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RECORDATION FORM COVER SHEET
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TO: The Commissioner of Patents and Trademarks: Please record the attached original document(s) or copy(ies).

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- [X] New
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- [ ] Assignment
- [ ] Security Agreement
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Name (line 1): Public Health Service
Execution Date (Month Day Year): 09- 30- 99

Name (line 2):

Second Party
Name (line 1):
Execution Date (Month Day Year):

Name (line 2):

Receiving Party

- [ ] Mark if additional names of receiving parties attached

Name (line 1): Genaissance Pharmaceuticals, Inc.

Name (line 2):

Address (line 1): Five Science Park

Address (line 2):

Address (line 3): New Haven (City) | CT (State/Country) | 06511 (Zip Code)

- [ ] If document to be recorded is an assignment and the receiving party is not domiciled in the United States, an appointment of a domestic representative is attached. *(Designation must be a separate document from Assignment.)*

Domestic Representative Name and Address

Enter for the first Receiving Party only.

Name: Inna Shtivelband, Esq.

Address (line 1): Genaissance Pharmaceuticals, Inc.

Address (line 2): Five Science Park

Address (line 3): New Haven, CT 06511

Address (line 4):

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Mail documents to be recorded with required cover sheet(s) information to:
Commissioner of Patents and Trademarks, Box Assignments , Washington, D.C. 20231

Correspondent Name and Address

Area Code and Telephone Number: 203-773-1450

Name: Inna Shtivelband, Esq.

Address (line 1): Genaissance Pharmaceuticals, Inc.

Address (line 2): Five Science Park

Address (line 3): New Haven, CT 06511

Address (line 4):

Pages

Enter the total number of pages of the attached conveyance document including any attachments. # 24

Application Number(s) or Patent Number(s)

☐ Mark if additional numbers attached

Enter either the Patent Application Number or the Patent Number (DO NOT ENTER BOTH numbers for the same property).

Patent Application Number(s)			Patent Number(s)		
09/060,023					

If this document is being filed together with a new Patent Application, enter the date the patent application was signed by the first named executing inventor. Month Day Year

Patent Cooperation Treaty (PCT)

Enter PCT application number only if a U.S. Application Number has not been assigned.

PCT | PCT | PCT

PCT | PCT | PCT

Number of Properties

Enter the total number of properties involved. # 1

Fee Amount

Fee Amount for Properties Listed (37 CFR 3.41): $ 40.00

Method of Payment: Deposit Account

Enclosed ☐ Deposit Account X

(Enter for payment by deposit account or if additional fees can be charged to the account.)

Deposit Account Number: # 50-1293

Authorization to charge additional fees: Yes X No ☐

Statement and Signature

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document. Charges to deposit account are authorized, as indicated herein.

Name of Person Signing	Signature	Date
Inna Shtivelband		9/26/00

CONFIDENTIAL

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT--*EXCLUSIVE*

COVER PAGE

For PHS internal use only:

Patent License Number: L-053-99/0

Serial Number(s) of Licensed Patent(s) and/or Patent Application(s):

PCT/US96/11478 and USPA 09/060,023

Licensee:

Genaissance Pharmaceuticals, Inc.

Five Science Park

New Haven, CT 06511

Cooperative Research and Development Agreement (CRADA) Number (if applicable): N/A

Additional Remarks:

Public Benefit(s):

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) and/or Patent Application(s)), Appendix B (Royalties), Appendix C (Modifications), Appendix D (Benchmarks), and Appendix E (Commercial Development Plan). The Parties to this **Agreement** are:

1) The National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), or the Food and Drug Administration ("FDA"), hereinafter singly or collectively

referred to as **"PHS"**, agencies of the United States Public Health Service within the Department of Health and Human Services (**"DHHS"**); and

2) The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as **"Licensee"**.

PHS PATENT LICENSE AGREEMENT--EXCLUSIVE

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.01 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.02 By assignment of rights from **PHS** employees and other inventors, **DHHS**, on behalf of the United States Government, owns intellectual property rights claimed in any United States and/or foreign patent applications or patents corresponding to the assigned inventions. **DHHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.03 The Secretary of **DHHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.04 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.05 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, and/or marketable products for public use and benefit.

2. DEFINITIONS

2.01 **"Benchmarks"** mean the performance milestones that are set forth in Appendix D.

2.02 **"Commercial Development Plan"** means the written commercialization plan attached as Appendix E.

2.03 **"First Commercial Sale"** means the initial transfer by or on behalf of **Licensee** or its sublicensees of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.04 **"Government"** means the Government of the United States of America.

2.05 **"Licensed Fields of Use-A"** means, and is limited to, the practice of Transformation Associated Recombination (TAR) cloning and/or Radial Tar cloning as described in a PATENT to provide GENOMIC SERVICES to third parties for commercial applications, where such services include providing tangible and/or intangible materials that embody Licensed Products or are produced by the practice of Licensed Processes, where such Licensed Products or Licensed Processes are also covered by the claims in U.S. Patent No. 5,866,404 (Clasper) and/or a patent issuing from U.S. Serial No. 08/987,966 (Genome Anthologies Patent);

2.06 **"Licensed Fields of Use-B"** means the practice of TAR cloning and/or Radial TAR cloning as described in **PATENT**.

2.07 **"PATENT or PATENTS"** shall mean:

a) Patent applications (including provisional patent applications and PCT patent applications) and/or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; iv) priority patent application(s) of a) above; and v) any reissues, reexaminations, and extensions of all such patents;

c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign and U.S. patent applications and patents to a) and b) above, including those listed in Appendix A.

PATENTS shall *not* include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in a) above.

2.08 **"Licensed Process(es)"** means processes which, in the course of being practiced would, in the absence of this **Agreement**, infringe one or more claims of the **PATENTS** that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.09 **"Licensed Product(s)"** means tangible materials which, in the course of manufacture, use, offer to sell, sale, or importation would, in the absence of this **Agreement**, infringe one or more claims of the **PATENTS** that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.10 **"Licensed Territory"** means worldwide.

2.11 **"Net Sales"** means the total gross receipts for sales of **Licensed Products** or practice of

Licensed Processes by or on behalf of **Licensee** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by **Licensee**, or sublicensees, and on its payroll, or for the cost of collections. **Net Sales** shall include all gross receipts received from subscription fees to DATABASES, CONTRACT RESEARCH AGREEMENTS, and licensing income arising out of such CONTRACT RESEARCH AGREEMENTS.

2.12 **"Practical Application"** means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.13 **"Research License"** means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or **Licensed Processes** as defined by the **PATENTS** or to make and to use tangible materials produced by such practice, for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase, or for developing a directly related secondary product that can be sold.

2.14 "**GENOMIC SERVICES**" means one or more of the following: discovery and analysis of genetic variation in animal and plant cells; discovery and analysis of genes, gene families, gene subtypes and gene patterns in animal and plant cells; the information derived from such analyses; clones containing variants of animal and plant genes and other loci; transgenic plants and transgenic nonhuman animals.

2.15 "**DATABASES**" means one or more collections of data, at least part of which are produced by using Licensed Products or the practice of Licensed Processes.

2.16 "**CONTRACT RESEARCH AGREEMENT**" means any agreement between Licensee and a third party for the provision by Licensee of GENOMIC SERVICES, where Licensee intends that at least part of said GENOMIC SERVICES will include providing Licensed Products or practicing Licensed Processes.

2.17 **"Licensee"** shall include **Genaissance** and any subsidiary or parent company. Any subsidiary or parent of Licensee means:

(a) an organization of which fifty percent (50%) or more of the voting stock is controlled or owned directly or indirectly by **Genaissance**;

(b) an organization which directly or indirectly owns or controls fifty percent (50%) or more of the voting stock of Genaissance;

(c) an organization, the majority ownership of which is directly or indirectly common to the majority ownership of **Genaissance**.

3. GRANT OF RIGHTS

3.01 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **PATENTS** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import and otherwise dispose of any **Licensed Products** in the **Licensed Fields of Use-A** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use-A**. **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive license under the **PATENTS** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import **Licensed Products** in the **Licensed Fields of Use-B** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use-B.**

3.02 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than **PATENTS** regardless of whether such patents are dominant or subordinate to **PATENTS.**

4. SUBLICENSING

4.01 Upon written approval by **PHS**, which approval will not be unreasonably withheld, **Licensee** may enter into sublicensing agreements under the **PATENTS** in the **Licensed Fields of Use-A. PHS** shall respond in writing within thirty (30) days of receipt of any written request by **Licensee** for approval of sublicensing agreements.

4.02 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.01-5.04, 8.01, 10.01, 10.02, 12.05, and 13.07-13.09 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement. Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.03 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between such sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. Such conversion is subject to **PHS** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.04 **Licensee** agrees to forward to **PHS** a copy of each fully executed sublicense agreement

postmarked within thirty (30) days of the execution of such agreement. To the extent permitted by law, **PHS** agrees to maintain each such sublicense agreement in confidence.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.01 **PHS** reserves on behalf of the Government an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the Government and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the Government is a signatory. Prior to the **First Commercial Sale**, **Licensee** may provide, as a courtesy, **PHS** reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.

5.02 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

5.03 **Licensee** acknowledges that **PHS** may enter into future Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. **Licensee** agrees not to unreasonably deny requests for a **Research License** from such future collaborators with **PHS** when acquiring such rights is necessary in order to make a Cooperative Research and Development Agreement (CRADA) project feasible. **Licensee** may request an opportunity to join as a party to the proposed Cooperative Research and Development Agreement (CRADA).

5.04 (a) In addition to the reserved license of Paragraph 5.01 above, **PHS** reserves the right to grant nonexclusive Research Licenses directly or to require **Licensee** to grant nonexclusive Research Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, **PHS** shall consult with **Licensee** before granting to commercial entities a Research License or providing to them research samples of materials made through the **Licensed Processes**.

6. ROYALTIES AND REIMBURSEMENT

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.01 Except as otherwise provided in this Article 7, **PHS** agrees to take responsibility for, but to consult with the **Licensee** in, the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **PATENTS** and shall furnish copies to **Licensee** of correspondence to and from U.S. and foreign patent offices. In addition, **PHS** agrees to provide copies of proposed responses to **Licensee** for comment prior to filing. **Licensee** shall use reasonable efforts to keep, and to ensure that its officers, directors, employees, consultants, contractors and attorneys keep completely confidential any information furnished to **Licensee** by **PHS** or its contract law firms. **Licensee** agrees that it and its attorneys will use such information only for prosecution of **PATENTS** and shall not use such information for any other purpose, including patent prosecution or interference proceedings involving patents or patent applications not owned by **PHS**. **Licensee's** obligations of confidentiality and non-use shall not extend to such information where it can be established by **Licensee** by competent proof that such information: (1) is or hereafter becomes generally available to the public other than by reason of any default by the **Licensee** with respect to its confidentiality obligations hereunder; (ii) was already known to **Licensee** as evidenced by prior written documents in its possession; (iii) is disclosed to **Licensee** by a third party (e.g. patent offices) who is not in default of any confidentiality obligation to **PHS**; or (iv) is independently developed by or for **Licensee** without reference to or reliance upon the information furnished by **PHS**.

7.02 Upon **PHS**'s written request, **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **PATENTS** and shall on an ongoing basis promptly furnish copies of all patent-related documents to **PHS**. In such event, **Licensee** shall, subject to the prior approval of **PHS**, select registered patent attorneys or patent agents to provide such services on behalf of **Licensee** and **PHS**. **PHS** shall provide appropriate powers of attorney and other documents necessary to undertake such actions to the patent attorneys or patent agents providing such services. **Licensee** and its attorneys or agents shall consult with **PHS** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **PATENTS** and shall provide **PHS** sufficient opportunity to comment on any document that **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.03 At any time, **PHS** may provide **Licensee** with written notice that **PHS** wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **PATENTS**. If **PHS** elects to assume such responsibilities, **Licensee** agrees to cooperate fully with **PHS**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **PATENTS** and to provide **PHS** with complete copies of any and all documents or other materials that **PHS** deems necessary to undertake such responsibilities. **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of **PHS**'s choice.

7.04 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **PATENTS** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of **PATENTS**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.01 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. Such records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection at the expense of **PHS** by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and payments hereunder. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any late charges as required by Paragraph 9.08 of this **Agreement**. All payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due.

8.02 Upon request of **PHS**, **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the **Licensed Product** or **Licensed Processes** are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalty funds owed to the **Government** under this **Agreement**, and whether the royalty amount owed has been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit if such sales and royalties are under reported for more than five percent (5.0%) by Licensee, otherwise **PHS** shall bear the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.01 Prior to signing this **Agreement**, **Licensee** has provided to **PHS** the **Commercial Development Plan** at Appendix E, under which **Licensee** intends to bring the subject matter of the **PATENTS** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.02 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed**

Fields of Use-A and Licensed Fields of Use-B within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee**'s public service activities that relate to the **PATENTS**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for such differences. In any such annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee**'s performance under this **Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written consent by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if such request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 CFR 404.3(d). **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **PHS** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

9.03 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.04 **Licensee** shall submit to **PHS** within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each such royalty report, **Licensee** shall submit payment of the earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine royalties due.

9.05 **Licensee** agrees to forward semi-annually to **PHS** a copy of such reports received by **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to **PHS** by **Licensee** for activities under the sublicense.

9.06 Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, P.O. Box 360120, Pittsburgh, PA 15251-6120. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or

conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.04 of this **Agreement** shall accompany each such payment, and a copy of such report shall also be mailed to **PHS** at its address for notices indicated on the Signature Page of this **Agreement**.

9.07 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay any such tax and be responsible for all filings with appropriate agencies of foreign governments.

9.08 Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.09 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of such records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. § 552 shall be subject to the predisclosure notification requirements of 45 CFR § 5.65(d).

10. PERFORMANCE

10.01 **Licensee** shall use its reasonable best efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable best efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** at Appendix E and performance of the **Benchmarks** at Appendix D. The efforts of a sublicensee shall be considered the efforts of **Licensee**.

10.02 Upon the **First Commercial Sale**, until the expiration of this **Agreement**, **Licensee** shall use its reasonable best efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.01 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **PATENTS,** as well as any facts which may affect the validity, scope, or enforceability of the **PATENTS** of which either Party becomes aware.

11.02 Pursuant to this **Agreement** and the provisions of Chapter 29 of title 35, United States Code, **Licensee** may: a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **PATENTS**; b) in any such suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for infringement of **PATENT** provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take such actions. If **Licensee** desires to initiate a suit for patent infringement, **Licensee** shall notify **PHS**

in writing. If **PHS** does not notify **Licensee** of its intent to pursue legal action within ninety (90) days, **Licensee** will be free to initiate suit. **PHS** shall have a continuing right to intervene in such suit. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such suit for patent infringement. **Licensee** may request the **Government** to initiate or join in any such suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action, including any and all costs incurred by the **Government** in opposing any such motion or other action. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.03 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **PATENTS** shall be brought against **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.02, pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code or other statutes, **Licensee** may: a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **PATENTS**; b) in any such suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for declaratory judgment involving the **PATENTS**-provided, however, that **PHS** and appropriate **Government** authorities shall have the first right to take such actions and shall have a continuing right to intervene in such suit. If **PHS** does not notify **Licensee** of its intent to respond to the legal action within a reasonable time, **Licensee** will be free to do so. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such declaratory judgment action. **Licensee** may request the **Government** to initiate or to join any such suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action. If **Licensee** elects not to defend against such declaratory judgment action, **PHS**, at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.04 In any action under Paragraphs 11.02 or 11.03, the expenses including costs, fees, attorney fees, and disbursements, shall be paid by **Licensee**. The value of any recovery made by **Licensee** through court judgment or settlement shall be treated as **Net Sales** and subject to earned royalties.

11.05 **PHS** shall cooperate fully with **Licensee** in connection with any action under Paragraphs 11.02 or 11.03. **PHS** agrees promptly to provide access to all necessary documents and to render

reasonable assistance in response to a request by **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.01 **PHS** offers no warranties other than those specified in Article 1.

12.02 **PHS** does not warrant the validity of the **PATENTS** and makes no representations whatsoever with regard to the scope of the **PATENTS**, or that the **PATENTS** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.03 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **PATENTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.04 **PHS** does not represent that it will commence legal actions against third parties infringing the **PATENTS**.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.01 This **Agreement** is effective when signed by all parties and shall extend to the expiration of the last to expire of the **PATENTS** unless sooner terminated as provided in this Article 13.

13.02 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Article 13.05, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding amounts owed through procedures provided by the Federal Debt Collection Act.

13.03 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon **Licensee**'s receipt of written notice.

13.04 **Licensee** shall have a unilateral right to terminate this **Agreement** and/or any licenses in

any country or territory by giving **PHS** sixty (60) days written notice to that effect.

13.05 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**: 1) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS**'s satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**; 2) has not achieved the **Benchmarks** as may be modified under Paragraph 9.02; 3) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license **Agreement**; 4) has committed a material breach of a covenant or agreement contained in the license; 5) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences; 6) cannot reasonably satisfy unmet health and safety needs; or 7) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.02 unless waived. In making this determination, **PHS** will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.02. Prior to invoking this right, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS**'s concerns as to the previous items 1) to 7). If **Licensee** fails to alleviate **PHS**'s concerns as to the previous items 1) to 7) or fails to initiate corrective action to **PHS**'s satisfaction, **PHS** may terminate this **Agreement**.

13.06 When the public health and safety so require, and after written notice to **Licensee** providing **Licensee** a sixty (60) day opportunity to respond, **PHS** shall have the right to require **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **PATENTS**, unless **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **PATENTS**. **PHS** will not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with **Licensee**.

13.07 **PHS** reserves the right according to 35 U.S.C. § 209(f)(4) to terminate or modify this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and such requirements are not reasonably satisfied by **Licensee**.

13.08 Within thirty (30) days of receipt of written notice of **PHS**'s unilateral decision to modify or terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR 404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.09 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred

but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **PHS** pursuant to Paragraph 4.03. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **PATENTS** to **PHS** or provide **PHS** with certification of the destruction thereof.

14. GENERAL PROVISIONS

14.01 Neither Party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any such term or condition by **Licensee**.

14.02 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **PATENTS**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.03 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.04 If either Party desires a modification to this **Agreement**, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.05 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.06 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party. Notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.07 This **Agreement** shall not be assigned by **Licensee** except: a) with the prior written

consent of **PHS**, such consent not to be withheld unreasonably; or b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**. **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**, and **Licensee** shall pay **PHS**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within thirty (30) days of such assignment.

14.08 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **DHHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

14.09 **Licensee** 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 such items may require a license from the cognizant Agency of the U.S. **Government** or written assurances by **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve **PHS** patent rights in such countries.

14.11 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of NIH, CDC, **PHS**, or **DHHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written consent of **PHS**.

14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the

final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Paragraphs 4.03, 8.01, 9.05-9.07, 12.01-12.05, 13.08, 13.09, and 14.12 of this **Agreement** shall survive termination of this **Agreement.**

SIGNATURES BEGIN ON NEXT PAGE

PHS PATENT LICENSE AGREEMENT--*EXCLUSIVE*

SIGNATURE PAGE

For **PHS**:

Jack Spiegel Date: 9/30/99

Jack Spiegel, Ph.D.
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices:

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.)
by:

Date: September 24, 1999

Signature of Authorized Official

Kevin Rakin

Executive Vice President and Chief Financial Officer

Official and Mailing Address for Notices:

Melodie W. Henderson

Genaissance Pharmaceuticals, Inc.

Five Science Park

New Haven, CT 06511

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A--Patent(s) or Patent Application(s)

Patent(s) or Patent Application(s):

PCT/US96/11478 and USPA 09,060,023

"Transformation Associated Recombination (TAR) System in Yeast for Specific Cloning of DNAs as Yeast Artificial Chromosomes (YACs)"

Canadian Application 2259158

Japanese Application 10-505170

Australian Application 64871/96

APPENDIX B--Royalties

APPENDIX C--Modifications

PHS and **Licensee** agree to the following modifications to the Articles and Paragraphs of this **Agreement**: None

APPENDIX D--Benchmarks and Performance

APPENDIX E--Commercial Development Plan