraph 2.4)

Basic Genetic Products (Paragraph 2.5)

Process Improvement Products (Paragraph 2.6)

Bulk Products (Paragraph 2.7)

2.4—*End Products* means marketable goods having at least one component coming within *Licensed Products*, or produced by a *Licensed Product*, which goods are sold in a form for utilization by the *Ultimate Consumer*, and are not intended or marketed for further formulation, processing, or chemical transformation, illustrative *End Products* include:

- (a) health care products, sold for patient care and use or dispensation by medical professionals (for example, dosage forms of hormones, vaccines, and biosynthesized drugs; films, fibers or dressings; and reagents or devices used for diagnostic purposes, incorporating biochemical agents such as antibodies, enzymes, specific binding proteins or polysaccharides);
- (b) products sold in a form ready for application to seeds, for addition to feed or crop treating agents, for administration to animals or for treatment of cells being cultured in order to improve agriculture, animal production, forestry or landscaping (such as fertilizers, vaccines, and nitrogen fixing or pesticidal microorganisms);
- (c) microorganisms and/or their products which are suitable for use as animal or human food, for degrading substances in an environment, or for increasing the production of desired substances (such as concentrating minerals, generating gas or useful compost from low value substrates);
- (d) reagents for research, such as enzymes or antibodies.

2.5—*Basic Genetic Products* means materials having at least one component coming within *Licensed Products* which are sold or used primarily for further processing or genetic manipulation and/or are neither *End Products*, *Process Improvement Products* or *Bulk Products*. Illustrative *Basic Genetic Products* include plasmids, transformants, and nucleic acid segments such as expression regulators and structural gene sequences. Also, *Basic Genetic Products* include services using *Licensed Products* and which services are provided by LICENSEE to customers on a contract basis.

2.6—*Process Improvement Products* means materials having at least one component coming within *Licensed Products*, which are developed by or for the LICENSEE, as opposed to being purchased by the LICENSEE, and are used by the LICENSEE in its manufacturing processes to enhance production efficiency and where the resulting product is essentially identical to a product manufactured by the previous process. Illustrative *Process Improvement Products* include microorganisms for production of chemical intermediates, amino acids, or pharmaceuticals; enzymes for chemical manufacturing; antibodies for separation processes; and nitrogen-fixing microorganisms used by an agricultural company to reduce fertilizer consumption.

2.7—*Bulk Products* means materials having at least one component coming within *Licensed Products*, or produced by a *Licensed Product*, which material is intended for further formulation, processing or chemical transformation by a manufacturer, formulator or the like (as distinguished from a distributor, retailer or *Ultimate Consumer*). Illustrative *Bulk Products* include an antibody or a hormone sold to a pharmaceutical company, a dipeptide sold to a beverage company to be used as a sweetener, an amino acid sold to a health care company, and a chemical intermediate sold to a chemical company for conversion into functional chemicals.

2.8—*Net Sales* means the gross sales, royalties or fees received by Licensee, whether invoiced or not, less: returns and allowances actually granted; packing, insurance, freight out, taxes or excise duties imposed on the transaction (if separately invoiced); wholesaler discounts and cash discounts.

2.9—*First Commercial Sale* means the initial transfer by LICENSEE of *Licensed Products* in exchange for cash or some equivalent to which value can be assigned for the purpose of determining *Net Sales*.

2.10—"LICENSEE" is understood to include all of its *Affiliates*. An *Affiliate* of LICENSEE shall mean any corporation or other business entity controlled by, controlling, or under common control with LICENSEE. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock, or at least fifty percent (50%) interest in the income of such corporation or other business.

3. GRANT

3.1—STANFORD grants to LICENSEE a non-exclusive, non-transferable right and license to make, have made, use and sell *Licensed Products* under *Licensed Patent Rights*.

4. COMPLIANCE WITH LAWS, REGULATIONS AND STANDARDS

4.1—LICENSEE agrees to comply with all governmental laws and regulations applicable to the use, production and/or sale of *Licensed Products*.

4.2—With respect to operations by the LICENSEE in the United States, its territories and possessions, LICENSEE specifically expresses its intent to comply with the physical and biological containment standards set forth in the NIH Guidelines for Research Involving Recombinant DNA Molecules, dated 21 November 1980, or any subsequent amended version of U.S. Government guidelines or regulations pertaining to such activities in effect during the term of this Agreement. LICENSEE further agrees to cooperate with government agency(ies) authorized to monitor compliance with such containment standards.

5. GOVERNMENT TERMS

5.1—This Agreement is subject to the terms and conditions of the HHS IPA with STANFORD dated April 5, 1972.

6. ROYALTIES

6.1—In consideration of the rights granted herein, LICENSEE shall pay to STANFORD upon execution of this agreement _____ . Thereafter, LICENSEE shall pay a minimum annual advance on earned royalties of _____ on or before the first day of February for each calendar year following execution of this agreement. Said payments are nonrefundable except that they can be credited against earned royalties to the extent provided in paragraph 6.3.

6.2—All sales or use of *Licensed Products* by LICENSEE, excepting sales under paragraph 10.1 to an *Affiliate* or another licensee of STANFORD or sales to the United States Government, shall be subject to royalty payments as provided in paragraphs 6.3 to 6.7 inclusive.

6.3—Earned royalty payments due under Article 8 in excess of the annual minimum _____ may be reduced up to 50% in any one year by a credit. This credit is equal to the unreimbursed cumulative excess of the advance royalties paid in accordance with paragraph 6.1 over the total of the earned royalties due under paragraphs 6.4 to 6.6 inclusive. This reduction in earned royalty payments may continue so long as is necessary to fully amortize the credit.

6.4—LICENSEE shall pay earned royalties for use of *Licensed Patent Rights* for production and sale of *End Products* based on the total royalty bearing *Net Sales of End Products* by LICENSEE. The earned royalty rate for *End Products* sold in the U.S. is _____ % in each calendar year.

6.5—LICENSEE shall pay earned royalties for use of *Licensed Patent Rights* to produce in the United States *End Products* and *Bulk Products* for sale outside of the United States of _____ % of *Net Sales of End Products* and _____ % of *Net Sales of Bulk Products* in each calendar year.

6.6—LICENSEE also shall pay earned royalties for use of *Licensed Patent Rights* for production and sale of *Licensed Products* that are not *End Products* as follows:

6.6.1—The earned royalty rate for *Basic Genetic Products* sold in the U.S. shall be _____% of *Net Sales*.

6.6.2—The earned royalty rate for *Bulk Products* sold in the U.S. is _____% in each calendar year.

6.6.3—The earned royalty rate for *Process Improvement Products* shall be _____% of cost savings and economic benefits enjoyed by LICENSEE in each calendar year.

6.6.4—If LICENSEE can demonstrate that the royalty payments for a product falling under *Basic Genetic Products* (paragraph 6.6.1), *Bulk Products* (paragraph 6.6.2) or *Process Improvement Products* (paragraph 6.6.3) are greater than the royalties that would result if calculated on the *End Product* (for sales in the U.S. and other territories) made from or with such product, it may request negotiation of a lower royalty comparable to the *End Product* royalty. Such negotiation will be initiated by notice in writing from LICENSEE to STANFORD giving the nature of the product(s) to be marketed by LICENSEE and expected use of the product(s).

6.7—If the parties cannot agree after negotiation upon equitable royalty terms for the use of *Licensed Patent Rights* under subparagraph 6.6.4, then either party may submit the matter for decision by arbitration in accordance with paragraph 14.4. Fees for arbitration shall be borne by the LICENSEE, but may be credited per paragraph 8.3 against royalties payable by LICENSEE under the agreement established by means of the arbitration, until such arbitration fees are fully recovered.

6.7.1—In arriving at a decision, the negotiators and arbitrator(s) shall consider such factors as the size of the potential market for the *Licensed Product(s)* involved, the anticipated profit margin, the royalty rates for *End Products*, the royalty that would be paid on the *End Products* most likely to be prepared for the *Ultimate Consumer* from the *Licensed Product(s)* in question, and prevailing royalty rates in the industry to which the *Licensed Product(s)* pertain.

7. MORE FAVORED TERMS

7.1—STANFORD intends that the terms of all licenses under *Licensed Patent Rights* are to be essentially similar to the terms of this license. STANFORD will advise LICENSEE as to those terms which are different in such other license agreements, unless said terms are consequent to the operation of any provision of paragraphs 6.6.4, 6.7, and 6.7.1, whereupon LICENSEE may determine whether such terms are more favorable than those granted herein. LICENSEE shall, at its election, be entitled upon written notice to STANFORD to have this Agreement amended to substitute all terms of such more favorable license for all terms of this Agreement as of the date upon which such more favorable license shall have become effective. Such amendment shall, as to royalty, apply only to prospective royalties.

7.2—In the event LICENSEE chooses to exercise its option under paragraph 7.1, LICENSEE agrees that it shall also accept and be bound by the same terms and conditions for the benefit of STANFORD as those which are a part of or shall accompany such other license granted by STANFORD to a third party. LICENSEE further agrees that in determining whether the royalty rate for a particular product or process accorded the third party licensee is more favorable, STANFORD may assign a reasonable value to any patent rights or other consideration it has or will receive in return for the grant of such other license.

7.3—STANFORD has entered into prior license agreements for *Licensed Patent Rights*. This Article 7 does not apply with respect to these prior license agreements.

8. PAYMENTS AND REPORTS

8.1—LICENSEE agrees to notify STANFORD promptly, in writing, of the date of the *First Commercial Sale* of a *Licensed Product* and date of first transaction under paragraph 10.1.

8.2—Beginning with date of *First Commercial Sale*, royalties from LICENSEE hereunder (less the credits allowed by paragraphs 6.3 and 6.7 and less the minimum annual royalty paid in advance for that calendar year) shall be paid to STANFORD within ninety (90) days after the close of each subsequent calendar quarter.

8.3—Total credits allowable by operation of paragraphs 6.3 and 6.7 shall in no case exceed 50% of the excess of current earned royalties over the minimum royalty due in any given year. Any amount so credited shall be credited only once against earned royalties payable hereunder.

8.4—LICENSEE shall provide with each earned royalty payment of paragraph 8.2 a statement of *Net Sales* and the applicable royalties in accordance with Article 6 and a report of each transaction under paragraph 10.1. All such reports shall be held in confidence by STANFORD. Such statements and reports shall be submitted whether or not a payment in excess of the minimum is due.

8.5—STANFORD is a nonprofit institution. Any taxes, fees, or other charges imposed by governmental authorities upon payments due STANFORD shall be paid by LICENSEE. The amounts remitted shall be pursuant to payment terms of the agreement.

8.6—To facilitate STANFORD's conformance with its Institutional Patent Agreement, LICENSEE agrees to make an annual report to STANFORD each March 1 covering its progress during the previous calendar year toward commercialization. Such report may be general in nature and shall not include company proprietary information.

8.7—LICENSEE also agrees to make a written report to STANFORD within ninety (90) days after the date of termination of this License Agreement, stating in such report the royalty payable hereunder which was not previously reported to STANFORD. LICENSEE shall also continue to make annual reports pursuant to the provisions of this Article 8 covering *Net Sales* and the applicable royalties in accordance with Article 6 received for sale of *Licensed Products* after termination of this License Agreement, until such time as all such sales shall have terminated. Concurrent with the submittal of each post-termination report, LICENSEE shall pay STANFORD all applicable royalties.

9. RECORDS

9.1—LICENSEE shall keep complete, true and accurate books of account and records for the purpose of showing the derivation of all amounts payable to STANFORD under this License Agreement. Said books and records shall be kept at LICENSEE's principal place of business for at least three (3) years following the end of the calendar year to which they pertain and shall be open at all reasonable times for inspection by a representative of STANFORD for the purpose of verifying LICENSEE's royalty statements or LICENSEE's compliance in other respects to this License Agreement. This representative is obliged to treat as confidential all relevant matters and should be acceptable to LICENSEE. LICENSEE may specify that this representative be an independent Certified Public Accountant.

10. OTHER TRANSFERS OF LICENSED PRODUCTS

10.1—It is anticipated that LICENSEE may supply *Licensed Products* to an *Affiliate* (as defined in paragraph 2.10) or to another licensee of STANFORD for further processing and/or sale by the *Affiliate* or other licensee under *Licensed Patent Rights*. No earned royalty shall be payable by LICENSEE with respect to such *Licensed Products*, so long as the *Affiliate* or second licensee shall be obligated to pay STANFORD royalty under *Licensed Patent Rights* on its use or sales thereof. However, reports made by LICENSEE as provided in paragraph 8.4 shall list each such transaction as a non-royalty bearing sale and identify such *Affiliate* or other licensee.

10.2—If an earned royalty payment has been made to STANFORD for a *Licensed Product* used by LICENSEE to make another *Licensed Product*, that payment may be deducted by LICENSEE from the earned royalty payment for such resulting *Licensed Product*.

11. TERM AND TERMINATION

11.1—The term of this Agreement shall extend from the above effective date until expiration of the last to expire of *Licensed Patent Rights*.

11.2—Upon any breach of, or default under, this License Agreement by LICENSEE, STANFORD may terminate this License Agreement by ninety (90) days written notice to LICENSEE. Said notice shall become effective at the end of such period unless during said period LICENSEE shall cure such defect or default.

11.3—LICENSEE shall have the right to terminate this Agreement at any time upon ninety (90) days written notice to STANFORD.

12. ASSIGNABILITY

12.1—This Agreement shall not be assigned except (a) with the advance written consent of STANFORD, or (b) as part of a sale or transfer of substantially the entire business of LICENSEE relating to operations pursuant to this license.

13. NEGATION OF WARRANTIES AND INDEMNITY

13.1—Nothing in this Agreement shall be construed as:

- (a) a warranty or representation by STANFORD as to the validity or scope of any *Licensed Patent Rights*; or
- (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 of third parties; or
- (c) an obligation to bring or prosecute actions or suits against third parties for infringement; or
- (d) conferring the right to use in advertising, publicity or otherwise any trademark, trade name, or names, or any contraction, abbreviation, simulation or adaptation thereof, of STANFORD; or
- (e) conferring by implication, estoppel or otherwise any license or rights under any patents of STANFORD other than *Licensed Patent Rights*, regardless of whether such patents are dominant or subordinate to *Licensed Patent Rights* (however, STANFORD is not aware of any STANFORD patent or application dominant to *Licensed Patent Rights*); or
- (f) an obligation to furnish any know-how not provided in *Licensed Patent Rights*.

13.2—STANFORD makes no representations other than those specified in Article 1. STANFORD MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

13.3—LICENSEE shall defend, indemnify and hold STANFORD harmless from and against all liability, demands, damages, expenses and losses for death, personal injury, illness or property damage ("claims and damages") arising (a) out of the use by LICENSEE of any method under *Licensed Patent Rights*, or (b) out of any use, sale or other disposition of *Licensed Products* by LICENSEE or its transferees. As used in this Section, "STANFORD" includes its trustees, officers, agents and employees, and "LICENSEE" includes its *Affiliates* described in paragraph 2.10. LICENSEE acknowledges that the technology licensed hereby is experimental and agrees to take all reasonable precautions to prevent death, personal injury, illness and property damage.

14. GENERAL

14.1—Neither party may waive or release any of its rights or interests in this Agreement except in writing. Failure to assert any right arising from this Agreement shall not be deemed or construed to be a waiver of such right.

14.2—This License Agreement constitutes the entire agreement between the parties relating to the subject matter thereof, and all prior negotiations, representations, agreements and understandings are merged into, extinguished by, and completely expressed by it.

14.3—This Agreement and its effects are subject to and shall be construed and enforced in accordance with the laws of the State of California.

14.4—Any dispute or controversy arising out of or relating to this License Agreement, its construction or its actual or alleged breach, shall be finally decided by arbitration conducted in San Francisco, California, by and in accordance with the Licensing Agreement Arbitration Rules of the American Arbitration Association. Judgment upon the award rendered may be entered in the highest court or forum, state or federal, having jurisdiction; provided, however, that the provisions of this Article 14 shall not apply to decision of the validity of patent claims or to any dispute or controversy as to which any treaty or law prohibits such arbitration.

14.5—All notices required or permitted to be given by the terms of this Agreement shall be given by prepaid registered or certified mail properly addressed to the other party at the address designated below or to such other address as may be designated in writing by such other party and shall be effective as of the date of the postmark of such mail notice.

LICENSEE:

Attention:

STANFORD:

Office of Technology Licensing
Stanford University
900 Welch Road, Suite 350
Palo Alto, CA 94304-1850
U.S.A.

Attention: Director

This Agreement is effective as of the date first given above.

LICENSEE

By _____

Title _____

Date _____

THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR UNIVERSITY

By _____

Title _____

Date _____