

FOIA / PA Officer John Livornese U.S. Securities & Exchange Commission FOIA Office 100 F Street NE, Mail Stop 5100 Washington, DC 20549 RECEIVED

FEB 13 2018

FOIA Services

February 13, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreements, as **FOIA Request: 10-01186-FOIA.** 

Exhibit 10.3 to Form SB-2 filed on 05/23/1996 by Amarillo Biosciences Inc.

Exhibit Title: License Agreement

CIK: 1014763

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos Research Assistant Sectilis LLC 6931 Arlington Rd. # 580 Bethesda, MD 20814



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

February 21, 2018

Ms. Stella Vasconcellos Sectilis LLC 6931 Arlington Rd., #580 Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552

Request No. 18-02462-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on February 13, 2018, for access to Exhibit 10.3 to Form SB-2 filed by Amarillo Biosciences, Inc. on May 23, 1996.

The search for responsive records has resulted in the retrieval of 35 pages of records that pertain to Exhibit 10.3. They are being provided to you in their entirety with this letter.

No fees have been assessed for the processing of this request. If you have any questions, please contact me at <a href="neilsonc@sec.gov">neilsonc@sec.gov</a> or (202) 551-3149. You may also contact me at <a href="foiapa@sec.gov">foiapa@sec.gov</a> or (202) 551-7900. You also have the right to seek assistance from Dave Henshall as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or <a href="Archives.gov">Archives.gov</a> or via e-mail at <a href="mailto:ogis@nara.gov">ogis@nara.gov</a>.

Sincerely,

Curtis Neilson

FOIA Research Specialist

Enclosure

#### LICENSE AGREEMENT

THIS LICENSE AGREEMENT is made and effective this 20th day of October, 1989, by and between AMARILLO CELL CULTURE COMPANY, INCORPORATED, a Texas corporation with its principal place of business at 6666 Amarillo Boulevard West, Amarillo, Texas 79106 (hereinafter "ACC") and INTERFERON SCIENCES, INC., with its principal place of business at 783 Jersey Avenue, New Brunswick, New Jersey 08901 (hereinafter "ISI") (ACC and ISI are hereinafter collectively referred to as the "Parties").

whereas, acc owns or controls patents and patent applications directed to the oral administration of interferons for the prophylactic and therapeutic treatment of animals and human beings and has expertise in such uses of interferon;

whereas, acc has already conducted or contracted for the conduct of preliminary tests demonstrating the efficacy of orally administered interferon, including cell culture derived interferons, in several vertebrate species, including humans;

whereas, ISI has substantial expertise in the production and use of cell culture derived human leukocyte interferon alpha (hereinafter, "IFN-a") and has proprietary

Jus

rights and know-how in the field of production, purification and formulation of IFN-a;

WHEREAS, ISI has ongoing research programs and product development efforts directed to the use of human IFN-a in human medicine and desires to expand use of human IFN-a to new human applications;

WHEREAS, ACC desires to promote non-human applications of its proprietary technology relating to administration of interferon and acknowledges that such efforts would be facilitated by the availability of a source of FDA-approved IFN-a for ACC and its Third Party Licensees;

WHEREAS, ISI has received FDA approval of a natural human IFN-a containing product ("IFN ALFA-N-3") with therapeutic claims in humans;

WHEREAS, ACC desires to be the exclusive agent for distribution of ISI IFN ALFA-N-3 for oral use in non-human species, all as provided in that certain Manufacturing and Supply Agreement of even date herewith, between the Parties;

WHEREAS, ISI desires to acquire a worldwide co-exclusive license under ACC's patents and patent applications for the manufacture, use and sale of human IFN-a formulations for oral use in human beings; and

WHEREAS, ACC has disclosed to ISI ACC Technical Information including preliminary animal and human data and



copies of ACC patents and pending patent applications, and ISI has disclosed to ACC certain ISI Technical Information;

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, ISI and ACC agree as follows:

#### ARTICLE I

#### DEFINITIONS

- 1.1. "ACC" and "ISI" shall mean and include not only the indicated company, but also its Affiliates and permitted Assignees.
- 1.2. "Affiliate" means a corporation, company, partnership, or other business entity which controls or is controlled by, or is under common control with, the designated party. In the case of a corporation or company, "control" means ownership either directly or indirectly of at least Fifty Percent (50%) of the shares of stock entitled to vote for the election of directors.
- 1.3. "Agreement" or "License Agreement" means this Agreement and all Exhibits hereto.
- 1.4. "Assignee" means any assignee or sublicensee of rights under this Agreement.
- 1.5. "Distributor" means any purchaser, other than a Manufacturing Sublicensee, of Licensed Products from ISI, its Affiliates or permitted assignees.



- 1.6. "Invention" means the use of interferons as disclosed and claimed in one or more Licensed Patents.
- 1.7. "ISI Interferon" means the ISI natural human IFN-a (IFN ALFA-N3) used to formulate IFN ALFA-N3-containing formulation(s) presently approved by the FOOD AND DRUG ADMINISTRATION ("FDA") for use as a treatment of human genital warts and which is produced, purified and formulated by ISI utilizing ISI Technical Information. It is contemplated that ISI Interferon will be utilized in the formulation of Licensed Products hereunder.
- 1.8. "Licensed Patent(s)" means those United States Patents and patent applications listed in Exhibit "A" hereof, and any continuations, continuations-in-part, divisions, reissues or extensions thereof, and each foreign counterpart of each United States Patent and patent application listed in Exhibit "A" and any extensions thereof, and any new patents, patent applications, continuations, continuations in part, divisions, reissues or extensions, filed or controlled by ACC either heretofore, or in the future, covering oral use of interferon in the human species.
- 1.9. "Licensed Product" means dose formulations or compositions containing interferon derived from any species and designated, detailed, or labeled for oral use in human species.

Jun C

- 1.10. "Manufacturing Sublicensee" means any Assignee of any of ISI's rights under this Agreement, under an arrangement (other than by virtue of a change or control of ISI) which requires or contemplates the manufacture of ISI Interferon by such Assignee.
- selling price paid to ISI by a Distributor, including any royalty, for Licensed Product, including all packaging, instructional or other charges made to a Distributor, but less customary trade discounts and refunds or credits allowed for return of defective products. If Licensed Products are sold in transactions which are not bona fide arms-length transactions, Net Sales Value for such sales shall be valued as equal to commercial sales of similar Licensed Products to unrelated third parties in similar quantities.
- 1.12. "Technical Information" means all information, reports, results, inventions, know-how, materials, and any other technical and scientific data, specifications and formulae directly related to the development, regulatory approval, manufacture, testing, use, marketing and/or sale of Licensed Products or other interferon-containing compositions, and any non-public information relevant to the business of the Parties which is necessarily disclosed by one to the other during the Parties' conduct under this Agreement.

  "ACC Technical Information" refers to Technical Information



originating with ACC or which ACC has obtained through its contractual relationships with third parties. "ISI Technical Information" refers to Technical Information originating with ISI. "Technical Information" when not otherwise specified herein means ACC Technical Information and ISI Technical Information.

- 1.13. "Territory" shall mean all countries of the World, except Japan.
- 1.14. "Third Party Licensees" refers to third parties licensed by ACC under Licensed Patents to use and/or sell interferon-containing products designated, detailed or labeled for use in non-human species.
- 1.15. "University Agreements" shall mean the agreement dated March 22, 1988, between ACC and the TEXAS A&M UNIVERSITY SYSTEM and the agreement dated April 1, 1984, between ACC and UNIVERSITY PATENTS, INC., and Amendment No. 1 thereto, dated July 26, 1984, all of which are attached hereto as Exhibit "B".

#### ARTICLE II

#### THE LICENSE GRANT

2.1. ACC grants to ISI, subject to the terms of this License Agreement, a royalty-bearing co-exclusive license under Licensed Patents and under ACC Technical Information to make, have made, use and sell Licensed



Products labeled for use only in human species in the Territory. The rights hereby granted are co-exclusive with ACC's and its sublicensees' rights to make, have made, use and sell HBL interferon under the HBL Agreement attached hereto as Exhibit "D", and with ACC's and its sublicensees' rights to make, have made, use and sell their own non-human interferon for use only in animals.

2.2. ISI shall have the right to grant sublicenses under the license granted herein. For purposes of this Paragraph 2.2, "sublicense" shall mean a sublicense by ISI of some, but less than all, of its rights under this License Agreement, and shall not require ACC's consent, such as would be required for an Assignment under Paragraph 11.5. All such sublicenses shall be made expressly subject to the terms and provisions of this Agreement, ISI shall, within thirty (30) days of the execution of each sublicense, provide to ACC a copy of each sublicense granted hereunder and shall promptly advise ACC in writing of any modification (and supply a copy of same) or termination of each sublicense. Upon termination sublicenses shall all such be of this Agreement, automatically terminated, and all such sublicenses shall contain an express provision to that effect.

## ARTICLE III

## CONSIDERATION

- 3.1. ISI shall pay to ACC a royalty of Ten Percent (10%) of the Net Sales Value of Licensed Products sold by ISI to Distributors.
- 3.2. The obligation to pay a royalty shall be imposed only once in respect of a particular unit of Licensed Product, regardless of the number of Licensed Patents

embracing the Licensed Product and/or the manufacture and/or use thereof.

- 3.3. Further in consideration of the grant of license under ARTICLE II hereof, ISI shall execute and deliver the Manufacturing and Supply Agreement (a counterpart of which is attached hereto as Exhibit "C") on the date of this Agreement.
- Paragraph 3.1, above, within thirty (30) days of receipt by ISI, ISI agrees that it will remit to ACC fifty percent (50%) of any option fee, license fee, or other payment, except royalty or specific research or patent expense reimbursements, and except payments received for sale of its stock at the then fair market value thereof, which it may receive from a Distributor, and fifty percent (50%) of any and all payments of whatsoever nature, except specific research or patent expense reimbursements, and except payment received for sale of its stock at the then fair market value thereof, which it may receive from a Manufacturing Sublicensee.
- 3.5. ISI shall maintain records of all ISI expenditures with respect to its business efforts toward development of Licensed Products hereunder and such records shall be sufficient to show the clinical indication for which each such expenditure is made. ISI shall provide ACC by January



31 of each year during the term of this Agreement, and upon the expiration of three (3) years from the date of this Agreement, a report of ongoing efforts for the development of each clinical indication for Licensed Products, including a report of all expenditures by ISI for each indication with respect to formulation development, pre-clinical and clinical testing, regulatory approval efforts, manufacturing facility development/procurement, product packaging, marketing/sales strategy, and any other areas into which ISI's reasonable business efforts in accordance with this paragraph should reasonably be categorized. Such a report shall be prepared more often if ACC so requests in writing, and if ACC pays to ISI the expenses incurred by ISI in generating such additional reports. It is understood that ACC will receive such information as ISI Technical Information, and ACC shall use it only for the purpose of monitoring ISI's efforts to develop Licensed Products under this Agreement.

3.6. Upon the expiration of three (3) years from the date of this Agreement, ISI shall provide to ACC within thirty (30) days of ACC's request, copies of all data relating to the development of Licensed Products generated by ISI or by others for ISI during the term of this Agreement to that date.

Jue gre

ISI shall expend for development of Licensed Products hereunder, a total of at least Four Hundred Thousand and no/100 Dollars (\$400,000.00) over the three (3) year period commencing on the date of this Agreement, for all indications for use of human interferon in humans, and a total of at least One Hundred Thousand Dollars (\$100,000) over the three (3) year period commencing on the date of this Agreement, for the use of non-human interferons for human indications.

3.7. This License Agreement, and all rights licensed hereunder by ACC to ISI, shall terminate upon the expiration of five (5) years from the date hereof, unless ISI or its Manufacturing Sublicensee shall be marketing Licensed Products in the United States at that date; provided, however, that such termination date shall be extended from year to year, and this Agreement shall not terminate, so long as ISI continues to expend a minimum of Fifty Thousand and No/100 Dollars (\$50,000.00) per year toward development of Licensed Products related to the use of human interferon in humans, and a minimum of Ten Thousand and No/100 Dollars (\$10,000.00) per year toward development of Licensed Products related to the use of non-human interferons in human indications hereunder ("Extension Payments"). If ISI should elect to

continue this Agreement in force by making such Extension Payments, ISI shall so notify ACC in writing within thirty (30) days of the expiration of five (5) years from the date of this Agreement. Thereupon, ISI shall have a period of twelve (12) calendar months during which to make such expenditures, and to document the same to ACC. If ISI

Anc

wishes, ISI may, at its election, satisfy said Extension Payment obligation by paying said \$50,000/\$10,000, as the case may be, to ACC within said twelve (12) month period, in which case said Extension Payment shall be treated as prepaid royalty, and applied to future obligations payable by ISI to ACC under ARTICLE III of this Agreement. If sufficient royalties shall not have been earned by ACC under the terms of this Agreement prior to its termination to offset all such prepaid royalties, then any excess amounts of prepaid royalties shall be nonrefundable, and shall be retained by ACC.

years from the date hereof ISI should commence marketing Licensed Products in the United States under this Agreement, then ISI shall thereupon no longer be required to make Extension Payments to hold this Agreement in force, but ISI shall not be entitled to the return or refund of any Extension Payments theretofore made. If at anytime after the expiration of five (5) years from the date of this Agreement, ISI should no longer be marketing any Licensed Products in the U.S., then this Agreement and ISI's rights thereunder shall thereupon terminate, unless ISI begins or recommences such Extension Payments all as set forth above. Until the termination of this Agreement pursuant to ARTICLE V, ISI may hold this Agreement in force at all times after expiration of



five (5) years from the date hereof, by either (i) marketing Licensed Products in the U.S., or (ii) making Extension Payments.

With respect to the making of Extension Payments by ISI, this Agreement may be held in force, as provided above, as to indications for use of human interferon in humans, by making the \$50,000 annual Extension Payments, and this Agreement may be held in force as to indications for use of non-human interferons in humans by making the \$20,000 annual Extension Payments.

- 3.8. In the United States, ISI shall commence marketing of each Licensed Product within one hundred eighty (180) days after receiving approval of the New Drug Application ("NDA") for that Licensed Product.
- 3.9. Upon request by ACC, ISI shall provide ACC a list of each country, other than the United States, in which ISI or any Manufacturing Sublicensee is marketing Licensed Product, identifying the Licensed Products, and details of distribution, for each such country.
- 3.10. The Parties to this Agreement contemplate the possibility that ISI's sale of Licensed Products under this Agreement may be subject to competition from oral interferon products sold by other companies; accordingly, the Parties hereto agree as follows:

Jul Jan

- (a) ISI shall be required to pay to ACC the full amounts set forth in ARTICLE III, above, regardless of whether or not other companies may be competing against ISI with respect to the same indications.
- The provisions of Paragraph (a) (b) notwithstanding, if ISI shall have demonstrated that sales of Licensed Product shall not "economically be viable" due to market competition from oral interferon products of companies other than HBL, then the royalty set forth in Paragraph (a) above shall be

Jun Churc

reduced, to that point mutually agreed upon by ACC and ISI, where such sales shall become, or may be expected to become, "economically viable". purposes of this provision, "economically viable" shall mean that such product sales, standing alone and without reference to other sales by ISI, will generate a net profit for ISI after taking into account costs of production and distribution, and royalties payable to ACC. In computing the amount of net profit on sales for purposes of this provision, none of ISI's general or indirect overhead, research and development costs, or depreciation shall be allocated to such sales as costs. If ACC and ISI should be unable to agree upon that royalty which would insure "economic viability", they jointly appoint an independent certified public accounting firm to make such determination, and the determination of such firm shall be final and conclu-Such firm shall be one which has sive. not previously been employed by either ACC or ISI. The expense of such firm shall be equally shared by ACC and ISI.

#### ARTICLE IV

#### REMITTANCES, RECORDS AND REPORTS

4.1. ISI shall keep accurate records in sufficient detail to enable the royalties payable hereunder to be determined. ACC shall have the right to nominate an independent public accountant, acceptable to and approved by ISI, which approval shall not be unreasonably withheld. Once in each calendar year, said accountant shall have access to the records of ISI relating to royalty payments under this License Agreement during reasonable business hours for the

Jun C

purpose of verifying the accuracy of the reports and payments made during the current year and/or the preceding calendar year. Said accountant shall disclose to ACC only information relative to the accuracy of the reports and the payments made in accordance with this License Agreement. Any and all fees charged by said accountant shall be paid by ACC except, if ACC's auditors should find discrepancies in ISI's quarterly reports that resulted in under-reporting or underpayment by a factor greater than Ten Percent (10%) of the amount due, then ISI shall reimburse ACC for the cost of the audit conducted on the sales and/or payments for that country.

4.2. With respect to sales to Distributors, payment of royalties shall be made to ACC within forty-five (45) days following the end of each calendar quarter of each year for all Licensed Products sold by or for ISI during said calendar quarter, and royalties to ACC shall accrue when Licensed Products are first sold, or otherwise transferred by or for ISI, and Licensed Products shall be considered sold when billed out. With respect to amounts received by ISI from Manufacturing Sublicensees, payment shall be made to ACC within forty-five (45) days following the end of each

Jun C

calendar quarter of each year for all payments received by ISI from Manufacturing Sublicensees during said calendar quarter. All payments to ACC shall be accompanied by statements certified by an officer of ISI which give sufficient information from which to calculate the amount of payment due hereunder, including the total quantity and Net Sales Value of each Licensed Product sold to Distributors for which royalty has accrued during the preceding calendar quarter, the amounts received by ISI from all Manufacturing Sublicensees during the preceding calendar quarter, and the aggregate amounts payable to ACC. A statement shall also be submitted in the event that no amounts are payable to ACC.

- 4.3. Payments hereunder shall be made in U.S. Dollars in the United States. With respect to sales to Distributors in countries outside the United States, royalties shall accrue in the currency of the country in which the sales are made and royalties shall be payable to ACC in U.S. Dollars at the official rate of exchange prevailing on the last day of the quarter during which the royalties accrued.
- 4.4. Any assignment under this Agreement shall require Assignee's compliance with the record keeping, royalty payment and record review provisions of this Agreement.



#### ARTICLE V

## TERM AND TERMINATION

- 5.1. This Agreement shall remain in effect until the date of the last to expire of the Licensed Patents unless terminated earlier in accordance with the provisions of this ARTICLE V or as otherwise provided in this Agreement.
- 5.2. ISI may surrender and thereby terminate this Agreement at any time upon ninety (90) days' prior written notice to ACC.
- make payments, render reports, meet the diligence or Extension Payment requirements of ARTICLE III, or otherwise fail to abide by the terms herein provided, ACC may notify ISI in writing of such default and ACC's intent to terminate this License Agreement unless such default is cured by ISI within sixty (60) days from receipt by ISI of such notice. If such default is not cured within the sixty (60) day period, ACC may provide ISI with written notice of termination, and this Agreement and the license and rights granted by it shall thereupon terminate.
- 5.4. This Agreement may be terminated by ACC at its option and without prejudice to any other remedy to which it may be entitled at law or in equity or elsewhere in this



Agreement, by giving written notice of termination to ISI if the latter should:

- (a) Be adjudicated a voluntary or involuntary bankrupt;
- (b) Institute or suffer to be instituted any proceeding for a reorganization or rearrangement of its affairs;
- (c) Make an assignment for the benefit of creditors;
- (d) Have a receiver of its assets or property appointed.

If at any time ISI should cease the conduct 5.5. of its interferon manufacturing business, then it is agreed by the Parties that this License Agreement may thereupon be terminated by ACC, upon thirty (30) days written notice; provided, however, that if ISI shall have theretofore assigned its rights hereunder to a Manufacturing Sublicensee, under terms and conditions requiring said Manufacturing Sublicensee to continue to manufacture and supply ISI Interferon to ACC pursuant to the terms and conditions of the Manufacturing and Supply Agreement, then this Agreement may not be terminated by ACC upon ISI's cessation of the conduct of its interferon manufacturing business, but may be terminated by ACC upon cessation by said Manufacturing Sublicensee of the conduct of its interferon manufacturing business, upon thirty (30) days written notice, unless said Sublicensee has Manufacturing



made arrangements satisfactory to ACC, for continuation of the manufacturing and supply to ACC of ISI Interferon.

If the ability of ISI to supply Manufactured Products (as defined in the Manufacturing and Supply Agreement) in the quantity and quality provided therein shall have been interrupted for a period of six (6) months or more, and if such interruption in supply was not the result of force majeure such as acts of God, strikes, wars, fire, inability to obtain raw materials, or civil disturbances, then as soon thereafter as ACC's inventories of Manufactured Products shall be or become exhausted, this License Agreement may thereupon be terminated by ACC, upon thirty (30) days written notice.

- 5.6. Termination of this License Agreement or any license granted hereunder by either Party for any reason shall not relieve the Parties of any obligation accruing prior to such termination.
- 5.7. On termination by ISI of this License Agreement for any reason, except natural termination in accordance with Paragraph 5.1 upon expiration of the last-to-expire of Licensed Patents, ISI shall cease to use or evaluate the Invention and shall cease to both make and sell Licensed Products and shall surrender to ACC all of ACC's confidential documents and information that it may have received during the term of this License Agreement. Any accrued royalties

shall be paid to ACC within thirty (30) days of the termination of this Agreement.

#### ARTICLE VI

## ENFORCEMENT OF LICENSED PATENTS

- 6.1. In the event ISI alleges that a third party infringes a Licensed Patent, a <u>prima facie</u> determination of infringement shall be made by an Independent Patent Attorney ("IPA") satisfactory to both ISI and ACC, at their joint cost and expense.
- 6.2. If the IPA finds that there is no <u>prima facie</u> infringement by the alleged infringer, then ISI's obligation to pay royalties under this License Agreement shall continue without abatement.
- 6.3. If the IPA finds <u>prima facie</u> evidence of the alleged infringement:
- 6.3.1. ACC or ACC's licensor may elect to institute an infringement action against any such third party, which election shall be made no later than one hundred twenty (120) days after the determination of prima facie infringement as aforesaid, in which event ISI shall continue to pay royalties during the pendency of the action; and
- 6.3.2. Whether or not ACC or its licensor finally prevails, ISI shall continue to pay royalties as set forth in ARTICLE III hereof.



- 6.3.3. If ACC or its licensor elects not to institute an action as aforesaid, ISI may elect to institute an action against a third party in which event:
  - (a) During the pendency of such action, ISI may suspend payment of royalties under the Licensed Patent in suit in the country of such action to the extent of any costs actually incurred in such action; and
  - (b) If ISI finally prevails it shall thereafter pay to ACC the amount of all royalties, the payment of which had been suspended under Paragraph 6.3.3(a), above, and shall resume paying royalties as set forth in ARTICLE III hereof, but may deduct from such amounts payable to ACC, ISI's actual out-of-pocket costs incurred in pursuing such litigation; in addition, ISI shall retain all damages which it may collect, but will pay to ACC Ten Percent (10%) of such damages as are compensatory damages for lost sales; and
  - (c) If ISI finally loses the infringement action, ISI shall thereafter resume paying royalties as set forth in ARTICLE III and shall, in addition, pay to ACC such royalty payments as were suspended under the terms of Paragraph 6.3.3(a) hereof.
- 6.3.4. If ISI elects to prosecute an infringement action, it shall be responsible for all fees and costs incurred therein.
- 6.3.5. Each party shall reasonably cooperate with the other Party in the conduct of the proceedings, whether joint or not (such as by joining in name only);

fu (forc

however, where ACC or its licensor is joined in any such proceedings in name only as a necessary party and not at its election, ISI shall indemnify and hold harmless ACC and its licensor from and against any and all actions, claims, and counterclaims brought against ACC and/or its licensor, and ISI agrees to pay all expenses, damages and costs which may be finally assessed against ACC or its licensor in such actions, claims and counterclaims.

- 6.4. In the event of a final judgment of invalidity, ISI shall not be entitled to recover, as a credit or otherwise, any royalties theretofore paid.
- elects to initiate an infringement action under Paragraph 6.3.1 in response to an alleged infringement in any country, ISI may not elect the course of action described in Paragraph 6.3.3 as to a subsequent infringer in that country until the first action is finally determined, unless otherwise agreed to by ACC.

#### ARTICLE VII

## ALLEGED INFRINGEMENT BY ISI

If ISI or a customer thereof (hereinafter "Defendant") is named as a defendant in a lawsuit charging Defendant with patent infringement as a result of its sale and/or use of a Licensed Product, when and only when such an



allegation of infringement arises specifically from uses which are described in a Licensed Patent or an application for a Licensed Patent, and Defendant provides ACC with copies of the complaint (or similar paper) and all papers associated with such suit, ISI shall have the right to establish an escrow account for the mutual benefit of ACC and ISI. For so long as the lawsuit is pending, including during any appeal from any judgment or decision of any court having jurisdiction of the suit, ISI shall have the right to deposit one-half (1/2) of the royalty payments to be paid to ACC under ARTICLE III hereof into said escrow account.

The amounts deposited into the escrow account may be used toward Defendant's out-of-pocket monetary expenses actually incurred in defending the lawsuit, limited to attorneys' fees, costs and any damages assessed against Defendant based specifically and only on such use or sale of Licensed Products by Defendant. The escrow account shall be established as one or more interest bearing, federally insured accounts. The agreement establishing the escrow account shall require the escrow agent to provide ACC and ISI with accurate accounting reports, to reimburse ISI for its said expenses as approved in writing by ACC, and to remit to ACC any balance left in said account immediately after the lawsuit is finally adjudicated or otherwise resolved. ACC



shall approve all of said out-of-pocket expenses for reimbursement by the escrow agent provided the expenses are accurately documented for ACC and shown to be reasonably necessary to the defense of the lawsuit or any actual payment of assessed damages. ISI shall have no recourse against ACC concerning such lawsuit other than as herein specifically provided.

Nothing in this ARTICLE VII shall be construed as allowing ISI to establish an escrow account, if Defendant is named as a defendant in a lawsuit charging Defendant with patent infringement as a result of ISI's or other Defendant's manufacture and/or purification of a Licensed Product. Both Parties recognize and hereby acknowledge that claims of patent infringement may be asserted by other persons or entities which claims may relate to the manufacture, sale and/or use of ISI Interferon. In the event such claims are asserted by other persons of entities against either of the Parties hereto, or their Affiliates or sublicensees, it is agreed and understood that neither the provisions of ARTICLE VI, nor the foregoing provisions of this ARTICLE VII shall apply, that neither Party shall have the obligation to defend such a suit for or at the request of the other Party, that either Party may defend such a suit against itself at its own, sole expense, and that no royalties paid hereunder shall



be reduced, withheld or escrowed by virtue of such suit, provided, however, that if such suit is brought against Defendant within two (2) years of ISI's having received any license fees under Paragraph 3.4 of this Agreement, and if ISI elects not to defend such suit, ISI shall reimburse to ACC the full amount of such license fees.

#### ARTICLE VIII

#### WARRANTY

- 8.1. ACC warrants and represents that it has the full right and power to grant the license set forth in ARTICLE II hereof, that the University Agreements are now in effect and that all payments and other actions required for the University Agreements to remain in effect for the duration of this License Agreement will be made or taken as the case may be.
- 8.2. ACC warrants that there are no outstanding agreements, assignments or encumbrances inconsistent with provisions of this License Agreement that would limit or infringe on this License Agreement, and the rights granted hereunder.
- 8.3. ISI warrants that the manufacture of ISI Interferon is fully compliant with all applicable state and federal regulations, including regulations promulgated under the Federal Food, Drug and Cosmetic Act. ISI further



represents and warrants that it owns or has access to FDA approved facilities for the manufacture of ISI Interferon and formulation of FDA compliant formulations therefrom.

#### ARTICLE IX

## DISCLAIMERS AND INDEMNIFICATION

- 9.1. ACC makes no representation or warranty that the sale of Licensed Products will not infringe any third party patent, nor does ACC assume any obligations with respect to infringements of patents of others arising as a result of ISI's activities under this License Agreement except as otherwise expressly provided in this License Agreement.
- 9.2. ACC makes no covenant either to defend any infringement charge by a third party or to initiate action against infringers of any Licensed Patent except as otherwise expressly provided in this License Agreement.
- 9.3. ACC makes no representation or warranty concerning the potential profitability of Licensed Products and shall not be liable for failure of licensee to obtain a profit or income from Licensed Products.
- 9.4. ACC SHALL NOT BE DEEMED TO HAVE MADE ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO THE CONDITION, MERCHANTABILITY, DESIGN, OPERATION OR FITNESS FOR USE OF LICENSED PRODUCTS OR ANY OTHER REPRESENTATION OR



WARRANTY WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO LICENSED PRODUCTS OR LICENSED PATENTS. ACC EXPRESSLY MAKES NO WARRANTY OF VALIDITY OF PATENTS LICENSED HEREUNDER.

ISI agrees that it shall indemnify and save ACC harmless from any and all claims, demands, actions and causes of action against ACC, whether groundless or not, in connection with any and all injuries, losses, damages or liability of any kind whatsoever, arising, directly or indirectly, out of the use, manufacture, distribution and/or sale of Licensed Products by or through ISI or its Affiliates or sublicensees, whether or not the claims, demands, actions or causes of action are alleged to have resulted in whole or in part from the negligent acts or omissions of ACC, or from acts or omissions of such persons for which they are or any of them would otherwise be strictly liable. This indemnification obligation shall include, without limiting the generality of the foregoing, reasonable attorneys' fees and other costs or expenses incurred in connection with the defense of any and all such claims, demands, actions or causes of action and shall extend to the officers, employees and agents of ACC. This indemnification obligation does not extend to any occurrences or events except those occurring in the use, manufacture, distribution and/or sale of Licensed Products by or through ISI, its Affiliates or sublicensees.



#### ARTICLE X

#### CONFIDENTIALITY

- 10.1. ACC owns or is licensed under confidential or secret information relating to the Invention, and it is the intention of ACC to maintain this confidentiality.
- 10.2. ISI possesses trade secrets and technical and marketing information that are proprietary to ISI, and it is its intention to maintain the confidentiality of its proprietary information.
- and secret all Technical Information which may be disclosed or provided to it by the other Party and that the Parties may together subsequently acquire in relation to the Invention and which is designated in writing by clearly identifiable legend as being confidential or secret in character.
- 10.4. Each Party's obligation to the other (to maintain confidentiality) hereunder shall terminate with respect to any particular item and only said item of the disclosing Party's confidential Technical Information, when the recipient Party can demonstrate that such item of information:
- 10.4.1. Is publicly known and available through some means other than by the recipient Party's act or omission; or



- 10.4.2. Was in the recipient Party's possession prior to its disclosure by the other Party, provided that written evidence of such possession is established; or
- 10.4.3. Has come into the recipient Party's possession through a third party free of any obligation of confidentiality to the disclosing Party, where said third party has acquired said information lawfully and not under circumstances forbidding its disclosure.
- 10.5. Neither Party will permit the other Party's confidential Technical Information or any part thereof to be disclosed to third parties or to employees except on a "need-to-know" basis and each will maintain confidential or secret information and/or documents with the same precautions it uses to safeguard its own confidential or secret information.
- 10.6. Each Party will notify the other promptly if it has knowledge that a third party possesses Technical Information of the other Party related to the Invention.
- 10.7. ISI shall have the right to use ACC's Technical Information to the extent reasonably necessary to accomplish the objectives of this License Agreement, including specifically the right to disclose such information to its Affiliates, actual and potential sublicensees, third party contract consultants and scientific investigators (from



whom ISI shall secure Confidential Disclosure Agreements) and to regulatory agencies in support of applications for regulatory agency approval to make, test and/or sell Licensed Products.

#### ARTICLE XI

## MISCELLANEOUS

- any of their Affiliates or sublicensees to take any act required by this License Agreement if occasioned by an act of God or the public enemy, fire, explosion, perils of the sea, floods, drought, war, riot, sabotage, accident, embargo or any circumstance of like or different character beyond the reasonable control of the Party so failing or by the interruption or delay in transportation, inadequacy, or shortage or failure of the supply of materials and/or equipment, equipment breakdown, labor trouble or compliance with any order, direction, action or request of any governmental officer, department or agency and whether in any case such circumstances now exists or hereafter arises, shall not subject said Party to any liability to the other.
- avoid and settle without litigation future disputes which may arise between them relative to this Agreement. Accordingly, the parties agree to engage in good faith negotiations to



resolve any such dispute. In the event they are unable to resolve any such dispute by negotiation, such dispute shall be submitted to arbitration as follows: If arbitration is initiated by ISI, it shall be held in the State of Texas, U.S.A. in compliance with the Commercial Arbitration Rules of the American Arbitration Association. If arbitration is initiated by ACC, it shall be held in New York, New York in compliance with the Commercial Arbitration Rules of the American Arbitration Association. The arbitration award shall be final and binding upon the parties hereto and may be filed with and enforced by any competent court having competent jurisdiction to enforce said award.

11.3. Communication. Any payment, notice or other communication required or permitted to be made or given to either Party pursuant to this License Agreement shall be sufficiently made or given on the date of sending if sent to such Party by certified or registered mail or by Federal Express or a similar overnight courier service, postage or delivery charge prepaid, or by telex or telefax addressed to it at its address set forth below, or to such other address(es) as it may have designated by written notice given to the other Party:

June

## In case of ISI:

Dr. Sam Ronel, President Interferon Sciences, Inc. 783 Jersey Avenue New Brunswick, New Jersey 08901

and

Ms. Irene Frangos National Patent Development Corp. 9 West 57th Street New York, New York 10019

### In case of ACC:

Dr. Joe Cummins, President Amarillo Cell Culture Company, Inc. 6666 Amarillo Boulevard West Amarillo, Texas 79106

- Agreement constitutes the entire agreement between the Parties hereto on this subject matter and supersedes all previous arrangements whether written or oral. Any amendment or modification of this License Agreement shall be effective only if made in writing, and executed by both Parties.
- assigned in whole or in part by ACC to any person or entity and may be assigned in whole or in part by ISI to any of its Affiliates. It shall otherwise not be assignable by ISI without the prior written consent of ACC, which consent shall not be unreasonably withheld. This Agreement shall inure to

June

the benefit of the permitted Assignees or successors of ISI and/or ACC.

Enforceability. 11.6. If one or more of the provisions of this License Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions hereof shall not in any way be affected or impaired thereby. To the extent permitted by law, each Party waives any provision of law which renders any provision herein invalid, illegal or unenforceable in any respect.

IN WITNESS WHEREOF, the Parties hereunto have caused this instrument to be executed in duplicate by their duly authorized representatives as of the date first above written.

ACC:

ISI:

AMARILLO CELL CULTURE COMPANY

INCOMPORATED

INTERFERON SCIENCES, INC.