

LICENSE AGREEMENT

This Agreement is entered into between the National Technical Information Service (NTIS), a primary operation unit of the United States Department of Commerce, having offices at 5285 Port Royal Road, Springfield, Virginia 22161, and Abbott Laboratories (LICENSEE), having offices in North Chicago, Illinois 60064.

WHEREAS, the Department of Health and Human Services (DHHS) has sponsored research on a Serological Detection of Antibodies to Retroviruses (HTLV-III) in Sera of Patients with AIDS and Pre-AIDS Conditions, on a Method of Continuous Production of said Retroviruses and has received by assignment certain valuable PATENT RIGHTS (hereinafter defined) in the United States, and certain foreign countries; and

WHEREAS, pursuant to 35 U.S.C. 207 and 41 C.F.R. 101-4.1, the DHHS has transferred custody of the entire right, title and interest to said PATENT RIGHTS to the United States Department of Commerce; and

WHEREAS, the United States Department of Commerce, pursuant to 35 U.S.C. 207 and 41 C.F.R. 101-4.1, is authorized to receive by transfer custody of the right, title and interest in federally owned inventions; to apply for, obtain and maintain patents on federally owned inventions in the United States and in foreign countries; to grant nonexclusive, partially exclusive or exclusive licenses under federally owned patents and patent applications; and to undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions; and

WHEREAS, the Secretary of Commerce, through Department Organization Order 30-7A, has delegated to NTIS the authority of the Secretary to acquire federally owned inventions from other Federal agencies for the purpose of licensing the use of those inventions in the United States and in foreign countries; and

WHEREAS, NTIS desires, in the public interest, that the subject inventions be perfected, marketed, and practiced so that the benefits are readily available for widest possible utilization in the shortest time possible; and

WHEREAS, in consideration of the grant of a license to practice the subject invention, LICENSEE agrees to expend reasonable efforts to achieve early practical application of the invention;

NOW THEREFORE, in accordance with the above cited statute and regulations and in consideration of the foregoing, NTIS and LICENSEE agree as set forth below.

ARTICLE I

Definitions

1.1 PATENTS RIGHTS shall mean U.S. Patent Applications Serial Number 6-602,945 and Serial Number 6-602,946 and corresponding foreign patent applications identified in the Schedule which is attached to this Agreement and made a part hereof and in all patents issuing therefrom including all continuations, divisions, and reissues. The Schedule shall be updated from time to time by NTIS to reflect the issuance of patents pursuant to the listed patent applications.

1.2 LICENSED PRODUCT(S) shall mean test kits for detection or assay of antibodies developed from cell line H9/HTLV-III_B on

deposit in the American Type Culture Collection (ATCC) under ATCC No. CRL 8543, that utilize the technology and methods described and claimed in PATENT RIGHTS.

1.3 DEVELOPMENT PRODUCT(S) shall mean vaccines and all other products except LICENSED PRODUCTS developed from cell line H9/HTLV-III_B on deposit in the American Type Culture Collection (ATCC) under ATCC No. CRL 8543 identified by LICENSEE that are derived from the technology and methods described and claimed in PATENT RIGHTS.

1.4 NET SALES PRICE shall mean the amount billed or invoiced on sales of LICENSED PRODUCTS less:

- (a) Customary trade, quantity, or cash discounts and nonaffiliated brokers' or agents' commissions actually allowed and taken;
- (b) Amounts repaid or credited by reason of rejections or returns; and
- (c) Any freight or other transportation costs, insurance charges, duties, tariffs and all sales and excise taxes based directly on sales or turnover or delivery of material produced under this Agreement.

1.5 AFFILIATE shall mean any company, corporation or business in which LICENSEE owns at least fifty percent (50%) of the voting stock.

1.6 FDA APPROVAL shall mean approval for commercial sale of a new biological material by the U.S. Food and Drug Administration (FDA).

ARTICLE II

Grant

2.1 NTIS hereby grants to LICENSEE, subject to the terms and conditions herein, a nonexclusive license under the PATENT RIGHTS, to make, have made, use and sell LICENSED PRODUCTS in the United States and to use and sell LICENSED PRODUCTS worldwide for the duration of this Agreement; provided however that although the grant set forth herein does not include any rights in respect of DEVELOPMENT PRODUCTS, it does not preclude LICENSEE from conducting research on DEVELOPMENT PRODUCTS.

2.2 NTIS hereby grants to LICENSEE the right to extend the license granted herein to any AFFILIATE subject to all of the terms and conditions of this Agreement. LICENSEE agrees to notify NTIS in writing with regard to any such extension of rights.

2.3 NTIS hereby grants to LICENSEE the right to grant sublicenses to nonaffiliated companies, subject to the approval of NTIS with the concurrence of the Assistant Secretary for Health, DHHS. Each sublicense shall make reference to this Agreement, including the rights retained by the United States Government, and a copy of such sublicense shall be furnished to NTIS.

2.4 NTIS hereby grants to LICENSEE, its AFFILIATES and its sublicensees the right to extend to their customers of the LICENSED PRODUCT the right to use and/or sell LICENSED PRODUCTS upon which royalty is payable or has been paid.

ARTICLE III

Payments

3.1 Upon execution of this license Agreement, LICENSEE

shall pay to NTIS a sum of Three Thousand Dollars (\$3,000), no part of which shall be refunded for any reason.

3.2 In addition, LICENSEE shall pay to NTIS an annual minimum payment of Five Thousand Dollars (\$5,000), no part of which shall be refunded for any reason. The first annual minimum payment shall be made by LICENSEE upon execution of the Agreement and shall be prorated for the balance of the year. Subsequent annual minimum payments when due shall be payable on January 1, for the duration of this Agreement. Royalties due NTIS in any given calendar year pursuant to Paragraph 3.3 below shall be credited against the annual minimum payment paid by LICENSEE for that year. Royalties due in any one calendar year shall not be credited against the annual minimum payment paid or to be paid in any other year. Should the costs to NTIS of patent maintenance, annuities and taxes exceed in any year the total annual royalties received from all licensees under the PATENT RIGHTS, NTIS may request LICENSEE to pay a portion of such excess costs, LICENSEE's portion to be determined by negotiation between NTIS and LICENSEE, taking into account the total number of licensees under the PATENT RIGHTS and the relative amount of royalty generated by LICENSEE compared to the total royalty generated by all licensees. Should LICENSEE not pay such portion of such excess costs, LICENSEE may elect to forfeit its license rights in one or more countries listed in the Schedule to bring its portion of such costs below its annual royalty.

3.3 LICENSEE shall pay NTIS a royalty of five percent (5%) of the NET SALES PRICE of all LICENSED PRODUCTS sold by LICENSEE, its AFFILIATES and sublicensees.

3.4 No royalty shall be payable hereunder to NTIS on the sales of LICENSED PRODUCTS billed or invoiced by LICENSEE, its

AFFILIATES or its sublicensees to the Government of the United States of America.

3.5 LICENSEE shall pay all necessary expenses for commercialization of LICENSED PRODUCTS and such expenses shall not be deducted from any annual minimum payment or royalty due NTIS as provided herein.

3.6 All payments due NTIS under this ARTICLE shall be payable in United States dollars for the account of "NTIS/Patent Licensing." All checks and bank drafts shall be drawn on United States banks. If payments are overdue, late charges will be applied as required by the Department of Treasury (Treasury Fiscal Requirements Manual, Section 8020.20).

ARTICLE IV

Markings

LICENSEE, its AFFILIATES and its sublicensees may, at their option and in conformity with applicable statutes, identify LICENSED PRODUCTS with the marking "Licensed Under (Pending) U.S. Patent or "U.S. Patent Pending." The name of the Government employee inventor of any invention licensed hereunder, the name of any agency or department of the United States Government, or any adaptation of the above shall not be used in any promotional activity without prior written approval from NTIS.

ARTICLE V

Reporting and Recordkeeping

5.1 LICENSEE shall provide written bimonthly status reports to DHHS detailing progress being made to bring the invention licensed hereunder to practical application. DHHS representatives shall have the right on reasonable notice to visit LICENSEE's premises, to review LICENSEE's written data relating

to the LICENSED PRODUCT and to monitor LICENSEE's facilities for the production of LICENSED PRODUCT and for research on DEVELOPMENT PRODUCTS, if any. After FDA APPROVAL only annual reports shall be required unless otherwise requested by NTIS. Bimonthly reports shall be retained until FDA APPROVAL and for one (1) year thereafter; and annual reports shall be retained for one (1) year.

5.2 Until FDA APPROVAL, LICENSEE shall, on a bimonthly basis, update the National Cancer Institute (NCI) Investigational New Drug (IND) master file with all clinical information and test data relating to LICENSED PRODUCT.

5.3 Any technical information including but not limited to clinical and non-clinical information developed under this Agreement will be made available to DHHS upon request. Such information generated under DHHS approved protocols will be made available to DHHS and, DHHS shall be free to release such information to third parties. ^{except for information in the possession of licensee prior to the effective date of this agreement,}

5.4 LICENSEE agrees to submit to NTIS, within sixty (60) days after each calendar half-year ending June 30 and December 31, reports setting forth for the preceding six (6) month period of the amount of LICENSED PRODUCTS sold, the NET SALES PRICE thereof, and the amount of royalty due thereon; and with each such report to pay the amount of royalty due. If no royalties are due to NTIS for any report period, the written report shall so state.

5.5 LICENSEE shall keep accurate and complete records of LICENSED PRODUCTS sold or otherwise disposed of under this Agreement, appropriate to determine the amount of royalties due

hereunder. Such records shall be retained for at least one (1) year following a given reporting period, and shall be available during normal business hours for inspection at the expense of NTIS by an accountant selected by NTIS and approved by LICENSEE for the sole purpose of verifying reports and payments hereunder. Such accountant shall not disclose to NTIS any information other than information relating to the accuracy of reports and payments made under this Agreement.

ARTICLE VI

Patent Enforcement

6.1 LICENSEE shall notify NTIS promptly in writing of any infringement of PATENT RIGHTS which becomes known to LICENSEE.

6.2 In the event that NTIS determines that a substantial infringement of PATENTS RIGHTS exists, which determination shall be made by written notice to LICENSEE, NTIS shall take prompt action to attempt to eliminate that substantial infringement. LICENSEE shall, at the request of NTIS, cooperate fully in gathering information concerning whether an infringement of PATENTS RIGHTS constitutes a substantial infringement for the purpose of this ARTICLE. NTIS shall notify LICENSEE (within thirty (30) days following LICENSEE's notice under Paragraph 6.1), in writing, of its determination that a substantial infringement of PATENT RIGHTS exists and that NTIS will attempt to eliminate that substantial infringement.

6.3 Should NTIS be unsuccessful in eliminating the substantial infringement within ninety (90) days following LICENSEE's notice under Paragraph 6.2, NTIS agrees to recommend to the appropriate United States Government authorities that an

infringement action based on PATENT RIGHTS be initiated. LICENSEE shall at NTIS' request cooperate in every respect including making available to NTIS records, information, evidence, and testimony by employees of LICENSEE relevant to the substantial infringement of the licensed PATENT RIGHTS.

6.4 If, after twelve (12) months from the date of the written decision by NTIS to attempt to eliminate infringement of the PATENT RIGHTS, NTIS has not eliminated the infringement of PATENT RIGHTS or if the United States Government has not initiated an infringement suit, LICENSEE may cease payment of royalties due hereunder resulting from sales of LICENSED PRODUCTS. When such infringement has been eliminated, or an appropriate infringement suit has ~~not~~ been initiated, the obligation to pay the royalties shall resume, royalties being due only from the date the infringement is eliminated or from the date an infringement action is initiated.

ARTICLE VII

Licensee Performance

7.1 LICENSEE agrees that it will:

- (a) provide sufficient LICENSED PRODUCT to meet the requirements of DHHS approved protocols; and
- (b) not ^{prior to FDA approval} distribute any LICENSED PRODUCT unless such distribution is under a DHHS approved protocol; and
- (c) not enter into any exclusive arrangement with any third party for the purpose of testing the LICENSED PRODUCT or any DEVELOPMENT PRODUCT without prior approval of DHHS; and
- (d) within fifteen (15) working days after its occurrence, report any adverse biosafety event in

writing to the Director, Division of Safety, National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, Maryland 20205 or by telephone at 301/496-1357.

7.2 LICENSEE, its AFFILIATES or sublicensees, as the case may be, shall expend reasonable efforts and resources to carry out the development and marketing plan in accordance with LICENSEE's application for a license and shall bring LICENSED PRODUCTS to the point of practical application (as defined at 41 C.F.R. 101-4.102(d)) within six (6) months of the effective date of this Agreement unless this period is extended by mutual agreement of the parties. NTIS shall not unreasonably withhold approval of any request of LICENSEE to extend this period, if such request is supported by a reasonable showing by LICENSEE of due diligence toward bringing the LICENSED PRODUCTS to the point of practical application. "Due diligence" shall include any reasonable and diligent application for approval required by any Government agency within the United States.

7.3 After bringing LICENSED PRODUCT(S) to the point of practical application, LICENSEE agrees to keep LICENSED PRODUCT(S) reasonably available to the public during the term of this Agreement.

7.4 LICENSEE agrees that any LICENSED PRODUCT sold in the United States will be substantially manufactured in the United States.

7.5 Failure to comply with the terms of this ARTICLE shall be cause for modification or termination of the license granted herein in accordance with ARTICLE VIII of this Agreement.

7.6 All requirements and obligations of LICENSEE, its AFFILIATES and its sublicensees under this Agreement are in addition to applicable Federal Statutes and Regulations.

7.7 LICENSEE agrees to cooperate with DHHS in collection, evaluation and maintaining data from tests of investigational biological assays.

ARTICLE VIII

Modification or Termination

8.1 Nonexclusive license granted pursuant to ARTICLE II may be modified or terminated by NTIS, subject to Paragraphs 8.2 and 10.4, if it is determined that:

- (a) LICENSEE is not executing the plan submitted with its request for a license under the PATENT RIGHTS or is not fulfilling the representations made to DHHS subsequent to its license request and has not otherwise demonstrated to the satisfaction DHHS and NTIS that it has taken or can be expected to take within a reasonable time effective steps to achieve practical application of the invention;
- (b) 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 the LICENSEE;
- (c) LICENSEE has willfully made a false statement or willfully omitted a material fact in the license application or in any report required by this Agreement;

(d) LICENSEE, its AFFILIATE or its sublicensee commits a substantial breach of a covenant or agreement contained in the license;

(e) LICENSEE is adjudged a bankrupt or has its assets placed in the hands of a receiver or made any assignment or other accommodation for the benefit of creditors;

(f) LICENSEE, its AFFILIATE or its sublicensee fail to comply with accepted P-3 biosafety containment facility requirements; or

(g) DHHS fails to approve LICENSEE's, its AFFILIATE's or its sublicensee's production facilities for the LICENSED PRODUCT after an inspection thereof.

8.2 Prior to any modification or termination of the license granted herein, NTIS shall furnish LICENSEE and any sublicensees of record a written notice of intention to modify or terminate the license, and the LICENSEE and any sublicensee shall be allowed ninety (90) days after receipt of such notice to remedy any such breach or default of any covenant or agreement of this Agreement or to show cause why the license granted herein should not be modified or terminated.

8.3 LICENSEE may terminate this Agreement or its license as to any of the PATENTS RIGHTS upon ninety (90) days written notice to NTIS.

8.4 Upon termination of this Agreement or of the license granted to any of the PATENT RIGHTS herein, sums due to NTIS from LICENSEE relating to such termination shall become immediately payable. In all other respects, the rights and

obligations of the parties affected by such termination shall cease as of the effective date of such termination.

ARTICLE IX

Duration

This Agreement, unless sooner terminated as provided herein, shall remain in effect until the expiration date of the last-to-expire patent included in the PATENT RIGHTS.

ARTICLE X

General

10.1 NTIS represents and warrants that the entire right, title and interest in the patent application comprising the PATENT RIGHTS have been assigned to the United States of America as represented by the Secretary of Commerce and that NTIS has the authority to issue licenses under the said PATENT RIGHTS. NTIS does not warrant the validity of the PATENT RIGHTS and makes no representations whatsoever with regard to the scope of the PATENT RIGHTS or that such PATENT RIGHTS may be exploited by LICENSEE, its AFFILIATES or sublicensee without infringing other patents.

10.2 NTIS shall notify LICENSEE of any subsequent agreement containing more favorable terms and conditions which may hereafter be granted by NTIS to any other party under PATENT RIGHTS, and LICENSEE, if it is in a position to do so, may substitute all the terms and conditions of such other agreement for the terms and conditions of this Agreement.

10.3 Without the prior written approval of NTIS, the license granted pursuant to this Agreement shall not be transferred by LICENSEE to any party other than to a successor or

assignee of the business interest of LICENSEE relating to LICENSED PRODUCTS.

10.4 The parties shall make every reasonable effort to resolve amicably any dispute concerning a question of fact arising under this Agreement. Any disputes not settled amicably between the parties concerning a question of fact arising under this Agreement shall be decided by the Director, NTIS, (with the concurrence of the Assistant Secretary for Health, DHHS) who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to LICENSEE. The decision of the Director, NTIS, to modify or terminate this Agreement shall be final and conclusive unless, LICENSEE mails or otherwise furnishes to the Director, NTIS, a written appeal under the Appeal Procedures of 15 C.F.R. Part 17, Subpart C. Pending final decision of a dispute hereunder, LICENSEE shall proceed diligently with the performance of its obligations under this Agreement.

10.5 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the United States as interpreted and applied by the Federal courts in the District of Columbia, United States of America.

10.6 Written notices required to be given under this Agreement shall be considered duly given if mailed first class, postage prepaid and addressed as follows:

If to NTIS:

Director, Office of Federal Patent
Licensing
National Technical Information Service
United States Department of Commerce
5285 Port Royal Road
Springfield, Virginia 22161

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LICENSE AGREEMENT

This Agreement is entered into between the National Technical Information Service (NTIS), a primary operating unit of the United States Department of Commerce, having offices at 5285 Port Royal Road, Springfield, VA 22161, and Petra Biomedical Products, Inc. (hereinafter "LICENSEE"), having offices at Tulsa, Oklahoma.

WHEREAS, the United States of America, as represented by the Department of Health and Human Services has sponsored research on a recombinant DNA which directed the production of human growth hormone when introduced into cultured mammalian cells and has received by assignment certain valuable PATENT RIGHTS in the United States and certain foreign countries; and

WHEREAS, pursuant to 35 U.S.C. 207 and 41 C.F.R. 101-4.1, the Department of Health and Human Services has transferred custody of the entire right, title, and interest to said PATENT RIGHTS (hereinafter defined) to the United States Department of Commerce; and

WHEREAS, the United States Department of Commerce, pursuant to 35 U.S.C. 207 and 41 C.F.R. 101-4.1, is authorized to receive by transfer custody of the right, title, and interest in federally owned inventions in the United States, to grant licenses under federally owned patents and patent applications, and to undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions; and

WHEREAS, the Secretary of Commerce, through Department Organization Order 30-7A, has delegated to NTIS the authority of the Secretary to acquire federally owned inventions from other federal agencies for the purpose of licensing the use of those inventions in the United States; and

WHEREAS, NTIS desires, in the public interest, that the subject invention be perfected, marketed, and practiced so that the benefits are readily available for widest possible utilization in the shortest time possible; and

WHEREAS, LICENSEE has the facilities, personnel, and expertise to bring the LICENSED PRODUCTS to the point of practical application at an early date; and

WHEREAS, in consideration of the grant of a license to practice the subject invention, LICENSEE agrees to expend reasonable efforts to achieve early practical application of the invention;

NOW THEREFORE, in accordance with the above cited statute and regulations and in consideration of the foregoing, NTIS and LICENSEE agree as set forth below.

ARTICLE I

Definitions

1.1 PATENT RIGHTS shall mean U.S. Patent Application Serial Number 452,783 and in all continuations and divisions thereof and patents issuing thereon and reissue patents resulting from such original patents and corresponding foreign patent applications identified in the Schedule attached to this Agreement and made a part hereof and in all divisions and continuations of such patent applications and all original and reissue patents resulting from such patent applications.

1.2 LICENSED PROCESS shall mean a method for producing human growth hormone encompassed by a valid claim in an unexpired patent under PATENT RIGHTS.

1.3 LICENSED PRODUCTS shall mean human growth hormone produced by the LICENSED PROCESS.

1.4 LICENSED TERRITORY shall mean those countries listed in the Schedule and in which PATENT RIGHTS have not expired or been abandoned by NTIS.

1.5 AFFILIATE(S) shall mean any company, corporation, or business in which LICENSEE owns at least fifty percent (50%) of the voting stock.

1.6 NET SALES shall mean the amount billed or invoiced on the sale of LICENSED PRODUCTS or, if disposed of other than by sale, the amount billed or invoiced for a like quality and quantity of LICENSED PRODUCTS sold by LICENSEE or its licensed AFFILIATES at or about the time of such disposal less:

- (a) Customary trade, quantity, or cash discounts and nonaffiliated brokers' or agents' commissions actually allowed and taken;
- (b) Amounts repaid or credited by reason of rejection or return of LICENSED PRODUCTS;
- (c) Any duty or tax based directly on NET SALES or turnover or delivery of LICENSED PRODUCTS; and/or
- (d) Any packaging, freight, or other transportation costs and insurance charges.

NET SALES of any LICENSED PRODUCTS sold or otherwise disposed of by LICENSEE or licensed AFFILIATES which are in combination with one or more active ingredients which contribute therapeutic value to the combination shall be calculated by multiplying the amount billed or invoiced of such combination of LICENSED PRODUCTS and such other ingredients which contribute therapeutic value by a fraction represented by the formula $A/(A+B)$, wherein A is the cost to the LICENSEE or licensed AFFILIATES of the LICENSED PRODUCTS and B is the cost of all other such active ingredients; provided, however, that in no event shall the adjusted NET SALES be less than fifty percent (50%) of the NET SALES of the combination product. For the purposes of this Paragraph, the costs to be used in

calculating adjusted NET SALES shall be the manufacturing cost for materials, direct labor, and manufacturing overhead calculated according to LICENSEE's customary and accepted accounting procedures.

ARTICLE II

Grant

2.1 NTIS hereby grants to LICENSEE, subject to the terms and conditions herein, a revocable (as provided in Article IX), partial exclusive license under PATENT RIGHTS to make and have made LICENSED PRODUCTS by the LICENSED PROCESS in the LICENSED TERRITORY and to use and sell LICENSED PRODUCTS by the LICENSED PROCESS worldwide for a term of seven (7) years from the effective date of this Agreement; it being understood that NTIS reserves the right to grant a similar license to one other party.

2.2 NTIS hereby grants to LICENSEE, subject to the terms and conditions herein, a nonexclusive license under PATENT RIGHTS to make and have made LICENSE PRODUCTS in the LICENSED TERRITORY and to use and sell LICENSED PRODUCTS worldwide for a term starting with the expiration of the partial exclusive license period of Paragraph 2.1 and extending for the life of the PATENT RIGHTS.

2.3 LICENSEE shall have the right to extend this Agreement to any AFFILIATE, subject to the terms and conditions hereof, and shall notify NTIS in writing with regard to any such extension of rights.

2.4 LICENSEE and its licensed AFFILIATES shall have the right to extend to any customer of LICENSEE or licensed AFFILIATES a royalty free right to use LICENSED PRODUCTS purchased from LICENSEE or licensed AFFILIATES.

2.5 LICENSEE shall not have the right to sublicense nonaffiliated third parties under PATENT RIGHTS to make, have made, use, or sell LICENSED PRODUCTS in the

LICENSED TERRITORY; except that, NTIS may require LICENSEE to grant sublicenses to responsible third parties on terms that are reasonable in circumstances as may be necessary to fulfill health or safety needs.

ARTICLE III

Reservation of Rights

3.1 The licenses granted in ARTICLE II are subject to the reservation by NTIS of an irrevocable, nonexclusive, non-transferable, royalty-free license for the practice of all PATENT RIGHTS throughout the world by and on behalf of the Government of the United States and on behalf of any foreign government pursuant to any existing or future treaty or agreement to which the United States is signatory.

ARTICLE IV

Royalties and Payments

4.1 Upon execution of this license Agreement, LICENSEE shall pay to NTIS the sum of Five Thousand Dollars (\$5,000), no part of which shall be a credit for other payments due or refunded for any reason.

4.2 LICENSEE shall pay to NTIS an annual minimum payment of Two Thousand Dollars (\$2,000). The first annual minimum payment shall be the pro rata portion remaining in the calendar year from the effective date of this Agreement and shall be made by LICENSEE upon execution of this Agreement. Subsequent annual minimum payments shall be payable on January 1 for the duration of this Agreement. The annual minimum payment made for a calendar year shall be a credit for royalties due for that year pursuant to Paragraph 4.3 but shall not be a credit for royalties due in any other year.

4.3 During the partial exclusive term of this Agreement, as provided in Paragraph 2.1, LICENSEE shall pay NTIS a royalty of three percent (3%) of the NET SALES of LICENSED PRODUCTS sold or otherwise disposed of by LICENSEE or licensed

AFFILIATES. Upon expiration of the partial exclusive term of this Agreement, the royalty paid by LICENSEE shall be reduced to one and one-half percent (1.5%) of the NET SALES of LICENSED PRODUCTS sold or otherwise disposed of by LICENSEE or licensed AFFILIATES.

4.4 No royalty shall be payable hereunder to NTIS on the NET SALES of LICENSED PRODUCTS by LICENSEE or licensed AFFILIATES to the Government of the United States of America.

4.5 LICENSEE and licensed AFFILIATES to which this license is extended shall pay all necessary expenses for commercialization of LICENSED PRODUCTS and such expenses shall not be deducted from any royalties due NTIS as provided in this ARTICLE.

4.6 All payments due NTIS under this ARTICLE shall be payable in United States dollars for the account of "NTIS/- Patent Licensing." All checks and bankdrafts shall be drawn on United States Banks. If payments are overdue, late charges will be applied as required by the Department of Treasury Fiscal Requirements Manual, Section 8020.20.

ARTICLE V

Markings

LICENSEE or licensed AFFILIATES may, at their option and in conformity with applicable statutes, identify LICENSED PRODUCTS with the marking "Licensed under Pending U.S. Patent Application 452,783" or other such patent designations included under PATENT RIGHTS. The name of the Government employee inventors, the name of any agency or department of the United States Government, or any adaptation of the above shall not be used in any promotional activity without the prior written approval of NTIS.

ARTICLE VI

Reporting and Recordkeeping

6.1 LICENSEE shall provide written annual reports within sixty (60) days of the end of each calendar year detailing progress toward development, regulatory approvals, and commercial use that has been made and is intended to be made of the invention licensed hereunder, including a statement of the time, nature, and amount of capital and other resources expended in such development and such other data and information as NTIS may request. No further annual progress reports will be required after NET SALES of LICENSED PRODUCTS by LICENSEE or licensed AFFILIATES unless otherwise requested by NTIS.

6.2 LICENSEE agrees to submit to NTIS, within sixty (60) days after each calendar half-year ending June 30 and December 31, reports setting forth for the preceding six (6) month period the NET SALES of LICENSED PRODUCTS by LICENSEE and licensed AFFILIATES, and the amount of royalty due, and with each such report to pay the royalties due. If no royalties are due to NTIS for any reporting period, the written report shall so state.

6.3 LICENSEE shall keep accurate records of LICENSED PRODUCTS sold or otherwise disposed of under this Agreement appropriate to determine the amount of royalties due under and of progress toward development, regulatory approval, and commercial use, appropriate to determine the time, nature, and amount of capital and other resources expended as required under Paragraph 6.1. Such records shall be retained for at least two (2) years following a given reporting period, and shall be available during normal business hours upon no less than seventy-two (72) hours prior notice for inspection at the expense of NTIS by an accountant selected by NTIS and approved by LICENSEE for the sole purpose of verifying reports and

payments hereunder. Such accountant shall not disclose to NTIS any information other than information relating to the accuracy of reports and payments required under this Agreement.

ARTICLE VII

Patent Enforcement

7.1 LICENSEE shall notify NTIS promptly in writing of any infringement of PATENT RIGHTS which becomes known to LICENSEE or licensed AFFILIATES. LICENSEE and licensed AFFILIATES agree to cooperate fully with NTIS in gathering and making available to NTIS information on the notified infringement. NTIS shall take prompt action to determine whether such infringement constitutes a substantial infringement of PATENT RIGHTS.

7.2 In the event NTIS determines under Paragraph 7.1 that a substantial infringement of PATENT RIGHTS exists, NTIS shall take prompt action to attempt to eliminate that substantial infringement. Should NTIS be unsuccessful in eliminating the substantial infringement, NTIS agrees to recommend to appropriate United States Government authorities that an infringement action be initiated. LICENSEE shall, at NTIS' request, cooperate in every respect, including making available to NTIS records, information, evidence, and testimony by employees of LICENSEE and licensed AFFILIATES relevant to the infringement of PATENT RIGHTS.

7.3 If after twelve (12) months from the date of LICENSEE's notice to NTIS under Paragraph 7.1, NTIS has not eliminated the infringement of PATENT RIGHTS specified in LICENSEE's notice and determined by NTIS under Paragraph 7.1 to be a substantial infringement of PATENT RIGHTS or the United States Government has not initiated an infringement suit or empowered LICENSEE to institute an infringement suit under Paragraph 7.4, LICENSEE shall be excused from payment of royalties thereafter due hereunder resulting from NET SALES of

LICENSED PRODUCTS. When the infringement has been eliminated or at least one infringement suit has been filed and when NTIS has notified LICENSEE in writing of either such event, LICENSEE's obligation to pay the royalties shall resume with respect to NET SALES made after LICENSEE's receipt of such notice from NTIS.

7.4 see attachment

ARTICLE VIII

Licensee Performance

8.1 LICENSEE, or licensed AFFILIATES, as the case may be, shall expend reasonable efforts and resources to carry out the development and marketing plan submitted with LICENSEE's application for a license and shall bring LICENSED PRODUCTS to the point of practical application (as defined at 41 C.F.R. 101-4.102(d)) within three (3) years of the effective date of this Agreement, unless this period is extended by mutual agreement of the parties. NTIS shall not unreasonably withhold approval of any request of LICENSEE to extend this period, if such request is supported by a reasonable showing by LICENSEE of due diligence toward bringing LICENSED PRODUCTS to the point of practical application. "Due diligence" shall include any reasonable and diligent application for approval required by any Government agency within the United States.

8.2 After bringing LICENSED PRODUCTS to the point of practical application, LICENSEE agrees to keep LICENSED PRODUCTS reasonably available to the public during the term of this Agreement.

8.3 LICENSEE agrees that LICENSED PRODUCTS sold or otherwise disposed of in the United States by LICENSEE or licensed AFFILIATES will be manufactured in the United States.

8.4 Failure to comply with the terms of this ARTICLE shall be cause for modification or termination of the license granted herein in accordance with ARTICLE IX of this Agreement.

ARTICLE IX

Modification and Termination

9.1 The license granted herein may, subject to Paragraphs 9.2 and 11.3, be modified or revoked by NTIS, in whole or in part, if it is determined that:

- (a) LICENSEE fails to meet its obligation under ARTICLE VIII;
- (b) 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 the licensee;
- (c) LICENSEE has willfully made a false statement of or willfully omitted a material fact in the license application or in any report required by this Agreement;
- (d) LICENSEE defaults in making any report required by this Agreement or commits a substantial breach of a covenant or agreement contained in this Agreement; or
- (e) The LICENSEE becomes insolvent or makes an assignment for the benefit of creditors or any proceeding is commenced by or against the licensee under any bankruptcy or receivership laws and such proceeding is not dismissed within sixty (60) days after its institution, or
- (f) The LICENSEE or licensed AFFILIATES misuse the patent.

9.2 Prior to any modification or termination of the license granted herein, NTIS shall furnish LICENSEE and any licensed AFFILIATES of record a written notice of intention to modify or terminate the license, and the LICENSEE and any licensed AFFILIATES shall be allowed thirty (30) days after receipt of such notice to remedy any such breach or default of any covenant or agreement of this Agreement or to show cause why the license granted herein should not be modified or terminated.

9.3 LICENSEE may terminate this Agreement as to any and all PATENT RIGHTS upon ninety (90) days written notice to NTIS.

9.4 Upon termination of this Agreement by LICENSEE or for cause by NTIS under the provisions of ARTICLE IX of the license granted herein, sums due to NTIS from LICENSEE shall become immediately payable. In other respects, the rights and obligations of the parties hereto shall cease as of the effective date of such termination.

9.5 NTIS shall notify LICENSEE of any subsequent agreement containing more favorable terms and conditions which may hereafter be granted by NTIS to any other party under PATENT RIGHTS; and LICENSEE, if it is in a position to do so, may substitute all terms and conditions of such other agreement for all the terms and conditions of this Agreement; and LICENSEE shall be bound by the terms and conditions of such other agreement as of the date LICENSEE notified NTIS of such substitution.

ARTICLE X

Duration

This Agreement, unless sooner modified or terminated as provided herein, shall remain in effect until the expiration date of the last patent included under PATENT RIGHTS.

ARTICLE XI

General

11.1 NTIS represents and warrants that the entire right, title, and interest in the patents and patent applications comprising the PATENT RIGHTS have been assigned to the United States of America as represented by the Secretary of Commerce and that NTIS has the authority to issue licenses under said PATENT RIGHTS. NTIS does not warrant the validity of the PATENT RIGHTS licensed hereunder and makes no representation

whatsoever with regard to the scope of the licensed PATENT RIGHTS or that such PATENT RIGHTS may be exploited by LICENSEE or licensed AFFILIATES without infringing other patents.

11.2 The licenses granted pursuant to this Agreement shall not be transferred by LICENSEE to any party other than to a successor or assignee of the business interest of LICENSEE relating to LICENSED PRODUCTS.

11.3 The parties shall make every reasonable effort to resolve amicably any dispute concerning a question of fact arising under this Agreement. Any disputes not settled amicably between the parties concerning a question of fact arising under this Agreement shall be decided by the Director, NTIS, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to LICENSEE. The decision of the Director, NTIS, shall be final and conclusive, unless within thirty (30) days from the date of receipt of such copy, LICENSEE mails or otherwise furnishes to the Director, NTIS, a written appeal addressed to the Secretary of Commerce. The decision of the Secretary or the Secretary's duly authorized representative for the determination shall be final unless appealed to a United States court of competent jurisdiction. In connection with any appeal proceeding under this provision, LICENSEE shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, LICENSEE shall proceed diligently with the performance of its obligations under this Agreement and in accordance with the decision of the Director, NTIS. This dispute provision does not preclude consideration of questions of law in connection with decisions provided for above; provided, however, that nothing in this Agreement shall be construed as making final the decision of any agency official, representative, or board on a question of law.

11.4 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the

United States as interpreted and applied by the federal courts in the District of Columbia, United States of America.

11.5 Written notices required to be given under this Agreement shall be addressed as follows:

If to NTIS: Manager, Patent Licensing
National Technical Information Service
United States Department of Commerce
5285 Port Royal Road
Springfield, Virginia 22161

If to LICENSEE: Michael D. Roark
Vice President for Research
and Production
Petra Biomedical Products Inc.
8740 East 11th Street
Tulsa, Oklahoma 74112

or such other address as either party may request in writing.

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

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

The effective date of this Agreement is _____.

Witness: National Technical Information Service

JOSEPH F. CAPONIO
Director

Date

Date

Witness: Petra Biomedical Products Inc.

Date

Date

ATTACHMENT

7.4 During the exclusive term of this Agreement as provided under Paragraph 2.1, NTIS may, at its option, empower LICENSEE pursuant to the provisions of 35 USC 29 and other relevant statutes to institute an infringement suit at its expense in the name of NTIS and LICENSEE, provided however, that NTIS and appropriate U.S. Government authorities shall have the continuing right to intervene in such legal action. Any recovery obtained by LICENSEE as a result of such proceeding, by settlement or otherwise, shall be the property of LICENSEE.

The GATT Mine Field

By JEFFREY E. GARTEN

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Misplaced Faith

The fact is that the momentum is over for progressive trade liberalization through omnibus, multilateral marathons like the coming session under the General Agreement on Tariffs and Trade (GATT). The push ended when tariffs were negotiated down to insignificant levels in most countries, including the U.S. and Japan, leaving non-tariff barriers—such as quotas and regulations on procurement, customs procedures, and protection of national security—as obstacles to commerce.

The administration has advocated global trade talks because this is how the executive branch has done things in the past and because it believes they will reduce congressional pressure for more protectionism in the face of a looming \$170 billion trade deficit. Unfortunately, such faith is misplaced.

Start with false historical analogies. Washington remembers such trade negotiations as the Dillon Round (1960-1961), the Kennedy Round (1963-1967), and the Tokyo Round (1974-1979)—which together gave a terrific boost to world trade by lowering tariffs from 40% to less than 5%. American officials recall that these events were successful because the U.S. was able to trade off concessions on its side for more-or-less equivalent breaks from other nations—lower duties on steel imports into the U.S. from Kobe, for example, for easier entry for Kansas grains into Japan.

The current scene is different. Unlike import duties, non-tariff barriers cannot be lowered with percentage cuts. Instead, a new system of regulation—a legal "code"—must be set up specific to each of the many different impediments to trade, agreed to by a host of countries, and monitored and enforced internationally. These highly detailed and legalistic arrangements provide very little opportunity for trade-offs. Is it realistic, for example, that Brazil would lower its national-security strictures against computer imports from all countries in exchange for everyone else's loosening up on health regulations concerning certain agricultural products? It is more likely, in fact, with so many countries and issues mixed together, that stalemate will prevail.

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There is also the problem of false expectations. Both the administration and Congress believe the problem with U.S. trade is that others cheat on the rules, and Washington is determined that the new negotiations will address this problem head on. But in 1984, only 5% of imports to the U.S. were challenged before the International Trade Commission for unfair practices and only half of that amount was officially declared unfair. The frustration of dashed hopes could lead to a backlash of even more protectionism.

Moreover, the sheer number of countries involved in the global negotiations is apt to result in a lowest-common-denominator approach to trade policy and thereby reinforce the trend toward "managed trade," a euphemism for more regulation along the lines of the Multifiber Agreement, the most recent version of which was signed last month. Codes dealing with non-tariff barriers involving nations of so many different stages of development are particularly susceptible to more bureaucratic intervention, more red tape and more fine print, since they have to address so many different legal and administrative systems.

For the U.S., it is vital to focus on issues where substantial results are achievable, and soon. This calls not for a global jamboree, but for negotiations on a more manageable scale, sometimes bilateral, sometimes involving several nations. And to make real headway, trade will have to be discussed alongside other economic issues.

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There is also the problem of false expectations. Both the administration and Congress believe the problem with U.S. trade is that others cheat on the rules, and Washington is determined that the new negotiations will address this problem head on. But in 1984, only 5% of imports to the U.S. were challenged before the International Trade Commission for unfair practices and only half of that amount was officially declared unfair. The frustration of dashed hopes could lead to a backlash of even more protectionism.

Moreover, the sheer number of countries involved in the global negotiations is apt to result in a lowest-common-denominator approach to trade policy and thereby reinforce the trend toward "managed trade," a euphemism for more regulation along the lines of the Multifiber Agreement, the most recent version of which was signed last month. Codes dealing with non-tariff barriers involving nations of so many different stages of development are particularly susceptible to more bureaucratic intervention, more red tape and more fine print, since they have to address so many different legal and administrative systems.

For the U.S., it is vital to focus on issues where substantial results are achievable, and soon. This calls not for a global jamboree, but for negotiations on a more manageable scale, sometimes bilateral, sometimes involving several nations. And to make real headway, trade will have to be discussed alongside other economic issues.

In fact, the GATT talks could divert attention from a really important trade agenda.

It is critical, for example, that the U.S. keep relentless pressure on Tokyo to open its markets, not just with lower quotas but also with a faster paced gross national product. Global negotiations make it easier for Japan to squirm out of the limelight and to defer decisions until "broad consensus" is reached.

The U.S. should intensively pursue a free trade and currency coordination pact with Canada; exports and imports with our largest trading partner exceed \$100 billion annually. It should likewise propose a package of debt-relief and trade promotion with Mexico, our most important Third World market. Yet focus on these issues will be blurred in the hubbub of Punta del Este.

We ought to negotiate hard to free up trade in wheat, telecommunications and financial services, for example, but the task is best accomplished in smaller forums and not with all the world's trade bureaucrats at the same table.

Tied Hands

The biggest setback would be if the new trade round distracted attention from our own home-grown competitive handicaps—an antitrust policy that ties our hands against corporate giants from abroad, an approach to research-and-development promotion that centers on military and not industrial technology, and a failure to devise a market-oriented system to lessen the impact on workers and communities clobbered by imports. Most of all, Washington needs to devise a policy toward the dollar that doesn't extol its sky-high value one day, then dramatically diminish it the next.

Paula Stern, recent head of the International Trade Commission, put it well: "Our chief concern need not be the tilt of the playing field. We must concentrate, instead, on building up the American team."

Mr. Garten, a managing director of Shearson Lehman Brothers Inc., just completed a two-year assignment in Tokyo.