

18-04670-E

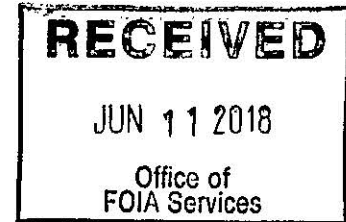
06/10/2018

U.S. Securities and Exchange Commission

Office of FOIA Services

100 F Street, NE Mail Stop 2745

Washington, DC 20549-5100



Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following:

Exhibit 10.43 to the form 10-K/A by ISTA PHARMACEUTICALS INC on 06/04/2003.

We authorize up to \$61.00 in processing fees.

Thank You,

Auguste Norkeviciute

RoyaltyRange

Registered Office: 138 South Street,

Romford, RM1 1TE, United Kingdom

Telephone: +44 20 3734 7558

E-mail: [auguste.norkeviciute@royaltyrange.com](mailto:auguste.norkeviciute@royaltyrange.com)

Website: [www.royaltyrange.com](http://www.royaltyrange.com)



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

July 17, 2018

Ms. Auguste Norkeviciute  
RoyaltyRange Europe UAB  
138 South Street  
Romford, 1U RM1 1TE  
United Kingdom

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-04670-E

Dear Ms. Norkeviciute:

This letter is in response to your request, dated June 10, 2018 and received in this office on June 11, 2018, for access to Exhibit 10.43 to the Form 10-K/A by Ista Pharmaceuticals Inc. on June 4, 2003.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at [reidk@sec.gov](mailto:reidk@sec.gov) or (202) 551-3504. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius 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 [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

*Kay Reid*

Kay Reid  
FOIA Lead Research Specialist

Enclosure

**AGREEMENT**

This AGREEMENT (hereinafter called this "Agreement") made and effective as of the 17th day of April, 2002 by and between;

Senju Pharmaceutical Co., Ltd., a legal entity duly organized and existing under the laws of Japan, having its principal office of business at 5-8, Hiranomachi 2-chome, Chuo-ku, Osaka 541-0046, Japan (hereinafter called "SENJU") and;

AcSentient Inc., a legal entity duly organized and existing under the laws of Delaware, having its principal office of business at 110 Doric Court, Morrisville, North Carolina 27560, U.S.A. (hereinafter called "ACSENTIENT");

**WITNESSETH THAT;**

WHEREAS, SENJU is developing in U.S.A. an ophthalmic product for the treatment of glaucoma containing a chemical compound named "timolol" (hereinafter called "Compound") as the active ingredient and is the owner of the patent covering the technology to make a long active solution of timolol;

WHEREAS, SENJU has provided ACSENTIENT with some technical information in its possession pertaining to Preparation under Secrecy Agreement concluded between two Parties effective as of the 8th day of August, 2001 (hereinafter called "Secrecy Agreement") and Memorandum of Understanding Concerning Bromfenac Ophthalmic Product and Timolol LA Ophthalmic Product of 7th day of January, 2002 (hereinafter called "MOU") for ACSENTIENT's evaluation of the feasibility to commercialize the Preparation in the Territory;

WHEREAS, ACSENTIENT is willing to commercialize the Preparation in the Territory subject to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the foregoing, the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, SENJU and ACSENTIENT thereby agree as follows:

(SENJU and ACSENTIENT collectively called "Parties" and/or individually called "Party")

**Article 1 - Definitions**

The following terms used in this Agreement shall have the meanings set forth in this Article unless the context clearly requires otherwise, and the singular shall include the plural and vice versa.

1.01 "Patent Rights" shall mean U.S. Patent No. 6,335,335, all divisions, continuations, continuations-in-part as well as other patents including any reissues, renewals, extensions or patents of addition thereto.

1.02 "Territory" shall mean United States of America as well as Puerto Rico, Guam and the U.S. Virgin Islands.

1.03 "Preparation" shall mean any ophthalmic product containing the Compound as an active ingredient, which is formulated and manufactured under the Patent Rights.

1.04 "Technical Information & Know-How" shall mean technical information and know-how which is available at the Effective Date or becomes available to Senju during the term of this Agreement relating to the Preparation, which is necessary or useful for the practice of the Patent Rights, including without limitation, manufacture of the Preparation in the Territory in possession of or under the control of Senju. Technical Information & Know-How shall include any and all technical information and know-how disclosed by SENJU to ACSENTIENT under MOU.

1.05 "Net Sales" shall mean the gross invoiced amount charged by ACSENTIENT or ACSENTIENT Agent to sell the Preparation to Third Parties in the Territory less (a) ordinary and reasonable trade discounts earned or granted for quantity purchases, prompt payment discounts and reasonable cash discounts actually allowed; (b) credits, and allowances actually granted on account of rejections, returns, rejections, destructions or billing errors; (c) custom duties, reasonable prepaid out bound transportation expenses and insurance, taxes and other governmental charges actually paid. Provided, however, that such reductions will be less than 10% of the gross invoiced price.

1.06 "First Commercialization" shall mean date of the first commercial sale by ACSENTIENT or ACSENTIENT Agent of the Preparation in commercial quantities to a Third Party under this Agreement.

1.07 "Governmental Approval" shall mean any kind of approvals by USFDA (U.S. Food and Drug Administration) or equivalent future governmental authority, necessary to commercialize the Preparation in the Territory, including, without limitation, any approvals necessary to conduct pre-clinical or clinical studies on the Compound or the Preparation, or necessary for the manufacture, distribution, and sale of the Preparation.

1.08 "ACSENTIENT Agent" shall mean any agent who sells, markets, distributes, promotes and offers to sell the Preparation in the Territory on behalf of ACSENTIENT.

1.09 "Manufacturers" shall mean a manufacturer who manufactures the Preparation on behalf of ACSENTIENT for commercialization of the Preparation in the Territory.

1.10 "Effective Date" shall mean the date first above written on which this Agreement shall become effective.

1.11 "Third Party" shall mean any party other than SENJU and ACSENTIENT and Manufacturer and ACSENTIENT Agent.

1.12 "Development Activity" shall mean, SENJU's activities to perform all tests, studies and other activities necessary to develop the Preparation and obtain Governmental Approval of the Preparation in the Territory.

1.13 "Transfer" shall mean transfer or assignment from SENJU to ACSENTIENT of all of the title and interest in Governmental Approval.

1.14 "Trademark" shall mean any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol to be used in connection with the marketing of the Preparation in the Territory.

## Article 2 - Undertaking and Scope of this Agreement

2.01 Subject to terms and conditions of this Agreement, SENJU shall, at its own expense;

- (i) conduct Development Activities;
- (ii) obtain Governmental Approval and transfer or assign said Governmental Approval to ACSENTIENT; and
- (iii) execute manufacturing agreement of the commercial Preparation with Manufacturer and transfer or assign any and all title and interest in said manufacturing agreement to ACSENTIENT.

2.02 Subject to terms and conditions of this Agreement, ACSENTIENT shall, at its own expense, commercialize the Preparation manufactured by Manufacturer in the Territory after Transfer of the Governmental Approval and transfer and assignment of all title and interest in manufacturing agreement of the Preparation from SENJU;

## Article 3 - Grant

3.01 Upon the obtaining of Governmental Approval, SENJU shall transfer and assign any and all title and interest in the Governmental Approval to ACSENTIENT and shall grant ACSENTIENT an exclusive license to manufacture, import, market, promote, sell and distribute the Preparation under the Governmental Approval. Such license shall include exclusive right to use the Patent Right and Technical Information & Know-How to the extent that it is necessary for the sole purpose of manufacturing, importing, marketing, promoting, selling and distributing the ophthalmic product containing the Compound in the Territory. Provided, however, that the license granted to ACSENTIENT by SENJU herein shall not include the right to grant sub-license in the Territory. SENJU hereby represents that it has full right and authority to enter into this Agreement, to grant rights provided herein and to perform its obligations hereunder.

3.02 The license granted to ACSENTIENT by SENJU herein shall include the right to permit Manufacturer to practice or use the Patent Right and the Technical Information & Know-How to manufacture the Preparation on behalf of ACSENTIENT and ACSENTIENT Agent to sell, market, distribute, promote and offer to sell the Preparation on behalf of ACSENTIENT in the Territory. Provided, however, that ACSENTIENT shall acknowledge and confirm that by permitting Manufacturer and ACSENTIENT Agent to manufacture, market, sell and offer to sell the Preparation hereunder it shall not be released from any of its contractual obligations under this Agreement and that it shall remain fully responsible for the complete performance of such obligations under this Agreement.

3.03 SENJU agrees that during the term of this Agreement, SENJU nor its Subsidiaries shall not (a) market or otherwise sell or distribute the Preparation in the Territory or (b) grant any license to the Patent Rights in the Territory that would entitle any other party to market or otherwise sell or distribute during the term of this Agreement, any product containing the Compound for use in the Territory. The term of Subsidiary provided in this paragraph 3.03 shall mean any legal entity fully or substantially fully owned or controlled by SENJU.

3.04 After Transfer, SENJU agrees to provide ACSENTIENT with reasonable access to all Technical Information & Know-How, and with copies of any and all patents and patent applications owned or controlled by SENJU covering the Patent Rights or Technical Information & Know-How, including all patent office actions received and amendments filed, if any, relative thereto.

#### Article 4 - Compensation

4.01 In consideration of SENJU's grant in accordance with the Article 3 hereof including Transfer of the Governmental Approval, ACSENTIENT shall, during the term of this Agreement, pay SENJU the following milestone payments:

Milestone:	Amount of Payment due:
(i) Within 60 days from the Effective Date	non refundable license fee of US\$500,000.00-
(ii) Within 60 days from the obtaining of Governmental Approval	non refundable license fee of US\$500,000.00-
(iii) Within 90 days from the First Commercialization	non refundable license fee of US\$1,000,000.00-

4.02 Unless otherwise provided herein, no payments to Senju under this Agreement shall be refundable in whole or in part.

#### Article 5 - Royalties

5.01 In consideration of the rights granted under this Agreement, ACSENTIENT shall pay SENJU as running royalties a sum corresponding to twenty percent (20%) of the Net Sales of the Preparation sold in the Territory during the period following the First Commercialization in the Territory until cumulative Net Sales reaches US\$10,000,000- from the First Commercialization. Thereafter, ACSENTIENT shall pay SENJU as running royalties a sum corresponding to twenty-five percent (25%) of the Net Sales of the Preparation until the expiration of the Patent Right.

5.02 Notwithstanding above paragraph 5.01, ACSENTIENT shall pay SENJU minimum annual royalty during the first three (3) years from the First Commercialization. The amount of minimum annual royalty shall be fifty percent (50%) of the annual sales forecast calculated by independent market research, which is acceptable to both Parties. Such independent market research shall be conducted within six (6) months following the First Commercialization.

5.03 No multiple running royalty will be payable even if the Preparation, its manufacture, use or sale, are or will be covered by more than one claim or patent.

5.04 All of the running royalties including minimum royalties in paragraph 5.01 and 5.02 shall be paid within ninety (90) days following the end of ACSENTIENT's fiscal year which commences following the First Commercialization. ACSENTIENT's fiscal year commences January 1st of a year and ends December 31 in the same year.

5.05 Unless otherwise expressly provided herein, no running royalty payment to Senju under this Agreement shall be refundable in whole or in part.

#### Article 6 - Payments and Records

6.01 Within **thirty (30) days** after the end of each fiscal year during the term of this Agreement, ACSENTIENT shall furnish SENJU with an accurate report stating the total quantity of the Preparation in units sold by ACSENTIENT and ACSENTIENT Agent during the preceding fiscal year, the grossed invoiced sales price and the Net Sales thereof and amount of the royalties accrued, together with written reports regarding marketing activities stipulated in paragraph 8.02 and 8.03 herein.

6.02 ACSENTIENT shall pay SENJU milestone payments under paragraph 4.01 and royalties under 5.01 and 5.02 pursuant to the applicable U.S. laws and to the regulation of the Convention for Avoiding Double Taxation between Japan and U.S.A. The official certificates issued by the U.S. taxation authority, which shall be acceptable to Japanese Taxation Authority, shall evidence taxes paid in U.S.A. SENJU shall be responsible for any withholding tax imposed on payments made by ACSENTIENT to SENJU.

6.03 ACSENTIENT shall make and keep true and accurate records of the production and sales of the Preparation by ACSENTEINT and ACSENTIENT Agent.

6.04 SENJU shall have the right to inspect, at its own expense, the records prepared and kept in accordance with paragraph 6.03 above. This inspection shall be carried out by a certified public accountant reasonably acceptable to ACSENTIENT for the sole purpose of verifying the accuracy of ACSENTIENT running royalty payments. This inspection shall be carried out during usual business hours at ACSENTIENT's appropriate facility.

6.05 ACSENTIENT shall not have any obligation to keep the records kept pursuant to paragraph 6.03 for more than **seven (7) years** from the date of a given running royalty payment.

6.06 Any payment from ACSENTIENT to SENJU under this Agreement shall be remitted to the bank account designated by SENJU.

#### Article 7 - Development Activities

7.01 SENJU shall continue to conduct its Development Activities currently on going in the Territory and shall obtain Governmental Approval no later than **October 31, 2005**, at its own risks and expense.

7.02 SENJU shall provide ACSENTIENT at least semi-annually with its written report in English language concerning the status and progress of its Development Activities in the Territory.

7.03 Upon the completion of its Development Activities and obtaining Governmental Approval, SENJU shall immediately notify ACSENTIENT of such effect and transfer any and all title and interest in Governmental Approval to ACSENTIENT.

7.04 SENJU shall have a right, without any compensation to ACSENTIENT, to use or make Third Parties outside the Territory use, the report generated from the Development Activities conducted by SENJU and a copy of certificate of Governmental Approval of the Preparation for the purpose of development, obtaining governmental approval, manufacture and the commercialization of the Preparation solely outside the Territory.

7.05 SENJU shall refund ACSENTIENT the milestone payment received from ACSENTIENT under paragraph 4.01 (i) (US\$500,000.00-) within sixty (60) days from SENJU's notice to ACSENTIENT in the event of the termination of this Agreement due to the following events;

(i) SENJU decides, in its bona fide business judgement, to discontinue Development Activities or to give up its efforts to obtain Governmental Approval in the Territory due to the circumstance beyond the SENJU's control and notify ACSENTIENT of such effect in writing, or

(ii) In spite of SENJU's diligence performance of Development Activity, SENJU fails to obtain Governmental Approval until October 31, 2005 and notifies ACSENTIENT of such effect in writing.

#### Article 8 - Marketing Activities and Promotional Materials

8.01 After Transfer of the Governmental Approval from SENJU according to paragraph 7.03, ACSENTIENT shall use reasonable effort to commercialize the Preparation within six (6) months after Transfer. Provided, however that if ACSENTIENT fails to commercialize said six (6) month period of term, this period of term shall be extended for reasonable period of term through the negotiation of SENJU and ACSENTIENT.

8.02 ACSENTIENT shall and shall cause ACSENTIENT Agent to, use their reasonable best efforts to make a minimum of thirty thousand (30,000) physician presentations to ophthalmologists and high prescribing optometrists during each of the first three (3) years following the First Commercialization.

8.03 ACSENTIENT shall spend a cumulative minimum of US\$3,000,000.00 (in addition to sales force costs) for marketing during the first three (3) years following the First Commercialization.

8.04 ACSENTIENT shall conduct, at its own risks and expenses, all sales, marketing and distribution of the Preparation in the Territory. ACSENTIENT shall prepare, at its own expense, appropriate marketing, advertising and promotional material for the Preparation in the Territory. ACSENTIENT shall furnish SENJU with those materials for SENJU's review.

8.05 ACSENTIENT shall not, nor shall it permit ACSENTIENT Agent and Manufacturers to submit for written or oral publication any manuscript, abstract or the like which includes data or other information relating to the Preparation, without first obtaining the prior written consent of SENJU, which shall not be unreasonably withheld.



## Article 9 - Exchange of Information/ Reports

9.01 From time to time during the term of this Agreement, SENJU shall provide ACSENTIENT with Technical Information & Know-How in English writing. Such Technical Information & Know-How is in possession of or under the control of Senju, has not been provided to ACSENTIENT under the Secrecy Agreement and MOU, will become available to SENJU thereafter and is useful for planning a marketing strategy of ACSENTIENT.

9.02 SENJU shall prepare level and package inserts of the Preparation taking ACSENTIENT opinion into consideration.

9.03 From time to time during the term of this Agreement, the Parties shall exchange information concerning any new finding relevant to the safety, efficacy, dosage formulation and new indications of the Preparation (including any process improvements which related solely to the Preparation) (hereinafter called "Improvements") when they become available to either Party.

9.04 SENJU may freely use or make any Third Party use, **without compensation**, Improvements made by ACSENTIENT under paragraph 9.03 in any countries outside the Territory. ACSENTIENT may freely use, **without compensation**, all Improvements made or otherwise obtained by SENJU under paragraph 9.03.

9.05 From time to time during the term of this Agreement, Parties shall exchange clinical and commercial information concerning the Preparation which is deemed useful for the sale and marketing of the Preparation. Furthermore, Party shall notify the other of any important regulatory advises or instructions which come to either Party's attention during the term of this Agreement concerning quality, safety, efficacy of Compound and/or Preparation.

## Article 10 - Availability of the Preparation

10.01 Upon the execution of this Agreement, SENJU shall enter into a negotiation with Third Party to conclude a manufacturing agreement for commercial Preparation under which said Third Party manufactures and supplies the Preparation to ACSENTIENT.

10.02 Upon obtaining of Governmental Approval, SENJU shall transfer and assign any and all title and interest in the manufacturing agreement of the Preparation to ACSENTIENT. Financial obligation under the manufacturing agreement after the transfer and assignment of the manufacturing agreement from SENJU to ACSENTIENT shall be sole responsibility of ACSENTIENT under terms of the manufacturing agreement.

## Article 11 - Adverse Event

11.01 As used in this Article the term of "Regulatory Information" shall mean any information regarding threatened or pending action by any regulatory authorities of the country where each party markets the Preparation, including, but not limited to, cancellation of the approval or order to terminate sales of its Preparation, to recall and destroy the Preparation on the market or to revise the approved indication, dosage and administration or important caution for use of the Preparation, or the government issue of Dear Doctor Letter regarding the Preparation which may give serious impact to the sales of Preparation. As used in this Article, the term of "Adverse Event" (as described in the most current U.S. Code of Federal Regulations) shall mean any noxious, pathological or unintended

change in anatomical, physiological or metabolic function as indicated by physical signs, symptoms occurring in clinical trials, post-marketing surveillance, or clinical practice during the use of Preparation, or published in the medical literature, whether or not considered casually related to Preparation. This includes an exacerbation of a pre-existing condition, inter-current illness, drug interaction, significant failure of expected pharmacological or biological action. With respect to Adverse Event, the following shall apply:

(a) As long as each Party maintains governmental approval of the Preparation in any country of the world, ACSENTIENT and SENJU shall report any Adverse Event known to it in respect of the Preparation or Compound to the appropriate regulatory authorities in the countries in which it is developing or commercializing the Preparation or Compound, in accordance with the laws and regulations of the relevant countries and authorities, provided that in the Territory, ACSENTIENT shall control all communications by the Parties to the FDA (including any its successor agency);

(b) ACSENTIENT will submit safety data on the Preparation in the Territory to FDA in accordance with the regulations of FDA;

(c) Promptly after the Effective Date, each Party shall appraise the other Party of the standard operating procedures for the investigation and reporting of Adverse Event and Regulatory Information regarding its products. The Parties shall then promptly develop and agree upon procedures to exchange information concerning Adverse Event and Regulatory Information of Preparation. The Parties shall immediately implement such agreed procedures and shall provide each other on a regular basis with any appropriate information which enables the other Party to meet its regulatory obligations including but not limited to submission of periodic safety update report (PSUR) in countries in which it is developing or commercializing and/or distributing the Preparation or which is relevant to the safe use of the Preparation. The agreed procedures will be reviewed jointly on a regular basis or when there is a change in regulations governing Adverse Event and Regulatory Information reporting;

(d) All Adverse Event reports and queries for SENJU should be addressed to Director, Post Marketing Surveillance Department, SENJU Pharmaceutical Co., Ltd., 4-9, Hiranomachi 2-chome, Chuo-ku, Osaka 541-0046, Japan (facsimile number: 81-6-6229-3293, telephone number: 81-6-6201-9621) and for ACSENTIENT should be addressed to Manager of Drug Safety, ACSENTIENT Inc., 110 Doric Court, Morrisville, North Carolina 27560, U.S.A. (facsimile number: 919-460-8729, telephone number: 813-631-9551) or such other safety representative as may be designated by SENJU for SENJU or by ACSENTIENT for ACSENTIENT.

11.02 Each Party shall immediately notify the other of any information received regarding any threatened or pending action by any regulatory authority, which may affect the Compound or the Preparation or the continued manufacture, marketing and/or distribution of the Preparation. Upon receipt of any such information, the Parties shall consult in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing set forth in this Paragraph 11.02 shall be construed as restricting the right of either Party to make a timely report of such matter to any governmental agency or take other action that it deems appropriate or required by applicable law or regulation.

## Article 12 - Confidentiality

12.01 Parties hereto undertake to keep confidential all of the information and reports, materials, data and results of the investigation and so on regarding the Compound and/or the Preparation which is/are received from or provided by the other Party under this Agreement, Secrecy Agreement and/or MOU, and is/are marked or otherwise indicated that the same is/are confidential nature (hereinafter collectively called "Information" in this Article 12), provided, however, that such Information as itemized below shall be excluded from this confidentiality obligation;

- (i) Information which was at the time of disclosure in the public domain,
- (ii) Information which after the time of disclosure became a part of the public domain, through no fault or act of omission by the recipient Party,
- (iii) Information which was at the time of disclosure lawfully in the recipient's possession on a non-disclosure basis,
- (iv) Information received from any Third Party who has no obligation to keep the Information confidential against any of Parties hereto,
- (v) Information which both Parties hereto agree in writing to disclose to a Third Party or to make the same public, or
- (vi) Information which is independently developed by recipient Party without actual knowledge of the Information:

provided, further, that the recipient Party shall have competent proof for proving the fact that the Information in question falls into the category of either one of the items herein above.

12.02 Notwithstanding the provision of Paragraph 12.01, ACSENTIENT may disclose the Information disclosed by SENJU to its officers, employees, consultants or contract workers engaging in any activity for the commercialization of the Preparation, so far as the disclosure is necessary for their performance of such activity, provided, however, that ACSENTIENT shall take any adequate measure to cause them to keep the Information disclosed confidential under the same conditions provided in any provision of this Agreement.

12.03 Notwithstanding the provision of Paragraph 12.01, SENJU may, in addition to the stipulations of paragraph 7.04 and paragraph 9.04, disclose the Information disclosed by ACSENTIENT, to its licensees, officers, employees, consultants or contract workers engaging in any activity for the commercialization of the Preparation including clinical studies and other activities for obtaining the governmental approval outside the Territory or for obtaining patent right including any patent application and prosecution of the patent application, so far as the disclosure is necessary for their performance of such activity, provided, however, that SENJU shall take any adequate measure to cause them to keep the Information disclosed confidential under the same conditions provided in any provision of this Agreement.

12.04 The stipulations in Article 12 will survive for **five (5) years** after expiration or termination of this Agreement.

12.05 Notwithstanding the provision of Paragraph 12.01 and 12.02, it is understood that Manufacturer and ACSENTIENT Agent shall be included in the definition of ACSENTIENT in ACSENTIENT's performing the obligations stipulated in this Article 12. ACSENTIENT undertakes to cause Manufacturer and ACSENTIENT Agent same confidentiality obligations as ACSENTIENT undertakes under this Agreement.

#### Article 13 - New Invention or Discovery

13.01 In the event that ACSENTIENT, Manufacturer, ACSENTIENT Agent, its employees or consultant will solely make, conceive, reduce into practice or generate any invention, discovery or know-how in the course or as a result of their activities undertaken pursuant to this Agreement, ACSENTIENT shall notify SENJU of the invention, discovery or know-how immediately. In the event that SENJU including its employees, consultants or agents and ACSENTIENT, Manufacturer, ACSENTIENT Agent including its employees or consultant will jointly make, conceive, reduce into practice or generate any invention, discovery or know-how in the course or as a result of their activities undertaken pursuant to this Agreement, each Party shall notify the other Party of the invention, discovery or know-how immediately.

13.02 Upon being notified of the invention, discovery or know-how under paragraph 13.01, each Party shall initiate a negotiation with the other Party as to;

(i) whether or not the application for patent regarding the invention, discovery or know-how shall be filed (if the Parties fail to agree, the Party who made, conceived, reduced into practice or generated any invention, discovery or know-how shall have the right to file a patent application),

(ii) which party shall be responsible to prepare, file and prosecute the patent application; and,

(iii) in which country such patent application shall be filed, provided, however, that such patent application claiming the invention, discovery or know-how recited in paragraph 13.01 shall be filed under the joint names of SENJU and ACSENTIENT in any country or area in the world unless otherwise agreed upon between the Parties;

13.03 Any external expense for the preparation, filing and prosecution of the patent application to be filed under the joint names of the Parties under paragraph 13.02 (iii) and for the maintenance of the patent rights incurred therefrom shall equally be shared between the Parties unless otherwise agreed upon between the Parties.

13.04 The ownership of such patent right covering the invention, discovery or know-how recited in paragraph 13.02 (iii) shall be equally shared between the Parties and SENJU shall have the right to use or make Third Party use freely such invention, discovery or know-how recited in paragraph 13.01 for any purpose outside the Territory and ACSENTIENT shall have the right to use or make Third Party use freely such invention, discovery or know-how recited in paragraph 13.01 for any purpose. However, each Party shall not transfer, assign, license, dispose or withdraw its share of the patent application under paragraph 13.02 (iii) and the patent rights generated therefrom without prior written consent of the other Party, and SENJU agrees not to use such invention, discovery or know-how in the Territory during the term of this Agreement.

13.05 In the event that SENJU including its employees, consultants or agents will make, conceive, reduce into practice or generate solely any invention, discovery or know-how regarding the Compound, such invention, discovery or know-how shall be sole property of SENJU. And, SENJU shall have a right to file a patent application in relation to the invention, discovery or know-how throughout the world under SENJU's sole name. The costs and expenses for the preparation, filing, prosecution and maintenance of such patent application (including the patent) shall be burdened by SENJU. Provided, however that ACSENTIENT shall have the right to use, during the term of this Agreement, the invention, discovery or know-how as long as ACSENTIENT manufactures and commercializes the Preparation. SENJU shall be compensated for ACSENTIENT' use of the invention, discovery or know-how under Article 4 and 5.

#### Article 14 - Representations and Warranties

14.01 SENJU represents and warrants the following with respect to the Patent Right and Technical Information & Know-How;

(i) SENJU solely owns the entire right, title and interest or right to license in and to the Patent Right and Technical Information & Know-How;

(ii) SENJU has not granted, at the Effective Date, any license or sublicense or entered into any contract with any Third Party concerning the Patent Right and Technical Information & Know-How within the Territory;

(iii) SENJU has not taken or failed to take any action that might result in the invalidity or enforceability of the Patent Right against any Third Party;

(iv) SENJU has no information, at the Effective Date after its investigation using reasonable due diligence that the Patent Right and Technical Information & Know-How may be subject to challenge or interference or be invalid or unenforceable; and

(v) SENJU has the full legal power, authority and right to enter into this Agreement and grant the exclusive license under the Patent Right to the extent that it is necessary for the sole purpose of manufacturing, importing, marketing, promoting, selling and distributing the ophthalmic product containing the Compound in the Territory and to perform its obligations under this Agreement. Upon execution and delivery by SENJU, this Agreement will constitute a valid and binding agreement of SENJU enforceable in accordance with its terms. The execution, delivery and consummation of this Agreement will not result in the breach of or give rise to cause for termination of any agreement to which SENJU may be a party which relates to the Patent Rights and Technical Information & Know-How.

14.02 Nothing in this Agreement or any license pursuant to it shall be construed or implied as a representation or warranty by SENJU that the Patent Right and Technical Information & Know-How are valid or that the commercialization of the Preparation or any other activities of ACSENTIENT under this Agreement shall not be an infringement of the rights of Third Party including, but not limited to, patent, know-how, trade-secret, trademark or other intellectual property right of Third party.

14.03 SENJU SHALL MAKE NO WARRANTIES WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO THE PREPARATION MANUFACTURED AND/OR SOLD HEREUNDER INCLUDING WITHOUT LIMITATION ANY WARRANTY OF THE MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE OF THE PREPARATION SOLD BY ACSENTIENT.

#### Article 15 - Patent Litigation

15.01 In the event that SENJU or ACSENTIENT become aware of any actual or threatened infringement by any Third Party upon SENJU' proprietary right relating to the Preparation, such Party shall immediately notify the other Party in writing. SENJU shall have the right to take whatever steps are necessary to stop the infringement and recover the damages. Nothing herein obligates SENJU to enter into litigation against such Third Party.

15.02 Notwithstanding paragraph 14.02, in the event of a claim or suit made by Third Party against SENJU and/or ACSENTIENT for patent infringement involving the manufacture, use, sale, importation, distribution or marketing of the Preparation in the Territory using the formulation which SENJU develops under its Development Activities and obtains Governmental Approval, the Party sued shall promptly notify the other Party in writing thereof. In this case following shall apply;

(i) SENJU and ACSENTIENT shall discuss how to cope with the situation under mutual cooperation;

(ii) If either Party wishes to settle the claim or suit or to negotiate for a patent license with Third Party, the other party may defend such claim or suit under its sole legal responsibility including the awards and sole responsibility of litigation cost including attorney fees. In this case, the Party who wishes to settle the claim or suit or to negotiate for a patent license with Third Party shall not be liable for legal responsibility including the awards and for litigation cost and attorney fees;

(iii) Except for the litigation cost and attorney fees under paragraph 15.02 (ii), SENJU and ACSENTIENT shall share equally the damages awarded to, all litigation cost and attorney fees as result of the suit or settlement. However, SENJU's total liability shall not exceed the milestone payments received from ACSENTIENT pursuant to paragraph 4.01 until such claim or suits made;

(iv) If Parties is obliged to pay the running royalty to the Third Party as a result of such claim or suit made by said Third Party, SENJU and ACSENTIENT shall equally burden such running royalty. However, the running royalty to be paid by SENJU to said Third Party shall not exceed 10% of the Net Sales:

15.03 In the event of a claim or suit made by Third Party against SENJU and/or ACSENTIENT for patent infringement involving the manufacture, use, sale, importation, distribution or marketing of the Preparation using the formulation which ACSENTIENT develops by itself, the Party sued shall promptly notify the other Party in writing thereof. In this case, ACSENTIENT shall settle or defend the claim or suit under the sole responsibility of ACSENTIENT with its total monetary obligation, and shall indemnify and hold harmless SENJU from said claim or suit.

## Article 16 - Indemnification

16.01 Except for SENJU's obligations to be imposed under paragraph 15.02 herein, ACSENTIENT shall defend, indemnify and hold SENJU, its directors, officers, shareholders, employees, consultants, contract workers and assigns harmless from and against any lawsuit, claims, loss, damages or expenses (including attorney's fees) arising from the the manufacture, use or sale of the Preparation by ACSENTIENT, Manufacturer or ACSENTIENT Agent.

16.02 Prior to First Commercialization and for a period of **ten (10) years** after the expiration of this Agreement or earlier termination, ACSENTIENT shall obtain and/or maintain, at its sole cost and expense, product liability insurance in an amount which is reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size. Such product liability insurance shall insure against all liability, including liability for personnel injury, physical injury and property damage.

16.03 SENJU shall defend, indemnify and hold ACSENTIENT, its directors, officers, shareholders, employees, consultants, contract workers and assigns harmless from and against any lawsuit, claims, loss, damages or expenses (including attorney's fees) arising from the Development Activity.

## Article 17 - Trademark/Indication

17.01 Trademark shall be selected and filed by ACSENTIENT in the name of ACSENTIENT and at ACSENTIENT's expense. Upon the registration of Trademark by USPTO (United States Patent and Trademark Office) and at the request of SENJU, ACSENTIENT shall promptly assign ownership of the Trademark to SENJU who will thereafter be obliged to maintain the Trademark during the term of this Agreement, provided that SENJU shall reimburse to ACSENTIENT the external actual cost and fees incurred by ACSENTIENT.

17.02 If following the expiration or earlier termination of this Agreement, neither SENJU nor Third Party on behalf of SENJU desires to market, sell and distribute the Preparation in the Territory, SENJU will, upon the request of ACSENTIENT and in consideration of reimbursement to SENJU of all fees and cost incurred by SENJU to obtain the right to the Trademark under paragraph 17.01 above, assign and transfer said Trademark to ACSENTIENT for use by ACSENTIENT in marketing, selling and distributing of the Preparation in the Territory.

17.03 If SENJU wishes so, ACSENTIENT shall indicate "developed by SENJU PHARMACEUTICAL CO., LTD., Japan" or its synonym on each package including eye drop bottle, outer packages, brochure, insert leaflet, advertising and/or promotion materials of the Preparation. Provided, however, that in the case where the space on the surface of the eye drop bottle does not technically permit such indication, this paragraph shall not be applicable so far as such eye drop bottle is concerned.

## Article 18 - Term and Termination

18.01 This Agreement shall become effective as of the Effective Date and shall terminate upon the expiration of the Patent Right.

18.02 Notwithstanding the stipulation of paragraph 18.01 above, either Party may terminate this Agreement at any time by giving notice to the other party in the event;

(i) that either Party materially defaults or is in breach of the performance of any material obligation imposed on it in this Agreement and such default is not remedied in all material aspects within **thirty (30) days** of receipt of written demand from the notifying Party to cure the default,

(ii) that either Party assigns or makes any composition or sequestration of its assets for the benefit of its creditors, or assigns its rights hereunder partially or in their entirety to any Third Party without express written consent of the other Party in breach of the stipulation in paragraph 22.01 herein; and

(iii) that either Party becomes insolvent, goes into liquidation, files a petition in bankruptcy, is adjudicated a bankrupt, is placed in judicial receivership or provisional administration, or dissolves, or its financial condition is such that it is unable to pay bills and obligations as and when due and payable to its creditors.

18.03 If and when SENJU notifies ACSENTIENT of discontinuance of the Development Activities according to paragraph 7.05, this Agreement shall be terminated upon receipt by ACSENTIENT of milestone payment returned from SENJU.

18.04 If and when ACSENTIENT decides in its bona fide business judgement, to discontinue the commercialization of the Preparation in the Territory, this Agreement shall be terminated, without any monetary obligations to either party, upon receipt by SENJU of ACSENTIENT's notification thereof in writing.

18.05 If this Agreement is terminated by ACSENTIENT in accordance with paragraph 18.04, ACSENTIENT shall promptly cease its commercial activities, as the case may be, concerning the Preparation, and, at its option, destroy the Preparation then stocked by ACSENTIENT including the cost of the inventory, or sell the remaining inventory of the Preparation and settle its obligation, if any, to pay any royalties or other payment due under this Agreement within **one hundred and twenty (120) days** after the termination thereof. Upon SENJU's request, ACSENTIENT shall return to SENJU all the Technical Information & Know-How provided by SENJU under this Agreement and shall assign to SENJU, without any compensation all of the rights, titles and interests pertaining to the Preparation including without limitation, all rights to Governmental Approval in the Territory.

18.06 If this Agreement is terminated by SENJU in accordance with paragraph 18.02 (i), (ii) and/or (iii), ACSENTIENT shall promptly cease its commercial activities of the Preparation, as the case may be, and, if requested by SENJU, destroy the Preparation then stocked by ACSENTIENT including the cost of the inventory, or, if requested by SENJU sell the remaining inventory of the Preparation and settle its obligation, if any, to pay any royalties or other payment due under this Agreement within **one hundred and twenty (120) days** of ACSENTIENT's receipt of SENJU's notice of the termination. Upon SENJU's request, ACSENTIENT shall return to SENJU all the Technical Information & Know-How provided by SENJU under this Agreement and shall assign to SENJU, without any compensation, all of the rights, titles and interests pertaining to the Preparation including without limitation, all rights to Governmental Approval in the Territory.

18.07 Notwithstanding anything to the contrary contained herein, in the event of the execution by ACSENTIENT of any kind of agreement pursuant to which ACSENTIENT would be controlled by, or be under common control with, or merge into or consolidate with, any Third Party after Transfer of Governmental Approval, and ACSENTIENT loses controlling interest in said Third Party (hereinafter called "Change of Control"), SENJU shall have following options;



(i) to continue this Agreement; or

(ii) to terminate this Agreement at the end of the one (1) year period following the Change of Control. In this case, all of the rights granted by SENJU to ACSENTIENT under this Agreement as well as Governmental Approval, data and other information regarding the Preparation provided by SENJU shall be returned to SENJU subject to SENJU's payment of the fair and reasonable market value of such assets of the Preparation as negotiated and agreed by the Parties. Upon such termination of this Agreement, ACSENTIENT will have no further obligation to make any running royalty payment pursuant to this Agreement.

#### Article 19 - Governing Laws and Arbitration

19.01 This Agreement shall be governed by and interpreted in accordance with the Laws of Japan.

19.02 All disputes, controversies or differences which may arise between the Parties hereto or for the breach thereof shall be referred to and settled by arbitration in accordance with the Arbitration Rules of the International Chambers of Commerce as currently in force by one or more arbitrators appointed under the Rules. Such arbitration hereunder shall be proceeded in English language and shall be held in Japan. The determination of the arbitration shall be final, binding and conclusive upon the Parties hereto.

#### Article 20 - Notice

Any notice to be given to a Party under or in connection with this Agreement shall be in writing and shall be (i) personally delivered, (ii) delivered by a nationally recognized overnight courier or (iii) delivered by certified mail, postage prepaid, return receipt requested to the Party at the address set forth below for such Party:

to SENJU:  
Executive Vice President  
SENJU Pharmaceutical Co., Ltd.  
5-8, Hiranomachi 2-chome  
Chuo-ku, Osaka, 541-0046  
Japan

to ACSENTIENT:  
Chief Business Officer  
AcSentient, Inc.  
110 Doric Court,  
Morrisville, NC 27560  
U.S.A.

or to such other address as to which the Party has given notice thereof.

#### Article 21 - Force Majeure

21.01 Neither Party hereto shall be liable for any failure to perform as required through this Agreement by reason of *Force Majeure*, to the extent such failure to perform is due to circumstances reasonably beyond the control of such Party, such as requisition or interference by any government, state or local authorities, war, strikes, lockout or other labor disputes, accidents, failure to secure required Governmental Approval, civil disorders or commotions, act of aggression, acts of God, energy or other conservation shortages, disease, or occurrences of a similar nature.

21.02 If and when any Party is hindered in its performance of its obligations under this Agreement by reason of Force Majeure, the performance of those obligations shall be suspended for the duration of, but not longer than, the continuance of such circumstances.

21.03 Either Party hereto whose performance of obligation has been hindered by reason of *Force Majeure* shall inform the other Party immediately, and shall use its reasonable best effort to overcome the effect of the *Force Majeure*.

#### Article 22 - Non-Assignability

22.01 This Agreement is personal to the Parties hereto and shall not be assignable to any Third Party by either Party without the prior express written consent of the other Party, such consent not to be unreasonably withheld; provided, however, subject to paragraph 18.07, that no such approval shall be required from SENJU if this Agreement is assigned in connection with the sale of all or substantially all of the assets or stock of ACSENTIENT, whether by merger, acquisition or otherwise.

22.02 In the event of the execution by ACSENTIENT of any kind of agreement pursuant to which ACSENTIENT would be controlled by, or be under common control with, or merge into or consolidate with, any Third Party before Transfer of Governmental Approval, ACSENTIENT shall immediately notice SENJU of such effect together with intention whether or not ACSENTIENT (including continued company) commercializes the Preparation. If ACSENTIENT (including continued company) intends not to commercialize the Preparation, this Agreement shall terminate, without any monetary obligation to either party, upon SENJU's receipt of such ACSENTIENT's intention.

#### Article 23 - Authentic Text

This Text of this Agreement in English language shall be the authentic text, and any text in another language, even if such text is made by translation of this Text of this Agreement or prepared by any of the Parties hereto for any purpose, shall have no meaning for any purpose between the Parties hereto.

#### Article 24 - Entire Agreement

24.01 Secrecy Agreement and Article 10 through Article 18 of MOU shall be replaced completely by this Agreement as of the Effective Date so that MOU shall terminate simultaneously.

24.02 This Agreement shall constitute the entire agreement between the Parties hereto concerning the subject matter hereof and shall supersede any other agreements, whether oral or written, express or implied, and may not be changed or modified or revised except as specifically agreed upon by the Parties hereto in a written document bearing the respective signatures of the authorized officers.

#### Article 25 - Separability

25.01 Even in the event that any portion of this Agreement shall be held illegal, void, ineffective or unenforceable, the remaining portion shall remain in full force and effect.

25.02 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, such terms and provisions shall be deemed inoperative to the extent that may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law.

25.03 in the event that the terms and conditions of this Agreement are materially altered as a result of the provision in paragraph 25.02, the Parties will re-negotiate the terms and conditions of this Agreement to resolve any inequities.

**IN WITNESS WHEREOF**, SENJU and ACSENTIENT have caused this Agreement to be executed in duplicate counterparts by their duly authorized officers, each fully executed copy hereof to be deemed as original, as of the date and year first above written.

SENJU:

ACSENTIENT:

Senju Pharmaceutical Co. Ltd.

AcSentient Inc.

signature: /s/ Shoji Yoshida

signature: /s/ John T. Musante

name: Shoji Yoshida

name: John T. Musante

title: President

title: Chief Business Officer