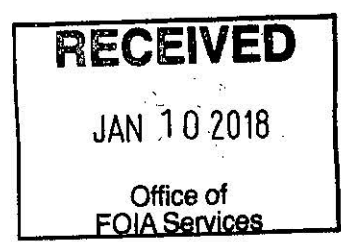


18-01862-E

January 10 2018

US Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE Mail Stop 5100
Washington, DC 20549-5100



Dear FOIA Office:

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

A copy of: Exhibit: 10.38 to the form 10-K filed by ANIKA THERAPEUTICS INC on March 30, 2004

In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to

\$61.00 in processing fees. Thank You,

Paul D'Souza
Editor - Deals

Clarivate Analytics Friars House, 160 Blackfriars Road London, UK SE1 8EZ
Phone: +44-2074334789
paul.dsouza@clarivate.com



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

Office of FOIA Services

January 22, 2018

Mr. Paul D'Souza
Clarivate Analytics
160 Blackfriars Road
London, SE18EZ
United Kingdom

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-01862-E

Dear Mr. D'Souza:

This letter is in response to your request, dated and received in this office on January 10, 2018, for access to Exhibit 10.38 to the Form 10-K filed by Anika Therapeutics Inc. on March 30, 2004.

The search for responsive records has resulted in the retrieval of 84 pages of records that may be responsive to your request. They are being provided to you in their entirety with this letter.

No fees have been assessed in this instance. If you have any questions, please contact Sonja Osborne of my staff at osbornes@sec.gov or (202) 551-8371. You may also contact Ms. Osborne at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from me at McInerneyR@sec.gov or (202) 551-6249 as a FOIA Public Liaison for this office, 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 or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink that reads "Ray J. McInerney".

Ray J. McInerney
FOIA Branch Chief

Enclosure

CONFIDENTIAL

EXHIBIT 10.38
Confidential Treatment¹

LICENSE
AGREEMENT
between
ANIKA THERAPEUTICS, INC.
and
ORTHO BIOTECH PRODUCTS, L.P.

Redacted portions have been marked with brackets containing asterisks(***). The redacted portions are subject to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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This License Agreement (this "Agreement") is made effective as of December 20, 2003 by and between Anika Therapeutics, Inc., a Massachusetts corporation, having a place of business at 160 New Boston Street, Woburn, Massachusetts 01801 ("ANIKA"), and Ortho Biotech Products, L.P., a New Jersey limited partnership, having a place of business at Route 22 East, P.O. Box 6914, Bridgewater, New Jersey, 08807-0914 ("OBI"). ANIKA and OBI are each referred to by name or as a "Party" or, collectively, as the "Parties." References to "ANIKA" and "OBI" shall include their respective Affiliates (hereinafter defined), where appropriate under the terms of *this* Agreement.

RECITALS

1. ANIKA develops, manufactures and commercializes therapeutic products and devices intended to promote the repair, protection and healing of bone, cartilage and soft tissue.
2. On May 30, 2003, ANIKA submitted the third and final module of a PMA to the FDA for HA for the treatment of pain associated with osteoarthritis of the knee by intra-articular injection of such preparation.
3. OBI possesses research, development and commercialization capabilities, as well as proprietary technology in a broad range of therapeutic fields.
4. ANIKA desires to license its hyaluronic acid preparation marketed as Orthovisc® to OBI so that OBI may develop, commercialize, distribute and sell such preparation for indications and applications within the Field and in the Territory as provided herein.
5. ANIKA also desires to supply Orthovisc® to OBI on an exclusive basis for use by OBI in the commercialization of Orthovisc® pursuant to the terms of this Agreement.
6. ANIKA and Pharmaceutical Sourcing Group Americas, an affiliate of OBI, are entering into the Quality Agreement, in the form attached hereto as Exhibit E, as of the date hereof.
7. Unless defined elsewhere in this Agreement, capitalized terms used in this Agreement shall have the meanings set forth in Article I.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE I-DEFINITIONS

When used in this Agreement, each of the following terms, when capitalized in their initials, shall have the meaning set forth below. The term shall have the same meaning whether the singular or plural form is used.

"Active Ingredient" shall have the meaning set forth in Section 6.10(ii) of this Agreement.

"Adverse Knowledge" shall have the meaning set forth in Section 6.10(iv) of this Agreement.

"Affiliate" of a Party means any company or entity which controls, is controlled by or is under common control with such Party, where control, for purposes of this definition, means (i) the possession, directly or indirectly, of the power to direct the management or policies of a Person or to veto any material decision relating to the management or policies of a Person or a majority of the composition of the board of directors (or similar governing body), in each case, whether through the ownership of voting securities, by contract or otherwise, or (ii) the Beneficial Ownership, directly or indirectly, of at least 50% of the voting securities of a Person. "Beneficial Ownership" shall be determined in compliance with Rule 13d-3 of the Securities Exchange Act of 1934.

"Agreement" shall have the meaning set forth in the first paragraph hereto.

"Alternative Supplier" shall have the meaning set forth in Section 6.10(i) of this Agreement.

"Alternative Supplier Agreement" shall have the meaning set forth in Section 6.10(i) of this Agreement.

"ANIK Area" shall have the meaning set forth in Section 3.3 of this Agreement.

"ANIK Disclosure Date" shall have the meaning set forth in Section 14.1(b) of this Agreement.

"ANIK Know-How" means Information in ANIK's Control, which is developed or acquired by ANIK, either as of the Effective Date or at any time during the Term of this Agreement, which relates to the use of a Licensed Product in the Field. Notwithstanding anything herein to the contrary, ANIK Know-How excludes ANIK Patents.

"ANIK Patents" means any patent granted by any governmental authority in any jurisdiction within the Territory relating to a Licensed Product, which Patent is Controlled by ANIK during the term of this Agreement.

"ANIK Potential Product" shall have the meaning set forth in Section 14.1(a) of this Agreement.

"ANS" or "Annual Net Sales" means the Net Sales in a Calendar Year excluding sales between Affiliates, and to distributors outside the United States.

"Audit" has the meaning set forth in Section 5.6(d) of this Agreement.

"Average Sales Price" shall have the meaning set forth in Section 6.2(a)(iii) of this Agreement.

"Bankruptcy Code" has the meaning set forth in Section 18.16 of this Agreement.

"Branding Materials" has the meaning set forth in Section 3.2U) of this Agreement.

"Business Day" means a day on which banking institutions in New York, New York are open for business.

"Calendar Quarter" means a quarter in a Calendar Year and as defined by the J&J Universal Calendar.

"Calendar Year" means those twelve months as defined by the J&J Universal Calendar.

"Claiming Party" shall have the meaning set forth in Section 13.6 of this Agreement.

"CMS" means Center for Medicare Services.

"Competing Product" has the meaning set forth in Article XI (i) of this Agreement.

"Confidential Information" shall have the meaning set forth in Section 7.1 of this Agreement.

"Control" or "Controlling" means owned by or possesses the right to grant a license or sublicense without violating the terms of any agreement with any Third Party.

"Customers" has the meaning set forth in the definition of Net Sales in this Article I.

"Date of First Sale" means the date on which OBI (or an Affiliate or any of their distributors) first sells a Licensed Product to an unaffiliated Third Party in an arms length commercial transaction.

"Develop" or "Development" means all activities relating to obtaining Regulatory Approval of Licensed Products within the Field and Territory, including, but not limited to, preclinical testing, toxicology, formulation, manufacturing process development, quality assurance and quality control, pharmacokinetics, clinical studies, Phase IV, development of kits and/or development of indications, applications and/or formulations to the extent formulation development is limited to optimization of the Licensed Product formulation such as formulation modifications to reduce specific adverse events, to reduce volume of Licensed Product per injection and to reduce the total number of injections by for example increasing the concentration of HA or viscosity of HA solution; provided that "Development" shall also mean any developments, inventions, processes, methods or works of authorship which is created, developed, invented or reduced to practice in connection with performing the foregoing described activities.

"Development Invention" shall have the meaning set forth in Section 8.1 of this Agreement.

"Dispute" shall have the meaning set forth in Section 16.2 of this Agreement.

"Diverted Product" has the meaning set forth in Article X(a)(iii) of this Agreement.

"DOJ" shall have the meaning set forth in Section 17.1 of this Agreement.

"Dollars" or "\$" means lawful money of the United States in immediately available funds.

"Domain Name Marks" shall have the meaning set forth in Section 3.3 of this Agreement.

"Drug Approval Application" means an application for Regulatory Approval required before commercial sale or use of a Licensed Product as a drug in a regulatory jurisdiction.

"Effective Date" means the last date of execution of this Agreement referred to above.

"Failure to Supply" shall have the meaning set forth in Section 6.10(i) of this Agreement.

"FDA" means the United States Food and Drug Administration or any successor agency.

"Field" means the treatment of pain in humans associated with osteoarthritis by intra-articular injection.

"Filing Party" shall have the meaning set forth in Section 8.4(b) of this Agreement.

"FTC" shall have the meaning set forth in Section 17.1 of this Agreement.

"GMP" means Good Manufacturing Practices as such term is generally understood in the medical device industry.

"Governmental Antitrust Authority" shall have the meaning set forth in Section 17.1 of this Agreement.

"Gray Market Product" has the meaning set forth in Article X (a)(ii) in this Agreement.

"HA" means a hyaluronic acid whether as an acid, a pharmaceutically acceptable salt, or a mixture thereof, in any solid or solution phase form thereof, including, but not limited to, a sterile, nonpyrogenic solution of sodium hyaluronate in physiologic saline solution.

"HSR Act" shall have the meaning set forth in Section 17.4(a) of this Agreement.

"HSR Clearance Date" shall have the meaning set forth in Section 17.4(c) of this Agreement.

"HSR Filing" shall have the meaning set forth in Section 17.4(b) of this Agreement.

"Information" means technical information, techniques and data, whether in writing or not, generally not known to the public, relating to the use of Licensed Product in the Field and including techniques and data, including, but not limited to, screens, models, inventions, practices, methods, knowledge, know-how, skill, experience, test data including

pharmacological, toxicological and clinical test data, analytical and quality control data, marketing, pricing, distribution, sales, manufacturing data, and patent and legal data or descriptions.

"Initial Estimated Transfer Price" shall have the meaning set forth in Section 6.2(a)(i) of this Agreement.

"Initial Period" shall have the meaning set forth in Section 6.2(a)(i) of this Agreement.

"Initial Report" shall have the meaning set forth in Section 6.2(a)(i) of this Agreement.

"J Code" means a code issued pursuant to the HCFA Conmland Procedure Coding System (HCPCS) recognized by Medicare carriers and Medicare agencies.

"J&J Universal Calendar means the rumual calendar put forth by Johnson & Johnson describing scheduled monthly, quarterly and yearly accounting periods for the purposes of calculating net sales, royalty payments and sales based milestone payments.

"Joint Patents" shall have the meaning set forth in Section 8.4(a) of this Agreement.

"Licensed Product(s)" means products covered by ANIKA's PMA No. P030019 (i.e. Orthovisc®), or products whose characteristics satisfy the Specifications. For purposes of this Agreement, Licensed Product shall also include any product Developed pursuant to Section 2.1(c).

"License Period" shall have the meaning set forth in Section 6.1O(iii) of this Agreement.

"Modified Licensed Product" shall have the meaning set forth in Section 8.9 of this Agreement.

"Net Sales" means, consistent with, in the United States, generally accepted accounting principles and, in the rest of the Territory, OBI worldwide practices and procedures, and in each such case as consistently applied with respect to all Licensed Products, the aJTIOlmt invoiced by OBI, its Affiliates, and its distributors and sub-licensees to Customers for sales of Licensed Product in the Territory, less accruals estimated, credits taken, and actual payments (to the extent not previously accrued) made for: (i) discounts, including, but not limited to, cash discounts, discounts to managed care or similar organizations or government organizations, rebates paid, credited, accrued or actually taken, including government rebates such as Medicaid charge backs or rebates, and retroactive price reductions or allowances actually allowed or granted from the billed anlount, and commercially reasonable and customary fees paid to wholesalers, buying groups, hospitals or physicians, excluding ruly distributors or sub-licensees ("Customers"), (ii) credits or allowances actually granted upon claims, rejections or returns of such sales of Licensed Products, including recalls (provided such recalls are in accordance with Section 6.9 of this Agreement and except to the extent ANIKA has otherwise paid for such recall), (iii) taxes, duties or other governmental charges levied on or measured by the billing anlount when included in billing, as adjusted for rebates, charge-backs, and refunds (and similar adjustments), (iv) actual write-offs for uncollectable accounts, provided, however, that if collected at a later date, such aJTioounts will be added to Net Sales, and (v) freight, postage, shipping and insurance charges paid

for delivery of such Licensed Products, to the extent billed and reflected on the invoices. For purposes of calculating "Net Sales," a Licensed Product shall be considered "sold" upon the invoicing of such Licensed Product by OBI to a Third Party (other than to any of its Affiliates), or upon invoicing of such Licensed Product by any of OBI's Affiliates or distributors or sub-licensees to a Third Party.

"OBI Area" shall have the meaning set forth in Section 3.3 of this Agreement.

"OBI Disclosure Date" shall have the meaning set forth in Section 14.2(b) of this Agreement.

"OBI Potential Products" shall have the meaning set forth in Section 14.2(a) of this Agreement.

"OBI Sellers" means OBI, its Affiliates, sub-licensees and distributors.

"Patent" means (i) valid and enforceable patent, including any extension, registration, confirmation, reissue, continuation, divisional, continuation-in-part, re-examination or renewal thereof, and (ii) pending applications for Letters Patents, in any jurisdiction within the Territory.

"Patent Costs" means the reasonable fees and expenses paid to outside legal counsel and other Third Parties, and filing and maintenance expenses, incurred in connection with the establishment and maintenance of rights under Patents.

"Person" shall mean any natural person, corporation, firm, limited liability corporation, limited liability partnership, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or any agency or political subdivision thereof.

"Per Unit Overpayment" shall have the meaning set forth in Section 6.2(a)(i) of this Agreement.

"Per Unit Underpayment" shall have the meaning set forth in Section 6.2(a)(i) of this Agreement.

"Phase IV" shall mean product support clinical trials of the Licensed Product with an approved label claim commenced after receipt of Regulatory Approval in the country where such trial is being conducted.

"PMA" means a premarket approval application filed with the FDA, or if a PMA is not the appropriate filing, then the suitable filing required to obtain Regulatory Approval. "PMA" includes the "Currently Filed PMA", which is ANIKA's PMA No. P030019 for ORTHOVISC® presently under consideration by the FDA, as may be supplemented, amended or augmented from time to time.

"Quality Agreement" has the meaning set forth in the recitals to this Agreement.

"R&D Pipeline" shall mean the research and development projects developed by ANIKA.

"Raw Materials" shall mean the materials, components, and packaging required to manufacture and package the Licensed Product in accordance with the Specifications.

"Reference Quarter" shall have the meaning set forth in Section 6.2(a)(iii) of this document.

"Regulatory Approval" shall mean all regulatory agency registrations and approvals by government, pricing or health authorities in a country which are required for first use or sale of a medical device or drug, including, importation, manufacture (where manufacture is required) or use, in each case, in the Field in the Territory.

"Replacement Product" shall have the meaning set forth in Section 5.2(a) of this Agreement.

"Retained Sample" shall have the meaning set forth in Section 6.8 of this Agreement

"Rolling Annual Forecast" shall have the meaning set forth in Section 6.3(a) of this Agreement.

"Second Period" shall have the meaning set forth in Section 6.2(a)(ii) of this Agreement.

"Second Period Per Unit Overpayment" shall have the meaning set forth in Section 6.2(a)(ii) of this Agreement.

"Second Period Per Unit Underpayment" shall have the meaning set forth in Section 6.2(a)(ii) of this Agreement.

"Second Period Average Sales" shall have the meaning set forth in Section 6.2(a)(ii) of this Agreement.

"Second Report" shall have the meaning set forth in Section 6.2(a)(ii) of this Agreement.

"Second Source Qualification" shall have the meaning set forth in Section 6.10(ii) of this Agreement.

"Shipping Point" shall have the meaning set forth in Section 6.6(b) of this Agreement.

"Site" shall have the meaning set forth in Section 3.3 of this Agreement.

"Specifications" shall mean the specifications for the composition, manufacture, packaging, and/or quality control of all Licensed Product, as set forth on Exhibit A, attached hereto and made a part hereof, as the same may hereafter be modified by mutual agreement of the Parties in writing and attached hereto as a replacement for, or as an addition to, Exhibit A.

"Steering Committee" has the meaning set forth in Article 15 of this Agreement.

"Supply Year" shall mean Calendar Year.

"Term" shall mean the period commencing on the Effective Date and terminating on the latest to expire of the effective periods of this Agreement with respect to any country in the Territory as may be extended pursuant to Section 12.1 of this Agreement.

"Territory" means the United States of America ("U.S."), and Mexico.

"Third Party" means any entity other than ANIKA, OBI or any Affiliates of ANIKA or OBI.

"Total Initial Units" shall have the meaning set forth in Section 6.2(a)(i) of this Agreement.

"Total Second Period Units" shall have the meaning set forth in Section 6.2(a)(ii) of this Report.

"Trademark" has the meaning set forth in Section 3.2(a)(i) of this Agreement.

"Unit" shall mean each syringe containing Licensed Product.

"Unit Price" shall have the meaning set forth in Section 6.2(a) of this Agreement.

"Validity Challenge Claim" shall have the meaning set forth in Section 8.6(i) of this Agreement.

"Vision System" means an automated system that reads information (either printing or bar codes).

ARTICLE II -PRODUCT DEVELOPMENT

2.1. Development Responsibilities.

(a) United States. With respect to the Currently Filed PMA for Licensed Product by ANIKA, ANIKA shall use commercially reasonable efforts consistent with its normal business practices to obtain Regulatory Approval with the FDA. ANIKA shall be solely responsible for obtaining such Regulatory Approval, at its sole cost and expense. ANIKA shall on a regular basis report to OBI on the progress of its efforts in obtaining such Regulatory Approval.

(b) Mexico. OBI shall have the right but not the obligation to file a Drug Approval Application in Mexico, at its sole cost and expense. Prior to making any decision on whether to file for Regulatory Approval in Mexico of Licensed Product, OBI shall discuss the matter through the Steering Committee. A decision of whether to file for Regulatory Approval and/or launch Licensed Product in Mexico is required to be mutually agreed upon by the Parties in advance of any filing. Subject to the foregoing, should OBI proceed with such filing of a Drug Approval Application in Mexico, ANIKA shall cooperate with the preparation and execution of such Drug Approval Application. OBI agrees to name ANIKA as the approved supplier of the Licensed Product in any such filings. ANIKA shall have sole ownership rights in any such Drug Approval Application in Mexico, notwithstanding OBI's participation in the filing thereof. If by the end of the second quarter of 2005 OBI has failed to commence material and concerted efforts to market and commercialize Licensed Product in Mexico, and if the Steering Committee has determined that commercialization of Licensed Product will not materially impair the sales of Licensed Product in the United States, then OBI shall immediately forfeit its rights and licenses under this Agreement with respect to any Licensed Product in Mexico, all such rights and licenses (including distribution rights), with respect to such Licensed Product in Mexico shall revert to or remain with ANIKA (as the case maybe), and all references to "Territory" herein will automatically exclude Mexico.

(c) General. OBI shall have the exclusive right to Develop Licensed Product in the Territory in the Field by carrying out clinical trials in the Territory. Prior to making any decision on whether to so Develop Licensed Product, OBI shall discuss the matter through the Steering Committee. OBI agrees to carry out such Development of any Licensed Product in the Territory and Field consistent with its normal business practices regarding a product of similar commercial potential. OBI hereby grants ANIKA the exclusive right to copy, modify, distribute and use any such new Developments or Information created or Development in connection with such Development outside the Territory including the right to cross reference any OBI Regulatory Approvals and use the data and Information contained therein at a cost equal to half of OBI's fully allocated Development costs associated with any such new Development used by ANIKA. OBI agrees to in good faith begin a clinical trial for a new indication for such Licensed Product or a Phase IV clinical trial within 12 months from receipt of approval of the Currently Filed PMA from the FDA unless otherwise mutually agreed to by the Parties.

2.2. Ownership and Obtaining of Drug Approval Applications and Regulatory Approvals.

With respect to all Regulatory Approvals, including the Currently Filed PMA and supplements thereto directed to new indications and formulations Developed by OBI hereunder, ANIKA shall have sole ownership rights in any Regulatory Approval received and all relevant documents associated with the Regulatory Approval and corresponding Drug Approval Application materials; provided, however, that ANIKA shall be permitted to assign or license such ownership rights to OBI in ANIKA's sole discretion. Except to the extent explicitly provided for in this Agreement, ANIKA will not be required to conduct any clinical trials and or other studies in connection with any Regulatory Approval and ANIKA's only obligation in connection herewith is to use commercially reasonable efforts to prepare and file applicable agency registrations and approvals. Notwithstanding anything to the contrary contained herein, upon reasonable request by OBI, ANIKA agrees to set up a meeting or initiate contact with the FDA in connection with Licensed Product. In such meeting or contact, OBI shall be permitted to communicate and interact directly with the FDA in connection with obtaining a Regulatory Approval from the FDA; provided that (a) OBI shall, notify ANIKA in advance of such desired communications or interaction (including the probable substance thereof); (b) ANIKA facilitates and coordinates such communications or interaction; and (c) a representative of Anika shall be present for and participate during such communications or interaction.

ARTICLE III -COMMERCIALIZATION

3.1. OBI's Marketing Obligations For Licensed Products.

All business decisions related to, the sale, price and promotion of Licensed Products under this Agreement and the decisions whether to market or not market any particular Licensed Product shall be within the sole discretion of OBI. To the extent permitted in Section 15(e), the Steering Committee shall review and comment on the relevant marketing and sales activities. Any marketing or commercialization of a Licensed Product in one country within the Territory shall not obligate OBI to market or commercialize said Licensed Product in any other country. Furthermore, subject to Article IX and XI of this Agreement, OBI makes no representation,

warranty or covenant that the marketing of a Licensed Product shall be the exclusive means by which OBI will participate in any therapeutic field. In commercializing any Licensed Product, OBI will use reasonable commercial efforts that are consistent with the efforts it uses in commercializing its own pharmaceutical products.

3.2. Trademarks.

(a)

(i) ANIKA hereby grants to OBI for the Term of this Agreement the exclusive, royalty-free right to use the trademark "Orthovisc®" (the "Trademark") only in connection with the marketing, distribution and sale of Licensed Product in the Territory and only in the Field. OBI expressly agrees that it will label all packaging containing the Licensed Product with the following designation, "Orthovisc® is a trademark of ANIKA Therapeutics, Inc.," and will sell all Licensed Product only under the trademark "Orthovisc®." ANIKA agrees that it will not use or give rights to a Third Party to use the Trademark in the Territory in connection with any other product. OBI agrees that all of its use of the Trademark will inure to the benefit of ANIKA.

(ii) OBI shall not use any trademark, service mark, trade name, logo, internet domain name or design which is the same or substantially similar to Trademark as such to cause confusion in the mind of a reasonable person.

(iii) All costs and expenses incurred with respect to the preparation of Trademark applications, and with respect to the filing and/or maintenance of Trademark registrations and other documentation required by government agencies shall be paid by ANIKA. OBI shall assist and cooperate with ANIKA in connection with the filing and/or maintenance of any such Trademark registrations and other documentation required by government agencies in the Territory as may be reasonably requested by ANIKA from time to time.

(iv) In the event OBI desires to market the Licensed Product under a trademark other than "Orthovisc," utilization of such alternative trademark shall be subject to the approval of ANIKA. OBI shall be fully responsible at its sole cost for obtaining such alternative trademark and shall own such trademark. ANIKA shall have no rights to use such trademark outside the Territory.

(b) OBI will supply ANIKA with samples of its use of Trademark upon ANIKA's request.

(c) OBI shall use the Trademark only in a manner and form designed to maintain the high quality of the Trademark. If ANIKA at any time finds that OBI's or any of its sublicensee's or distributor's use of the Trademark is not consistent with standards of quality acceptable to ANIKA, ANIKA may notify OBI in writing of such deficiencies, and if OBI fails to correct such deficiencies within sixty days after receipt of such notice, ANIKA, may, at its election, terminate the license granted in Section 3.2(a)(i) immediately.

(d) OBI may not sublicense, other than to an Affiliate of OBI, the Trademark to any Third Party without ANIKA's prior written consent; provided that any permitted sublicensee must agree to be bound by the terms and conditions of this Section 3.2.

(e) ANIKA reserves all other rights in and to the Trademark, including, without limitation, the right to license the Trademark in all countries outside the Territory.

(f) OBI shall never challenge ANIKA's ownership of or right to license, or the validity of, the Trademark or any application for registration thereof or any trademark registration thereof. OBI shall never file any application for a registration for the Trademark in any office or agency anywhere in the world.

(g) Each of the Parties shall promptly notify the other Party of any infringement of the Trademark by a Third Party in the Territory and cooperate with each other in deciding how to proceed. If the Trademark is infringed by a Third Party in the Territory, ANIKA shall either (i) bring an action for infringement, at its sole expense, against such third party, in which case ANIKA shall be entitled to any and all proceeds resulting from such action, and shall keep OBI informed as to the prosecution of the action; or (ii) notify OBI in writing that it will not pursue an infringement action against the Third Party. In the event ANIKA exercises option (ii) in the immediately preceding sentence, OBI shall either (i) bring an action for infringement, at its sole expense, against such Third Party, in which case OBI shall be entitled to any and all proceeds resulting from such action, and shall keep ANIKA informed as to the prosecution of the action; or (ii) notify ANIKA in writing that it will not pursue an infringement action against the third party. In the event OBI exercises option (ii) in the immediately preceding sentence, the Steering Committee shall meet within ten (10) days of OBI's receipt of ANIKA's notification to determine whether the third party infringement prevents OBI from competing effectively in the affected market(s) and, if so, how best to proceed.

(h) If a Third Party asserts that a trademark owned by it is infringed by the use of Orthovisc® by OBI in the Territory in accordance with this Agreement, ANIKA has an obligation under to defend against such assertion or resulting litigation within thirty (30) days after receiving written notice thereof, and OBI shall assist and cooperate with ANIKA in the defense of such suit. ANIKA shall bear the full costs and expenses of such defense and shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement entered into by ANIKA. ANIKA shall not enter into any settlement, consent decree or other voluntary final disposition of the suit without the prior written notice to OBI, and OBI is not responsible in any way whatsoever for any such settlement or compromise entered into without such prior written consent.

(i) Upon termination of this Agreement for any reason, the license granted in this Section 3.2 shall immediately terminate, and OBI and all of its sublicensees shall immediately cease all use of the Trademark.

(j) Branding Materials. OBI shall bear the costs associated with its efforts to establish and promote the Orthovisc® brand in the Territory, as set out in any marketing plan(s) reviewed by the Steering Committee. The Parties agree that the materials and information

developed by OBI for this purpose (the "Branding Materials"), are the sole property of OBI. As used herein, the term "Branding Materials" includes without limitation promotional, training, and public relations materials, trademarks, slogans, advertising tag lines, logos and other trade dress, whether in print, video or other format (including, without limitation, the content contained in the website referred to in Section 3.3), but expressly excludes the Trademark, any logo, and "trade dress" of the Licensed Product's package, which is licensed to OBI hereunder, which Trademark, logo and trade dress shall be the sole property of ANIKA. ANIKA may elect to purchase from OBI a paid-up perpetual license to sell, sublicense, reproduce, modify distribute any or all of the Branding Materials for use outside the Territory, provided ANIKA shall have no right to purchase OBI trademarks and logos, and other Branding Materials, which Branding Materials are used to promote other OBI products. If ANIKA so elects, OBI shall provide one copy of the digital file containing the Branding Materials ANIKA has selected, and ANIKA shall pay to OBI within 45 days after receipt of the digital file a one-time fee equal ten percent (10%) of OBI's documented Third Party hard costs for conceptualization, preproduction, and production of the selected Branding Materials (excluding printing costs).

3.3. Subject to the terms and conditions of this Agreement, ANTKA hereby grants to OBI for the Term of this Agreement the exclusive, non-sublicensable, royalty-free right to use the domain name orthovisc.com. OBI shall have the sole authority to create and post content on the Territory portion of any website identified by the orthovisc.com domain name, and all such content, including copyrights therein, shall belong to OBI. ANIKA shall maintain the orthovisc.com domain name registration in good order for the duration of this Agreement and any extensions thereof. OBI will, at its cost, design, develop, host, operate and maintain a web site located at www.orthovisc.com, (the "Site") which will, among other things, market and promote Licensed Product. ANIKA shall have the right, at its cost, to develop, launch and update an ANIKA branded area on the Site (the "ANIK Area") which targets users outside of the Territory. OBI will cooperate with ANIKA in connection with the development, launch and updating of the ANIK Area, including, but not limited to modifying the Site from time to time to incorporate ANIK Area content delivered by ANIKA. The orthovisc.com website will be constructed in a manner so as to allow visitors to be directed to either the OBI portion of the website, which will relate to the Territory (the "OBI Area"), and to the ANIK Area, which will relate to the ANIK regions of the world excluding the Territory. Reference herein to OBI's authority to create and post content on the orthovisc.com website only relates to the portion or link relating to the OBI Area. OBI acknowledges and agrees that (a) OBI has no right, title and/or interest in the orthovisc.com domain name, or any trademarks, trade names and service marks that may be contained in the orthovisc.com domain name (collectively, "Domain Name Marks"), other than the limited license granted in this Section 3.3, (b) all rights arising from OBI's use of the Domain Name Marks inure to the benefit of ANIKA, (c) OBI will only use the orthovisc.com domain name and any website identified by such domain name for lawful purposes only and (d) upon termination of this Agreement, OBI shall immediately discontinue all use of the orthovisc.com domain name.

ARTICLE IV -INTELLECTUAL PROPERTY LICENSE GRANTS

4.1. ANIKA hereby grants to OBI an exclusive, non-transferable royalty bearing, license under ANIKA Know-How and ANIKA Patents in the Territory solely to use and sell Licensed Products in the Field in the Territory, with a right to grant sublicenses (to sublicensees and distributors), provided, however, (a) in the United States, OBI may only grant sublicenses to Affiliates or, if approved in advance in writing by ANIKA, to Third Parties and, (b) OBI may grant sublicenses in Mexico to its Affiliates or to Third Parties who are OBI's customary historical normal course distributors in accordance with past practice, without prior notice or approval by ANIKA, and to non-customary distributors only upon prior written notice or approval by ANIKA, which will not be unreasonably withheld; provided, however, that any such sublicensee or distributor shall be responsible for marketing and promotion of such Licensed Product within the distribution territory. With respect to any such sublicensees or distributors, OBI shall be responsible for making any payments due under this Agreement to ANIKA resulting from sales made by such sublicensees or distributors and the compliance by sublicensees or distributors with all applicable terms of this Agreement.

ARTICLE V -PAYMENTS

In consideration of the rights and licenses granted under this Agreement, OBI agrees to pay ANIKA the following non-refundable amounts:

5.1. Upfront Payment.

OBI agrees to pay to ANIKA a non-refundable upfront payment of two million dollars (\$2,000,000) within 5 Business Days of the Effective Date.

5.2. Payment Events

(a) OBI agrees to make the following non-refundable payments to ANIKA under this Section 5.2 upon the first occurrence of each event for the first Licensed Product. If the first Licensed Product is replaced by another Licensed Product (a "Replacement Product"), OBI shall not be obligated to make the same event payments for the Replacement Product as it already made in connection with the first Licensed Product which was replaced. It is understood that in no event shall OBI be obligated to make the payment due on any event more than once with respect to the same Licensed Product (or its Replacement Product) in connection with any indication, application, formulation, and/or use, regardless of the number of any of such indications, applications, formulations and/or uses.

(b) Within twenty (20) Business Days following receipt from ANIKA of a notice and invoice regarding the achievement of each of the following events in connection with the Currently Filed PMA for Licensed Product as follows:

(i) Five million dollars (\$5,000,000) upon approval by FDA of the Currently Filed PMA with a four injection label claim;

(ii) Fifteen million dollars (\$15,000,000) if the FDA approved label for the Currently Filed PMA with a three injection label claim;

(iii) Seven million five hundred thousand dollars (\$7,500,000) if CMS assigns a J Code by the end of the first quarter of fiscal year 2005; and

(iv) Five million dollars (\$5,000,000) upon FDA approval of an upgrade of the packaging operation with Vision System to ensure that every syringe is labeled with the proper product name, lot, and expiration date; and that every carton has the proper package insert included.

For avoidance of doubt, if each of the items (i)-(iv) above were achieved, ANIKA would receive a total of thirty two million five-hundred thousand dollars (\$32,500,000).

(c) Provisions (i)-(iii) in this subsection 5.2(c) as set forth below refer to Annual Net Sales ("ANS") in the Territory:

(i) Referring to the 2005 ANS, either, and only one of,

(i)(1) if such 2005 ANS exceed one hundred million dollars (\$100,000,000), OBI agrees to pay ANIKA seven million five hundred thousand dollars (\$7,500,000), or

(i)(2) if such 2005 ANS exceed one hundred and twenty five million dollars (\$125,000,000), OBI agrees to pay ANIKA twelve million and five hundred thousand dollars (\$12,500,000),

within thirty (30) Business Days from the end of the 2005 Calendar Year;

(ii) Referring to the 2006 ANS, either, and only one of,

(ii)(1) if such 2006 ANS exceed one hundred and twenty five million dollars (\$125,000,000), OBI agrees to pay ANIKA seven million and five hundred thousand dollars (\$7,500,000), or

(ii)(2) if such 2006 ANS exceed one hundred and seventy five million dollars (\$175,000,000), OBI agrees to pay ANIKA fifteen million dollars (\$15,000,000),

within thirty (30) Business Days from the end of the 2006 Calendar Year; and

(iii) Referring to the 2008 ANS, either, and only one of,

(iii)(1) if such 2008 ANS exceed two hundred and twenty five million dollars (\$225,000,000), OBI agrees to pay ANIKA fifteen million dollars (\$15,000,000), or

(iii)(2) if such 2008 ANS exceed two hundred and seventy five million dollars (\$275,000,000), OBI agrees to pay ANIKA twenty five million dollars (\$25,000,000),

within thirty (30) Business Days from the end of the 2008 Calendar Year.

5.3. Earned Royalties For Licensed Products. In addition to any payments pursuant to Section 5.2 of this Agreement, ANIKA shall be entitled to the following royalty payments:

(a) With respect to each Calendar Year (including 2004), OBI shall pay ANIKA a royalty according to the following Net Sales:

(i) For the portion of ANS in the Territory up to two hundred million dollars (\$200,000,000), a royalty ~~of~~ on such portion of Net Sales during such Calendar Year; ply_s

(ii) For the portion of ANS in the Territory that is in excess of two hundred million dollars (\$200,000,000) up to and including three hundred million dollars (\$300,000,000), a royalty of 8% on such portion of Net Sales during such Calendar Year; provided however, if CMS assigns a J code by the end of the first quarter of 2005 such royalty shall be 7% on such portion of Net Sales during such Calendar Year and each subsequent Calendar Year; ply_s

(iii) For the portion of ANS in the Territory that is in excess of three hundred million dollars (\$300,000,000), a royalty of +8% on such portion of Net Sales during such Calendar Year.

(b) Royalties shall be paid in respect of all Licensed Products in the Territory for the entire Term of this Agreement, including extensions or renewals thereof.

5.4. Third Party Patents.

If a Patent or Patents of a Third Party should be in force in any country in the Territory during the term of this Agreement covering the use or sale of any Licensed Product, and if after receiving such notice from such Third Party it should prove in OBI's reasonable judgment after consultation with ANIKA, impractical or impossible for OBI or any OBI Affiliate to continue performing the activity or activities licensed hereunder without obtaining a royalty bearing license from such Third Party under such Patent or Patents in said country, then OBI shall promptly notify ANIKA in writing. If ANIKA agrees that a license is required it shall use commercially reasonable efforts to procure such license from the Third Party at its cost paying any compensation to such Third Party for such license. If ANIKA disagrees that such a license is required, the Parties shall submit the issue to an independent patent attorney selected mutually by the Parties to determine whether a license is needed. The decision of such patent attorney shall be final and to the extent that such patent attorney decides that a license is required, ANIKA will use commercially reasonable efforts to procure such license from the Third Party at its cost. The cost of such patent attorney shall be borne by the non-prevailing party in the disagreement.

5.5. Currency Restrictions.

Except as herein provided in this Section 5.5, all royalties and milestones shall be paid in Dollars. If, at any time, legal restrictions prevent the prompt remittance of part of or all royalties and milestones with respect to any country where Licensed Products are sold, OBI shall document such restrictions to ANIKA and shall then have the right and option to make such payments by depositing the amount thereof in local currency to ANIKA's accounts in a bank or depository designated by ANIKA in such country.

5.6. Reports and Records.

(a) During the Term of this Agreement and commencing with the Date of First Sale of a Licensed Product, OBI shall furnish, or cause to be furnished to ANIKA, written reports, including the calculation of royalty payment due, within thirty (30) Business Days following the end of each Calendar Quarter, showing:

(i) the Net Sales of each Licensed Product sold by each of OBI, its Affiliates and its Sublicensees in each country of the Territory, during the Calendar Quarter and the total for all quarters of the current Calendar Year;

(ii) the Units of each Licensed Product sold by each of OBI, its Affiliates and its Sublicensees in each country of the Territory, during the Calendar Quarter and the total for all quarters of the current Calendar Year;

(iii) the royalties payable in Dollars, which shall have accrued hereunder in respect to such Net Sales for the current Calendar Year; and

(iv) a detailed calculation of Net Sales for the Calendar Quarter and the total amount of Net Sales for the current Calendar Year through the most recently completed Calendar Quarter.

(b) All royalty payments to be made by OBI to ANIKA under Section 5.3 shall be made in Dollars by same day wire transfer no later than forty (40) Business Days from the end of the applicable Calendar Quarter.

(c) In the case of sales outside the United States, for the purpose of this Article 5, such sales shall be converted to Dollars in accordance with OBI's current customary and usual procedures for calculating same which are the following: the rate of currency conversion shall be calculated using a simple monthly period average of the end "spot rates" provided by Brown Brothers Harriman, 59 Wall Street, NY, NY 10005, for each Calendar Quarter, or if such rates are not available, the same computation using the spot rates as published by a leading United States commercial bank for such accounting period. These methods of conversion are consistent with OBI's current accounting methods. OBI shall give ANIKA prompt written notice of any proposed changes to OBI's customary and usual procedures for currency conversion, which shall only apply after such notice has been delivered to and approved by ANIKA, provided that such changes continue to maintain a set methodology for currency conversion.

(d) Each report shall be made within thirty (30) Business Days from the end of each calendar quarter. OBI shall keep accurate records in sufficient detail to enable royalties and other payments payable hereunder to be determined. OBI shall be responsible for all royalties and late payments that are due to ANIKA that have not been paid by OBI, its Affiliates, its sublicensees and distributors. All costs of enforcing or collecting payment hereunder, including attorney's fees and court costs, shall be paid by the non-prevailing Party.

OBI shall maintain complete and accurate records, in accordance with U.S. generally accepted accounting practices, which are relevant to costs, expenses and payments under this Agreement and such records shall be open during reasonable business hours for a period of five (5) years from creation of individual records for examination at ANIKA's expense and not more often than once each year by a certified public accountant or other representative selected by ANIKA and acceptable to OBI for the sole purpose of verifying the correctness of calculations or such costs, expenses or payments made under this Agreement (the "Audit"). If OBI disagrees with the calculation of the Audit, and OBI and ANIKA cannot resolve their disagreement, the matter shall be submitted to arbitration in accordance with Article XVI. In the absence of material discrepancies (in excess of 5% of the disputed amount) in any request for reimbursement resulting from such audit, the accounting expense shall be paid by ANIKA. If material discrepancies do result, OBI shall bear the reasonable audit expense. Any records or

accounting information received from OBI shall be Confidential Information for purposes of Article VII.

5.7. Taxes.

(a) OBI will make all payments to ANIKA under this Agreement without deduction or withholding for taxes except, solely with respect to sales of Licensed Product in Mexico, to the extent that any such deduction or withholding is required by law in effect at the time of payment.

(b) Solely with respect to sales of Licensed Product in Mexico, any tax required to be withheld on amounts payable under this Agreement will promptly be paid by OBI on behalf of ANIKA to the appropriate governmental authority, and OBI will furnish ANIKA with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by ANIKA.

(c) OBI and ANIKA will cooperate with respect to all documentation required by any taxing authority or reasonably requested by OBI or ANIKA to secure a reduction in the rate of applicable withholding taxes solely with respect to sales of Licensed Product in Mexico.

(d) If OBI had a duty to withhold taxes in connection with any payment it made to ANIKA under this Agreement but OBI failed to withhold, and such taxes were assessed against and paid by OBI, then ANIKA will indemnify and hold harmless OBI from and against such taxes. If OBI makes a claim under this Section 5.7(d), it will comply with the obligations imposed by Section 5.7(b) as if OBI had withheld taxes from a payment to ANIKA.

ARTICLE VI-MANUFACTURE

6.1. Supply of Products.

Subject to the Terms of this Agreement, during the term of this Agreement, ANTKA agrees to supply OBI with those quantities of Licensed Product as ordered by OBI pursuant to this Agreement, and OBI shall purchase from ANIKA 100% of OBI's requirements for Licensed Products to be sold in the Territory subject to the ordering procedures set forth in Article VI.

6.2. Prices for Product.

(a) Transfer Prices. The price for each Unit of Licensed Product sold by ANIKA to OBI shall be set at M%-ofthe Unit Price (as defined below); provided, however, in no event shall B%-ofthe Unit Price be less **than**.. "Unit Price" is hereby defined as follows:

(i) First Calendar Quarter. The Unit Price for the period from the Date of First Sale until the last day of the first Calendar Quarter ended immediately following the Date of First Sale (the "Initial Period"), shall be the Initial Average Sales Price for such Initial Period where "Initial Average Sales Price" shall mean the fraction the numerator of which is the total Net Sales during such Initial Period and the denominator of which is the

total Units sold by the OBI Sellers during such Initial Period (the "Total Initial Units"). As the Unit Price for such Initial Period cannot be determined until after the end of such Initial Period, ANIKA shall invoice OBI at a transfer price equal to of OBI's published list price ("Initial Estimated Transfer Price") for Units sold during such Initial Period.

Within ten (10) days following the end of such Initial Period, OBI will provide ANIKA with a report containing the Net Sales for such Initial Period and the total Units sold during such Initial Period (the "Initial Report"). Within ten (10) days following the receipt of the Initial Report, (A) if the Initial Average Sales Price is greater than the Initial Estimated Transfer Price (such difference, the "Per Unit Underpayment"), OBI shall pay to ANIKA the product of (1) the Per Unit Underpayment and (2) the Total Initial Units, and (B) if the Initial Estimated Transfer Price is greater than the Initial Average Sales Price (such difference, the "Per Unit Overpayment"), ANIKA shall pay to OBI the product of (a) the Per Unit Overpayment and (b) the Total Initial Units, but in no event shall ANIKA pay any such amount to the extent such payment would result in ANIKA retaining a Unit Price of less than \$-!+,..

(ii) Second Calendar Quarter. The Unit Price for the Calendar Quarter immediately succeeding the Initial Period (the "Second Period") shall be the Second Period Average Sales Price for such Second Period where "Second Period Average Sales Price" shall mean the fraction the numerator of which is the total Net Sales during such Second Period and the denominator of which is the total Units sold by the OBI Sellers during such Second Period (the "Total Second Period Units"). As the Unit Price for such Second Period cannot be determined until after the end of such Second Period, ANIKA shall invoice OBI at a transfer price equal to Initial Estimated Transfer Price for Units sold during such Second Period.

Within ten (10) days following the end of such Second Period, OBI will provide ANIKA with a report containing the Net Sales for such Second Period and the total Units sold during such Second Period (the "Second Report"). Within ten (10) days following the receipt of the Second Report, (A) if the Second Period Average Sales Price is greater than the Initial Estimated Transfer Price (such difference, the "Second Period Per Unit Underpayment"), OBI shall pay to ANIKA the product of (1) the Second Period Per Unit Underpayment and (2) the Total Second Period Units, and (B) if the Initial Estimated Transfer Price is greater than the Second Period Average Sales Price (such difference, the "Second Period Per Unit Overpayment"), ANIKA shall pay to OBI the product of (a) the Second Period Per Unit Overpayment and (b) the Total Second Period Units, but in no event shall ANIKA pay any such amount to the extent such payment would result in ANIKA retaining a Unit Price of less than \$-/-7:

(iii) Subsequent Calendar Quarters. The Unit Price for each Calendar Quarter ended after the Second Period shall be the Average Sales Price determined from the Calendar Quarter ended two Calendar Quarters immediately preceding such Calendar Quarter (the "Reference Quarter") (for instance, in the case of Q4, the Calendar Quarter ended two Calendar Quarters immediately preceding would be Q2), where "Average

Sales Price" shall mean the fraction the numerator of which is the total Net Sales during such Reference Quarter and the denominator of which is the total Units sold by the OBI Sellers during such Reference Quarter.

Within five (5) Business Days following the end of each Calendar Quarter, OBI shall provide ANIKA with a preliminary and unaudited report containing the Net Sales for each such Calendar Quarter. These preliminary and unaudited reports will be superceded by the reports under Section 5.6(a) at the time those reports are required to be furnished.

(b) Payment Terms. Payment terms on all orders of Licensed Product shall be forty-five (45) days net of invoice date. OBI shall keep accurate records in sufficient detail to enable transfer fees and other payments payable hereunder to be determined. OBI shall be responsible for all transfer prices and late payments that are due to ANIKA. Any past due amounts will be subject to a late fee of 1% per month, or the highest rate allowed by law, whichever is less, with such interest accrual commencing on the thirtieth day after the end of the month such payment was due. All costs of enforcing or collecting payment hereunder, including attorney's fees and court costs, shall be paid by the non-prevailing Party. Breach for non-payment commences on the forty-sixth day following shipment of the Product by ANIKA, assuming all invoice data from ANIKA is accurate.

6.3. Forecasts. Orders.

(a) Prior to the beginning of each Calendar Quarter during the term of this Agreement, OBI shall provide ANIKA with a non-binding written forecast of OBI's expected requirements for Licensed Products during the following twelve months, designated M1-M12 and broken down by months and which shall include order dates, quantity and shipping dates ("Rolling Annual Forecasts"). As pertains for each Rolling Annual Forecast, the forecast for months designated M7-M9, once set, may only be increased or decreased by up to 50% in the aggregate from the original forecast for such month as the forecast is rolled forward at the beginning of the next quarters, unless otherwise agreed to by ANIKA. By way of example, assume the following four annual rolling forecast.

Forecast	M1-M3	M4-M6	M7-M9	M10-M12
1	Jan- March	April- June	<i>July- Sept</i>	Oct.- Dec.
2	April- June	July- Sept	<i>Oct.-Dec.</i>	Jan- March
3	July- Sept	Oct.- Dec.	<i>Jan -March</i>	April- June
4	Oct.- Dec.	Jan- March	<i>April- June</i>	July- Sept

Assume during Forecast 1, the forecast for July - September was 100 Units. Accordingly, in each of Forecasts 2 and 3, the maximum forecast for July-September is 150 Units and the minimum forecast for July-September is 50 Units.

The initial Rolling Annual Forecast shall be delivered by OBI within 2 weeks of the Effective Date of the Agreement.

(b) Orders. The initial launch and inventory build quantities will be exempt from this schedule, and determined by mutual agreement between ANIKA and OBI. OBI shall place any binding orders for Licensed Product by written or electronic purchase order (or by any other means agreed to by the Parties) to ANIKA, which shall be placed at least 3 months prior to the desired date of delivery and shall be consistent with the forecast provided for such Calendar Quarter in the latest Rolling Annual Forecast. The Parties acknowledge that OBI is not obligated to buy any specific amount of Licensed Product under this Agreement, except for the quantities which OBI shall actually order through such binding purchase orders in compliance with this Section 6.3(b).

(c) Conflicts. To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern.

6.4. Most Favored Customer.

In consideration of the arrangements provided in this Agreement for the OBI to purchase Licensed Product exclusively from ANIKA, ANIKA agrees that during the term of this Agreement OBI shall be treated with "most favored nation" status in connection with allocation of HA for manufacturing Licensed Product, and, accordingly, if ANIKA is unable to supply all of the quantities of Licensed Product ordered by OBI pursuant to binding orders in accordance with this Agreement, ANIKA shall not provide any other customer (which customer is similarly situated or purchases equivalent or less volume of products from ANIKA than OBI in the aggregate) with preferential or more favorable treatment with respect to allocation of Licensed Product (taking into account reasonable forecasts, past sales and sales performance against forecast).

6.5. Improvements.

(a) Change in Specifications. Either Party shall have the right to request a change to the Specifications or packaging of Licensed Product during the Term of this Agreement. In such event, the Party wishing to request a change shall notify the other Party of its request in writing. If the receiving Party agrees to such request, the Parties shall cooperate with each other to have such change to the Specifications or packaging of Licensed Product approved by the FDA, if such approval is necessary. ANIKA shall not be obligated to make any changes to the Specifications or packaging of Licensed Product requested by OBI. If the FDA requires a change to the Specifications or packaging of Licensed Product (other than changes requested by the OBI), ANIKA shall use commercially reasonable efforts to make such change with respect to the Licensed Product sold in the Territory, and the costs for making such change as required by such regulatory agency shall be born by ANIKA. OBI shall reimburse ANIKA for the actual, documented expenses incurred by ANIKA in connection with changes to the Specifications or the packaging of product requested by OBI, including, without limitations, any necessary Regulatory Approval costs. Notwithstanding any other terms of this paragraph, if the change to the Specifications or packaging of the Licensed Product creates obsolescence in existing inventory held by ANIKA or OBI or any other person or entity, the actual costs of such obsolescence, together with any actual hard disposal costs, shall be the responsibility of OBI.

ANIKA shall have the right to appoint an independent certified accountant mutually acceptable to both parties to audit and review OBI's financial records pertaining directly to such costs for obsolescence. Any disputes arising from a request for cost-sharing or reimbursement of expenses incurred in connection with a change in Specifications or packaging of the Licensed Product under this Section 6.5(a) and not resolved informally within 30 days shall be referred to the Steering Committee for resolution. If the Steering Committee does not resolve the matter within 60 days, either Party may submit the matter to arbitration as provided in Article XVI.

(b) Records. ANIKA shall keep complete and accurate records pertaining to the manufacture, including quality control, of the Licensed Product. OBI shall keep complete and accurate records pertaining to the use, sale and other disposition of the Licensed Product, including for each lot number of Licensed Product, the quantity shipped and where the lot was shipped. Each party shall keep its respective records for at least five (5) years or for such longer period if and as required by law. Each party shall make available such records to the other party for such lawful purpose as such other party may reasonably request in writing.

6.6. Deliyezy.

(a) All charges for packing, hauling, storage, bar coding and transportation to the Shipping Point are included in the transfer price as set forth in Section 6.2 hereunder unless otherwise agreed to by the Parties. OBI will pay all freight, shipping, insurance, duties, forwarding and handling charges, taxes, storage and all other charges applicable to Licensed Product after it is delivered by ANIKA to the Shipping Point. All shipments will be accompanied by a packing slip which describes the articles, states the purchase order number and shows the shipment's destination. ANIKA agrees to promptly forward the original bill of lading or other shipping receipt for each shipment in accordance with OBI's instructions.

(b) Shipment. The risk of loss with respect to Licensed Product shall remain with ANIKA through production until Licensed Product is delivered to OBI FOB ANIKA's manufacturing facility (currently located in Woburn, Massachusetts), or other manufacturing facility that has received Regulatory Approval from the FDA (the "Shipping Point"). ANIKA will pack all Licensed Product ordered hereunder in a manner suitable for shipment and sufficient to enable the Licensed Product to withstand the normal effects of shipping, including handling during loading and unloading. OBI is responsible for designating the carrier(s) and negotiating terms for shipment of Licensed Product, and is responsible for payment of all shipping insurance, handling, storage and custom duties and fees.

(c) Inventory. ANIKA and OBI agree to reasonably cooperate to improve the process for ordering Licensed Product with the mutual objectives of expediting the supply process to a just-in-time process and reducing inventory costs.

6.7. Inspections.

(a) During the Term, OBI shall have the right, upon reasonable notice to ANIKA and during regular business hours, to inspect and audit the facilities being used by ANIKA (or any Third Party) for production and storage of the Licensed Product to assure compliance by ANIKA

(and its suppliers) with GMP and applicable FDA rules and regulations pertaining to Licensed Product and with other provisions of this Agreement.

(b) ANIKA shall have the right to visit OBI's facilities where the Licensed Product is stored or delivered from time to time during the term of this Agreement to perform a quality audit of OBI's records concerning storage and distribution (including shipping and handling) of the Licensed Product. Such visits shall be conducted during normal business hours upon at least ten (10) days prior written notice and each party shall be limited to not more than one visit per year, except in the event of a recall of the Licensed Product or governmental action involving the Licensed Product.

6.8. Non-Conforming Product.

OBI shall evidence any claims of nonconformity of Licensed Product with an analysis of the allegedly nonconforming Licensed Product that shall have been prepared by OBI or its agent. Such report shall be accompanied with a copy of the records pertaining to such testing and a sample of the Licensed Product from the batch analyzed. If, after its own analysis of a sample stored by ANIKA from such lot of Licensed Product (which such sample ANIKA is required to retain) (the "Retained Sample"), ANIKA confirms such nonconformity, ANIKA shall, at ANIKA's election, either replace the nonconforming Licensed Product with conforming Licensed Product as soon as reasonably practicable at ANIKA's expense or refund to OBI the entire transfer price therefore. The foregoing, and the rights under this Section 6.8, shall be OBI's sole and exclusive remedy with respect to such nonconformity. The nonconforming Licensed Product shall either be returned to ANIKA, at ANIKA's request and its expense, or destroyed, at ANIKA's expense.

If, after ANIKA's own analysis, ANIKA does not confirm conformance to the Specifications or whether the Licensed Product has such a defect, either Party may deliver the Licensed Product to an independent Third-Party laboratory, mutually and reasonably acceptable to both Parties, for analytical testing to confirm the Licensed Product's conformance to the Specifications or the presence or absence of defects. All costs associated with such Third-Party testing shall be at OBI's expense unless the tested Licensed Product is deemed by such Third-Party to be materially defective or not in compliance with the Specifications, in which case all such costs, including reimbursement of freight and disposition costs, shall be promptly paid by ANIKA. No inspection or testing of or payment for Licensed Product by OBI or any Third-Party agent of OBI shall constitute acceptance by OBI thereof, nor shall any such inspection or testing be in lieu or substitution of any obligation of ANIKA for testing, inspection and quality control as provided in the Specifications or under applicable local, state, or federal laws, rules, regulations, standards, codes or statutes. In the event that any such shipment or batch thereof is ultimately agreed or found to meet the specifications, OBI shall retain such shipment or batch, and all the terms and conditions of this Agreement shall continue to apply to such Licensed Product.

6.9. Corrective Action.

(a) Reportable Events. ANIKA shall be responsible for notifying all applicable regulatory authorities of reportable events (including without limitation complaints) involving the Licensed Product for which ANIKA receives written notification, as required by applicable laws. OBI shall notify ANIKA of potentially reportable events promptly but in no event later than twenty-four (24) hours after the event. In addition, all such notices by OBI shall be consistent with the requirements of law in the applicable jurisdictions.

(b) Licensed Product Complaints. OBI shall promptly communicate to ANIKA by facsimile, telephone or email (and confirm any such telephone communication as instructed at the time) any complaint received from users of the Licensed Product, in the configuration supplied by ANIKA. Each notification of a complaint shall contain, but not be limited to, the lot number, dosage size, expiration date, indication for actual use and description of circumstances involved in the failure of the Unit(s) in question. Each complaint notification will contain all the information available to OBI at that time, including all information then available which is required in the ANIKA Complaint Form attached hereto as Exhibit F, and a summary of the proposed action to be taken by OBI to comply with its legal obligations. OBI will provide additional information promptly as it becomes available. OBI acknowledges that complaint investigation is the responsibility of ANIKA, but OBI reserves the right to directly contact its customers.

(c) Safety or Efficacy Concerns. Each party agrees to notify the other party as soon as practicable of any information of which it becomes aware which relates to the safety or efficacy claims of the Licensed Product. Upon receipt of any such information, the parties shall consult with each other in an effort to arrive at a mutually agreeable course of action that is consistent with the obligations of the parties under this Agreement and constant with applicable laws.

(d) Licensed Product Recalls. If (i) the Licensed Product is subjected to a recall by any governmental agency, or (ii) ANIKA after notification to OBI elects to make a Licensed Product recall or (iii) in the event either Party, after notification to, and consultation with, the other, elects to make a Licensed Product withdrawal or corrective action, the expense of such recall, withdrawal or corrective action shall be borne as provided below. If (i) it is established that the Licensed Product was nonconforming pursuant to Section 6.8 upon delivery by ANIKA to a common carrier at ANIKA's Shipping Point, or (ii) such recall, withdrawal or corrective action arises from any breach by ANIKA of the provisions of this Agreement, then ANIKA, subject to Article XII, shall hold OBI harmless and shall bear all expenses related to the recall, withdrawal or corrective action, including the replacement of the recalled or withdrawn Licensed Product, which shall be replaced as soon as reasonably practicable. If such recall, withdrawal or corrective action arises as a result of actions or omissions on the part of OBI or its Affiliates, distributors or sublicensees, or from any breach by OBI, its Affiliates, distributors or sublicensees of the provisions of this Agreement, then OBI, subject to Article XII, shall hold ANIKA harmless and shall bear all costs and expenses in connection with such recall, withdrawal or corrective action. OBI shall keep, and will use its reasonable efforts to the extent required by law to cause its Affiliates, distributors and sublicensees to keep, detailed distribution records for each lot

number detailing the quantity shipped and the location where the lot was shipped, so that in event of a recall, OBI will be able to contact all physicians and/or end users.

6.10. Failure to Supply: License To Manufacture.

(i) If ANIKA fails, for a period of three consecutive months, to deliver eighty percent (80%) of the aggregate cumulative quantity of all Licensed Products which ANIKA has agreed to deliver to OBI pursuant to binding purchase orders pursuant to Section 6.3(b) of this Agreement during that period, without being able to complete the delivery requirements along with any other scheduled delivery requirement in the next subsequent two months (including a failure caused by a force majeure) (hereinafter referred to as a "Failure to Supply"), then during any such License Period (as defined), OBI shall be permitted (with no obligation or liability to ANIKA) to obtain such Licensed Product from another supplier (an "Alternative Supplier"), to use, sell, make and have made Licensed Product pursuant to the license granted in this Section 6.10; provided, however, OBI shall use commercially reasonable efforts to ensure that the term of any agreement with an Alternative Supplier (the "Alternative Supplier Agreement") is as short as possible; provided further however, in no event shall the term of any Alternative Supplier Agreement extend beyond 30 months inclusive of any termination notice requirements under the terms of such Alternative Supplier Agreement. Upon the occurrence of any such Failure to Supply and through and until the later of such time as ANIKA fully resumes its supply obligations hereunder: ANIKA shall make available to OBI or its designee access to all Information, ANIKA Patents and ANIKA Know-How for OBI to procure required raw materials or product or arrange an alternative supplier of Licensed Product and (b) ANIKA shall provide reasonable advice and consultation in connection therewith and (c) ANIKA will not be entitled to implied royalties or compensation for lost profits as a result of Licensed Product obtained from such Alternative Supplier and (d) OBI shall bear all costs necessary to relocate manufacturing to an Alternative Supplier's facility in accordance with this Section 6.10. Notwithstanding anything to the contrary contained in this Agreement, in the event that OBI shall manufacture or have manufactured the Licensed Product, pursuant to this Section 6.10(i), (1) OBI shall be permitted to disclose to any Third Party any Confidential Information as is reasonably necessary in connection with such activities (subject to such Third Party agreeing in writing to be bound by the terms of Article VII hereof), and (2) ANIKA shall supply on commercially reasonable terms the Active Ingredient (as defined below) if requested by OBI.-:-

(ii) From and after the Effective Date ANIKA will use commercially reasonable efforts to identify and qualify a second source of the hyaluronic acid active ingredient (the "Active Ingredient") in Licensed Products (the "Second Source Qualification"). Until such time as the Second Source Qualification, ANIKA will maintain a minimum inventory of the Active Ingredient for a 12-month period sufficient to manufacture Licensed Products as set forth in the Rolling Annual Forecast. OBI shall pay all administrative and regulatory fees in connection with the Second Source Qualification in an amount not to exceed ofte hl::Hldred thot:l5!lftd Elollftfs (\$100,000). _

(iii) ANIKA hereby grants to OBI a fully paid up license, with the right to grant sublicenses to its Affiliates, to manufacture and have manufactured Licensed Products solely in the Field and Territory; provided, however, that the license granted hereunder shall be effective only during the period of time commencing upon the occurrence of a Failure to Supply and continuing through and until such time as ANIK.A fully resumes its supply obligations hereunder (such period is hereinafter referred to as a "License Period") and OBI shall not exercise its rights to make or have made the Licensed Products pursuant to such license other than during such a License Period. For the avoidance of doubt, the license granted hereunder shall automatically be terminated upon the end of the License Period.

(iv) In the event that either OBI or ANIKA has actual knowledge of any facts or circumstances that are likely to result in a material disruption to the manufacture or sale of Licensed Products ("Adverse Knowledge"), such Party that has such Actual Knowledge shall give prompt notice to the other Party, and such Parties or the Steering Committee shall work together in good faith to address such Adverse Knowledge.

6.11. Insurance.

Each Party agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby which ANIKA policies shall be in compliance with Exhibit F attached hereto. Upon the other Party's request, each Party shall provide the other with a certificate of coverage or other written evidence reasonably satisfactory to the requesting Party of such insurance coverage.

6.12. Packaging.

OBI shall have the right to determine the appearance and text of any labeling and packaging consistent with the approved label used in connection with the Licensed Product in the Territory or any finished product containing or contained in the Licensed Product in the Territory. OBI shall pay all of the costs associated with the design of the labeling and packaging for the Licensed Product. Once the initial labeling and packaging has been decided upon and confirmed in writing, ANIKA shall not be required to make subsequent changes to such labeling unless OBI agrees to pay all additional costs associated with the implementing of changes and to pay ANIK.A's out of pocket costs associated with all packaging inventory rendered obsolete by the change in labeling. Notwithstanding the foregoing, if any changes are required to be made to the packaging or labeling as a result of the changes required by ANIKA, ANIKA shall bear the expenses thereof.

6.13. Clinical Trial Supplies

ANIKA agrees to supply up to 1000 Units of Licensed Product per clinical trial at no cost only if, and to the extent, both the Steering Committee and ANIKA have approved such clinical trial.

For approved clinical trials requiring more than 1000 units, ANIK.A will provide Licensed Products at a price of \$15.00 per unit, subject to Section 6.2(b).

ARTICLE VII -PUBLICATIONS; TRANSFER OF DATA; CONFIDENTIALITY

7.I . Confidentiality:Exceptions.

The Parties acknowledge that discussions between ANIKA and OBI will necessarily require the exchange of information (including detailed financial and product information) that is considered confidential and proprietary by the disclosing Party. The Parties agree that any information relating to the business of the disclosing Party which such Party discloses to the other Party pursuant to this Agreement shall be considered "Confidential Information" and shall include, without limitation, (i) the ANIKA Know-How; (ii) earnings, costs, and other financial information; (iii) drawings, formulations, samples, technical data, photographs, specifications, manufacturing methods, testing procedures; (iv) marketing, sales and customer information relating to the disclosing Party's business; (v) all clinical studies and data developed by either party in connection with this Agreement; and (vi) all other Information related to Licensed Product in the Field. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the time royalties are due and for five (5) years thereafter, subject to and except as permitted by Section 7.4 of this Agreement, each Party shall keep confidential (and shall cause the directors, officers, employees and agents of such Party or its Affiliates and sublicensees and distributors) to keep completely confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement the Confidential Information, except to the extent the receiving Party's (and their Affiliates) employees and/or agents (including consultants) need to know such Confidential Information in order to discharge such Party's obligations and exercise its rights hereunder. Each Party will protect the other Party's Confidential Information from unauthorized use, access or disclosure in the same manner that it protects its own similar Confidential Information. Confidential Information shall not include information which:

(i) was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed to, or learned by, the receiving Party, or was otherwise developed independently by the receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(iv) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

(v) was or is required to be disclosed as a result of a judicial order or decree or applicable law or regulation; provided, however, that the Party whose Confidential Information is the subject of such judicial order or decree is given the opportunity (to the extent not violative of applicable law) to contest the judicial order or decree prior to any disclosure.

Each Party will be responsible and liable for all breaches of the confidentiality provisions of this Agreement by its directors, officers, employees, agents and Affiliates, and shall indemnify the other for any breaches thereof.

7.2. Authorized Disclosure.

Except as expressly provided otherwise in this Agreement, each Party may disclose Confidential Information as follows: To Third Parties (including without limitation investors and potential investors of ANIKA, Affiliates, sublicensees, distributors and suppliers of ANIKA and Affiliates of OBI) under appropriate terms and conditions that include confidentiality provisions substantially equivalent to those in this Agreement as is reasonably necessary to exercise the rights granted herein.

7.3. Publications.

Notwithstanding any other provision of this Agreement, including, but not limited to the provisions of Section 7.4, ANIKA may not publish the results of any of OBI's Development activities relating to Licensed Products in the Field without the prior written consent of OBI. ANIKA may publish without the prior written consent of OBI results of its Development activities relating to Licensed Products for use outside the Territory.

7.4. Public Announcements.

Neither Party shall originate any publicity, press release or public announcements, written or oral, whether to the public or press, relating to this Agreement, including its existence, the subject matter to which it relates, performance under it or any of its terms, to any amendment hereto or performances hereunder without the prior written consent of the other Party (not to be unreasonably withheld), save only such announcements that are required by applicable law or any securities exchange or Nasdaq to be made or that are otherwise agreed by the Parties.

In the event of such publication, press release or public announcement (other than those required by applicable law or any securities exchange or Nasdaq), the Party making the announcement will give the other Party at least reasonable advance notice, where possible, of the text of the announcement so that the other Party will have an opportunity to comment upon the announcement. Notwithstanding anything contained in this Agreement to the contrary, (i) upon execution of this Agreement, ANIKA may issue a press release in the form of Exhibit C, and (ii)

OBI acknowledges that ANIKA is permitted to file this Agreement with the Securities and Exchange Commission.

Notwithstanding the foregoing, however, where urgent, unusual and rare circumstances require immediate disclosure in the opinion of the Party's counsel, the Party will, unless impossible because of legal reasons, provide at least one (1) Business Day's advance written notice.

ARTICLE VIII - OWNERSHIP OF INTELLECTUAL PROPERTY AND PATENT RIGHTS

8.1. .itk.

Title to all Patents claiming inventions made solely by an employee of a Party in the course of performing Development ("Development Invention") shall be owned by such Party. Title to Patents claiming inventions made jointly by employees of OBI and ANIKA shall be jointly owned by OBI and ANIKA. The laws of the United States with respect to joint ownership of inventions shall apply in all jurisdictions; accordingly, except as expressly provided in this Agreement, neither Party shall have any obligation to account to the other for profits, or to obtain any approval of the other party to license a jointly-owned patent, by reason of joint ownership thereof.

8.2. License to OBI Development Inventions.

OBI hereby grants ANIKA and its Affiliates a perpetual, royalty-free, fully paid-up, exclusive, worldwide license to use the OBI Development Inventions, with the right to sublicense, to use, manufacture, have manufactured, sell, offer for sale, import, have imported, offer to import, Licensed Products outside the Territory for a cost equal to half of OBI's fully allocated direct Development costs associated with any such OBI Development Invention used by ANIKA.

8.3. Disclosure of Patentable Inventions.

Each Party shall provide to the other any invention disclosure submitted in the normal course of disclosing an invention arising in the course of the Development or relating to Licensed Product. Such invention disclosures shall be provided to the other Party promptly after creation.

8.4. Patent Filings.

(a) Each Party may prepare, file, prosecute and maintain Patents to cover discoveries and inventions made solely by its own employees or consultants relating to any Licensed Products being developed or sold hereunder by OBI and use reasonable efforts to file initially all such applications in the United States. Inventions relating to the discovery, evaluation, manufacture, use or sale of Licensed Products that are made jointly by OBI and ANIKA in the course of this Agreement (hereinafter referred to as "Joint Patents") may be filed, prosecuted and maintained by ANIKA. The determination of the countries in which to file Joint Patents shall be made by ANIKA, provided, however, ANIKA agrees to file in the United States and Mexico.

ANIKA shall have the right to direct or control all material actions relating to the prosecution or maintenance of Joint Patents.

(b) The Party who is responsible for filing a Patent, will be termed the "Filing Party". In the case of a solely owned invention the Filing Party shall bear all Patent Cost associated therewith. With respect to a joint patent each of the Parties shall bear one half of all Patent Cost associated therewith. The filing Party shall keep the other Party apprised of the status of each Joint Patent, and shall seek the advice of the other Party with respect to patent strategy and drafting applications and shall give reasonable consideration to any suggestions or recommendations of the other Party concerning the preparation, filing, prosecution, maintenance and defense thereof. The Parties shall cooperate reasonably in the prosecution of all Joint Patents and shall share all material information relating thereto, including all material communications from patent offices, promptly after receipt of such information. If, during the term of this Agreement, the filing Party intends to allow any Joint Patent to lapse or leave abandoned, the filing Party shall, whenever practicable, notify the non-filing Party of such intention at least sixty (60) business days prior to the date upon which such Patent shall lapse or become abandoned, and the non-filing Party shall thereupon have the right, but not the obligation, to assume responsibility for the prosecution, maintenance and defense thereof and all expenses related thereto.

8.5. Infringement by Third Parties.

(i) If any ANIKA, OBI or Joint Patent covering a Licensed Product is infringed by a Third Party in any country in connection with the manufacture, use and sale of a Licensed Product in such country, the Party to this Agreement first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the known facts of that infringement in reasonable detail.

(ii) ANIKA shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement of the Joint Patent, by counsel of its own choice, and at its own expense. If ANIKA fails to bring an action or proceeding within a period of one hundred eighty (180) days after a request by OBI to do so, OBI shall have the right to bring and control any such action by counsel of its own choice, and at its own expense.

(iii) The Party bringing suit under this Paragraph 8.5 regarding a Joint Patent shall bear all costs and expenses of the suit, with any damages or other monetary awards recovered being split with 70% to OBI and 30% to ANIKA after costs of the prosecuting Party are reimbursed..

(iv) A settlement or consent judgment or other voluntary final disposition of a suit brought by a Party related to a joint patent under this Paragraph 8.5 may be entered into without the consent of the other Party; provided that such settlement, consent judgment or other disposition does not admit the invalidity or unenforceability of any Joint Patent; and provided further that any rights to continue the infringing activity in

such settlement, consent judgment or other disposition shall be limited to the product or activity that was the subject of the suit.

(v) Each Party shall have the sole and exclusive right, but no obligation, to enforce any Patent that it solely owns against infringement or alleged infringement thereof by a Third Party.

8.6. Validity Challenge Claims.

(i) In the event that any person shall assert any claim that any of ANIKA, OBI or Joint Patents are invalid or unenforceable, or seeks to limit the scope of enforcement thereof (each a "Validity Challenge Claim"), whether in defense against an enforcement action brought by a party, by a separate action for declaratory judgment, or otherwise, the party receiving notice of such claim shall promptly notify the other party.

(ii) ANIKA shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to any Validity Challenge Claim relating to a Joint Patent, by counsel of its own choice, and at its own expense. If ANIKA fails to bring an action or proceeding within a period of one hundred eighty (180) days after a request by OBI to do so, OBI shall have the right to bring and control any such action by counsel of its own choice, and at its own expense.

(iii) The Party bringing suit under this Paragraph 8.6 regarding a Joint Patent shall bear all costs and expenses of the suit, with any damages or other monetary awards recovered being split with 70% to OBI and 30% to ANIKA after costs of the prosecuting Party are reimbursed. The other party will reasonably cooperate with and use commercially reasonable efforts to assist the Party bringing suit under this Paragraph 8.6, and the Party bringing such suit shall reimburse the other Party for its out-of-pocket expenses incurred as a result of such cooperation.

(iv) A settlement or consent judgment or other voluntary final disposition of a suit brought by a Party relating to a Joint Patent under this Paragraph 8.6 may be entered into without the consent of the other Party; provided that such settlement, consent judgment or other disposition does not admit the invalidity or unenforceability of any Joint Patent.

(v) Each Party shall have the sole and exclusive right, but no obligation, to institute, prosecute and control any action or proceeding with respect to any Validity Challenge Claim relating to any Patent that it solely owns.

8.7. Patent Assignment.

Neither Party may assign, license or otherwise transfer its rights under any Joint Patent except with the prior written consent of the other Party; provided, however, that either Party may assign such rights without consent to permitted assignee under this Agreement in connection with a merger or similar reorganization or the sale of all or substantially all of its assets.

8.8. Notices Relatjnto the Act.

ANIKA shall notify OBI of (a) the issuance of each U.S. and Mexican Patent included among the ANIKA Patents, giving the date of issue and patent number for each such patent.

8.9. Defense and Settlement of Third Party Claims

If a Third Party asserts that a patent right owned by it is infringed by the use or sale of Licensed Product, OBI will be solely responsible for defending against any such assertions at its cost and expense. OBI shall have the right to defend and settle against such charge of infringement. ANIKA shall have the same responsibility and rights in such Third Party actions if the alleged infringement relates to the manufacture of Licensed Product. If an action has not been brought but an assertion has been made that a patent right owned by a Third Party is infringed by the use or sale of Licensed Product, then the parties shall first exercise their rights and/or perform their obligations set forth in Section 5.4. If an action for patent infringement is brought against OBI for the use or sale of Licensed Product by a Third Party, OBI shall promptly notify ANIKA. ANIKA shall have the right, but not the obligation, to settle the litigation at its sole cost and expense. In no event, however, shall any such settlement by ANIKA modify the rights and licenses granted hereunder to OBI. If OBI is defending such charge of infringement, OBI shall have the right to apply up to 50% of the royalties due ANIKA on sales of the allegedly infringing Licensed Product against its litigation expenses during the pendency of any litigation, but only in the event that the infringement action is not based on or not related to a Modified Licensed Product. "Modified Licensed Product" means Licensed Product not in the Currently Filed PMA (except that Modified Licensed Product shall not include Licensed Products which result solely from changes initiated by ANIKA). If, as a result of judgment in the litigation or settlement with the Third Party not in connection with or not related to a Modified Licensed Product, OBI is required to pay royalties or other monies to such Third Party, OBI may thereafter deduct from the royalties due ANIKA on net sales of the Licensed Product charge to infringe, an amount of which is the lesser of 50% of all sums actually paid by OBI to such Third Party or 50% of all royalty payments otherwise payable to ANIKA on the net sales of such Licensed Product. In the case of a litigation involving a Modified Licensed Product, OBI shall be fully responsible for all costs and expenses of such litigation or settlement thereof.

ARTICLE IX -REPRESENTATIONS AND WARRANTIES.

9.1. Representations and Warranties of ANIK.A.

ANIKA hereby represents and warrants to OBI as follows:

(a) ANIKA is a corporation duly organized, validly existing and in good standing under the laws of the Commonwealth of Massachusetts and has all requisite corporate power and lawful authority to own, lease and operate its assets and to carry on its business as heretofore conducted. ANIKA has the full legal right, corporate power and authority to execute and deliver this Agreement and the other agreements contemplated hereby and to consummate the transactions contemplated hereby and thereby. This Agreement has been duly executed and

delivered by ANIKA and constitutes the valid and binding obligation of ANIKA, enforceable against ANIKA in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally or by general equitable principles.

(b) ANIKA owns all rights, title and interest in the Licensed Product necessary to grant the rights contained in this Agreement to OBI for Licensed Product in the Territory. The Licensed Product does not infringe upon any proprietary right, other than patents of any Person in the Territory; provided, however, that ANIKA makes no such representation and warranty with respect to any trademarks or trade dress not licensed to OBI hereunder which may be used by OBI in the marketing, distribution and sale of the Licensed Product. ANIKA does not have actual knowledge of any infringement by the Licensed Product of any issued United States or Mexican patent; however, ANIKA makes no representations or warranties regarding patents in any foreign jurisdictions other than Mexico. ANIKA makes no representation or warranty with respect to any marketing, distribution sale or use of the Licensed Product not in accordance with any applicable PMA or any other Regulatory Approval. Nothing contained in this Agreement is in conflict with any other agreement to which ANIKA is a Party or is otherwise bound. ANIKA has not granted the right to market, sell or distribute the Licensed Product in the Field in the Territory to any other Person.

(c) ANIKA represents and warrants to OBI that at the time of delivery to a common carrier at ANIKA's Shipping Point, all Licensed Product supplied in connection with this Agreement shall be of merchantable quality, fit for the purpose intended by this Agreement and free from defects in material and workmanship and shall be manufactured and provided in accordance and conformity with the Specifications and in compliance with this Agreement. ANIKA represents and warrants that it shall materially comply with all pertinent present and future statutes, laws, ordinances and regulations relating to the manufacture and supply of the Licensed Product in the Territory and in the Field being provided hereunder, including, without limitation, those enforced by the United States Food and Drug Administration (including compliance with GMP) and International Standards Organization Rules 9000 et seq.

(d) ANIKA'S WARRANTIES SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ANY OTHER WARRANTY, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, AND, ANIKA HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT, TITLE OR FITNESS FOR A PARTICULAR PURPOSE.

(e) EXCEPT AS OTHERWISE EXPRESSLY PROVIDED FOR IN THIS AGREEMENT, NEITHER PARTY SHALL IN ANY EVENT BE LIABLE TO THE OTHER FOR PUNITIVE, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS.

9.2. Representations and Warranties of OBI.

OBI hereby represents and warrants to ANIKA as follows:

(a) OBI is a limited partnership duly organized, validly existing and in good standing under the laws of the State of New Jersey and has all requisite power and lawful authority to own, lease and operate its assets and to carry on its business as heretofore conducted. OBI is a wholly-owned indirect subsidiary of Johnson & Johnson. OBI has the full legal right, power and authority to execute and deliver this Agreement and the other agreements contemplated hereby and to consummate the transactions contemplated hereby and thereby. This Agreement has been duly executed and delivered by OBI and constitutes the valid and binding obligation of OBI, enforceable against OBI in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally or by general equitable principles.

(b) Nothing contained in this Agreement is in conflict with any other agreement to which OBI or its Affiliates or sub-distributors is or may become a party or is otherwise bound.

(c) OBI and its Affiliates and sub-distributors shall store, distribute, market and sell Licensed Product in accordance with directions for storage and use as indicated in this Agreement and any amendments hereto.

(d) OBI and its Affiliates and sub-distributors shall distribute, market and sell Product in accordance with all applicable international, national and local laws of each country within the Territory, including without limitation, applicable drug and medical device laws.

ARTICLE X - ANIKA'S GENERAL OBLIGATIONS AND COVENANTS

(a) During the Term of this Agreement, ANIKA shall, in accordance with any marketing plan, strategy and direction approved by the Steering Committee:

(i) Provide to OBI reasonable technical, scientific, sales and marketing support with respect to the Licensed Product, to the extent OBI makes available opportunities to provide such support;

(ii) Use commercially reasonable efforts to ensure that products manufactured by the ANIKA for the purposes other than the treatment of osteoarthritis (other than the Licensed Product) are not marketed or used in the Field in the Territory (the "Gray Market Product"). If OBI reasonably believes that Gray Market Product is being marketed or used in any country in the Territory, and has caused financial loss to OBI of at least \$500,000» OBI shall promptly notify ANIKA of such belief, and provide ANIKA with a written description of the basis for OBI's belief. Within five (5) Business Days of ANIKA's receipt of such notice, the matter shall be submitted to the Steering Committee for resolution of the following issues: (A) whether or not the goods believed by OBI to be Gray Market Product are actually goods manufactured by ANIKA; (B) whether or not the goods believed by OBI to be Gray Market Product are actually being marketed or used in the Field in the Territory; (C) upon determination that the goods are in fact Gray Market Product, whether or not the financial loss to OBI is at least- \$500,000, and if so, the approximate amount; and (D) upon determination that Gray

Market Product has caused financial loss to OBI of at least \$500,000, what commercially reasonable course of action ANIKA shall be required to take, including without limitation taking such action, including legal and/or equitable action as required to prevent the Gray Market Product from entering the Territory and to prevent it from being marketed or used therein. In the event the Steering Committee does not reach a resolution concerning the Gray Market Product within thirty (30) days after such issues are presented to it, either Party may submit the matter to arbitration as provided in Article XVI herein, for resolution of the same issues as outlined in clauses (A) through (C) in the immediately preceding sentence;

(iii) Use commercially reasonable efforts to ensure that products manufactured by ANIKA for the purposes of treatment of osteoarthritis outside of the Territory (including the Licensed Product) are not marketed or used in the United States of America (the "Diverted Product"). If OBI reasonably believes that Diverted Product is being marketed or used in the United States of America, and has caused financial loss to OBI of at least \$500,000, OBI shall promptly notify ANIKA of such belief, and provide ANIKA with a written description of the basis for OBI's belief. Within five (5) Business Days of ANIKA's receipt of such notice, the matter shall be submitted to the Steering Committee for resolution of the following issues: (A) whether or not the goods believed by OBI to be Diverted Product are actually goods manufactured by ANIKA (B) whether or not the goods believed by OBI to be Diverted Product are actually being marketed or used in the Field in the United States of America; (C) upon determination that the goods are in fact Diverted Product, whether or not the financial loss to OBI is at least \$500,000, and if so, the approximate amount; and (D) upon determination that Diverted Product has caused financial loss to OBI of at least \$500,000, what commercially reasonable course of action ANIKA shall be required to take, including without limitation, taking such action, including legal and/or equitable action as required to prevent the Diverted Product from entering the United States of America and to prevent it from being marketed or used therein (including, without limitation, terminating the supply agreement(s), if permitted thereunder, with the parties to whom ANIKA had originally sold such Diverted Product). In the event the Steering Committee does not reach a resolution concerning the Diverted Product within thirty (30) days after such issues are presented to it, either Party may submit the matter to arbitration as provided in Article XVI herein, for resolution of the same issues as outlined in clauses (A) through (C) in the immediately preceding sentence;

(iv) Except as otherwise explicitly provided for herein, maintain ownership of all Licensed Product Regulatory Approvals and be responsible for making all regulatory filings for the Licensed Product within the Territory;

(v) No earlier than thirty (30) days after the execution and delivery of this Agreement, upon OBI's request, ANIKA shall deliver to OBI copies of all Information in ANIKA's possession related to ANIKA's Know-How and ANIKA's Patents available as of such date which ANIKA and OBI reasonably determine is relevant to the safety, efficacy, regulatory status, sale, marketing or distribution of a Licensed Product in the

Territory; provided, however, that all such transferred Information shall be subject to the confidentiality provisions of Article VII of this Agreement; and

(vi) ANIKA agrees that it will not use or grant rights to a Third Party to use the Trademark in connection with any product intended for use in animals other than humans.

ARTICLE XI-OBI's GENERAL OBLIGATIONS

During the Term of this Agreement, OBI shall:

(a) Store and distribute Licensed Product in accordance with direction for storage and use as indicated in the applicable PMA and Regulatory Approvals which are in effect at the time of such storage and use;

(b) Market and sell Licensed Product in accordance with approved labeling for Licensed Product at the time of such distribution, marketing or sales;

(c) Use its commercially reasonable efforts to commercialize Licensed Product in the Territory in a manner consistent with the efforts that OBI uses in commercializing its own pharmaceutical products;

(d) Subject to Article IV, notify ANIKA prior to engaging any distributor(s) to market, sell or distribute Licensed Product in the Territory and cause any such distributor(s) to agree in writing to be bound by the terms of this Agreement as if OBI hereunder. Notwithstanding the foregoing, OBI shall remain solely and primarily responsible under this Agreement.

(e) Be responsible for the entire cost of selling, marketing, advertising, promoting and distributing Licensed Product in the Territory;

(f) Supply ANIKA with any information as required by the FDA or other governmental agencies for U.S. and international regulatory filings related to the sale of the Licensed Product in the Territory;

(g) Timely advise ANIKA in writing of any suit, claim or complaint known to OBI resulting from the distribution or use of any Licensed Product;

(h) Refrain from soliciting orders from or selling Licensed Products to any Person located outside the Territory or to any Person inside the Territory for sales which OBI knows are intended to be distributed to users outside the Territory;

(i) Neither acquire directly or indirectly through its Affiliates from any Third Party, any products containing HA as the sole active ingredient for use in the Field (a "Competing Product"), nor distribute such Competing Product;

G) Furnish to ANIKA all advertising, marketing and promotional materials related to the Licensed Product, for review and approval as to their conformance with regulatory requirements, not to be unreasonably withheld, at least five (5) days prior to utilizing such materials, including, without limitation, any content to be displayed on the website pursuant to Section 3.3 of this Agreement; provided, however, that if there is an unresolved dispute as to whether ANIKA has unreasonably withheld approval of such materials, such matter shall be submitted to arbitration as provided in Article XVI; provided further, however, that should ANIKA fail to respond to any request for approval within the applicable five (5) day period then such approval will be deemed to have been granted;

(k) Invoice Third Parties (and ensure any distributors invoice Third Parties appropriately, consistently and on a timely basis with respect to sales of any and all Licensed Products; and

(l) OBI, and its Affiliates, sublicensees and distributors will, to the extent required by applicable law, keep detailed distribution records for each lot number detailing the quantity shipped and the first location where the lot was shipped by OBI, and will provide ANIKA with reasonable access to records for purposes of conducting quality control audits as provided in Section 5.6(d). ANIKA will generate and promptly transfer to OBI the same detailed distribution records for any and all units of the Licensed Product drop-shipped directly from ANIKA to a customer of OBI.

ARTICLE XII - TERM AND TERMINATION

12.1. Term.

This Agreement shall commence on the Effective Date and shall remain in effect for ten (10) years subject to the termination provisions set forth herein. OBI shall have the right, but not the obligation, to choose to extend the term of this Agreement for additional periods of (5) five-year intervals subject to the termination provisions set forth herein, so long as notification of any five-year extension of the Term is provided by OBI to ANIKA at least one-year prior to the expiration of the original ten (10) year Term or the then-current five (5) year Term, as the case may be, and at such time of notification extensions are permitted for the next five-year period only. Absent a provision to the contrary, any extension of this Agreement shall be subject to the terms set forth hereunder.

12.2. Termination Rights.

(a) Notwithstanding any of the foregoing, this Agreement may be terminated by either Party upon written notice to the other party, upon the occurrence of any of the following: (i) a material breach of any term or condition of this Agreement by the other Party which is amenable to cure, and the breaching party shall have failed to cure such breach within ninety (90) days from the receipt by it of written notice thereof from the other Party; (ii) either Party commits a material breach which is not amenable to cure; (iii) the other Party (or, in the case of OBI, its general partner or ultimate parent Affiliate) shall commence any case, proceeding or other action

(A) under any applicable law relating to bankruptcy, insolvency, reorganization or relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, wind-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (B) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any substantial part of its assets; (iv) there shall be commenced against the other Party (or, in the case of OBI, its general partner or ultimate parent Affiliate) any such case, proceeding or other action referred to in clause (iii) of this Section 12.2 which results in the entry of an order for relief; (v) the other Party (or, in the case of OBI, its general partner or ultimate parent Affiliate) shall take any action authorizing, or in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth above in clauses (iii) or (iv) of this Section 12.2; or (vi) the other Party (or, in the case of OBI, its general partner or ultimate parent Affiliate) shall admit in writing its inability to pay its debts as they become due; provided, however, that OBI may not terminate under Section 12.2(iii)-(vi) if ANIKA has not materially breached Section 6.1 of this Agreement.

12.3. Results of Termination.

In the event of termination of this Agreement by ANIKA, except as expressly provided in this Article 12, all the rights and obligations, including without limitation, the licenses granted to OBI in Article II and Article V hereof, shall immediately terminate. Upon termination by either Party, OBI shall provide ANIKA at no cost to ANIKA copies of all relevant communications and correspondence with and from regulatory agencies pertaining to Licensed Products and copies of all relevant marketing and promotional materials including customer lists, together with all Information relating to OBI's product development pursuant to Article II hereof. Except as otherwise provided in this Section 12.3, upon the termination of this Agreement, each Party shall promptly: (i) upon request return to the requesting Party all of the requesting Party's relevant records, materials and Confidential Information relating to the Licensed Product in the possession or control of the other Party, or its Affiliates, suppliers or Third Party distributors or sublicensees, and (ii) discontinue all distribution of the Licensed Product and the use of know-how in connection therewith. Notwithstanding anything herein to the contrary, upon termination of this Agreement for any reason, OBI shall have the right for one (1) year to dispose of all Licensed Product then in OBI's, OBI's Affiliate's, or Third Party distributor's possession, and the payments pursuant to Sections 5.2 and 5.3 shall be paid to ANIKA with respect to such Licensed Product as though this Agreement had not terminated. Termination of this Agreement shall not terminate OBI's obligation to pay ANIKA for Licensed Product which has been shipped to OBI under this Agreement or under the supply provisions if it is sold to a Third Party, including, without limitation, any applicable payments under Article V hereof. Subject to the provisions of this Section 12.3 with respect to OBI's right to dispose of Licensed Product post-termination of this Agreement, ANIKA shall have the right upon termination of this Agreement to purchase all of OBI's unsold inventory in merchantable condition or having a remaining shelf life acceptable to ANIKA, at the price of \$17.00 per Unit.

12.4. Termination by OBI.

OBI shall have the right to terminate this Agreement as follows:

(i) at any time after March 31, 2004, upon 30 days prior written notice, if the Currently Filed PMA is not approved;

(ii) upon thirty (30) days written notice to ANIKA at any time during the Term if material data regarding the safety of the Licensed Product arise after the Effective Date that indicate a materially and adversely different safety profile as compared to the profile as of the Effective Date;

(iii) during the period from the Effective Date to the second anniversary of the Effective Date, OBI may not terminate other than pursuant to Section 12.4(i)-(iii);

(iv) upon two hundred and seventy (270) days written notice to ANIKA if such notice to terminate is given after two (2) years from the Effective Date; and

(v) upon one hundred and eighty (180) days written notice to ANIKA if such notice to terminate is given after three (3) years from the Effective Date.

In the event of a termination under this Section 12.4, ANIKA shall retain all payments made by OBI under this Agreement and all payments made by OBI to purchase Licensed Product prior to the termination date, and OBI shall also make any such payments to which ANIKA is then entitled under this Agreement but payment of which have not previously been made by OBI. In addition, ANIKA shall have no right to use OBI owned trademarks even if such were used by OBI in connection with the Licensed Product.

Article VII and any relevant definitions in Article I shall survive the expiration and any termination of this Agreement for any reason.

12.5. Accrued Rights. Surviving Obligations.

Termination of the Agreement for any reason shall be without prejudice to any Party's obligations which shall have accrued prior to such termination, including, without limitation, the payment obligations under Article V hereof or to the remedy, in accordance with the terms herein, of either Party hereto in respect of any previous breach on any covenant contained herein. Such termination shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of the Agreement.

12.6. Termination Not Sole Remedy.

Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE XIII -INDEMNIFICATION

13.1. ANIKA shall indemnify, defend and hold harmless OBI, and any Affiliates of OBI, together with their respective officers and directors, from and against any and all losses (except consequential losses, such as, for example, loss of business profits) including compensatory losses for personal injury, damages, liabilities, costs and expenses, including without limitation reasonable attorney's fees, arising out of or in connection with:

- (a) the breach of any of ANIKA's representations and warranties made in Section 9.1;
- (b) the breach by ANIKA of any of its obligations, covenants or undertakings hereunder;
- (c) any Licensed Product recall for which ANIKA is required to bear all costs and expenses pursuant to Section 6.9(d); and
- (d) any act or omission of ANIKA in connection with the design, development, manufacture, packaging, testing, warehousing or handling of the Licensed Product;
- (e) any infringement or alleged infringement of a Third Party's patent rights resulting solely from the manufacture of any Licensed Product other than Modified Licensed Products.

13.2. OBI shall indemnify, defend and hold harmless ANIKA and any Affiliates of ANIKA, together with their respective officers and directors, from and against any and all losses (except consequential losses, such as, for example, loss of business or of profits) including compensatory losses for personal injury, damages, liabilities, costs and expenses, including without limitation reasonable attorney's fees, arising out of or in connection with:

- (a) the breach of any of OBI's representations and warranties made hereunder;
- (b) the breach by OBI of any of its obligations, covenants or undertakings hereunder;
- (c) any claim made by OBI, its distributors, sublicensees or Affiliates, as to the safety or effectiveness of the Licensed Product or the use to be made of the Licensed Product by any purchaser of Licensed Product, contained in any advertising or other promotional material created and disseminated by OBI, its distributors, sublicensees or Affiliates, to the extent that such claim (A) is not supported by the Licensed Product label and package insert as approved by the FDA (or, in Mexico, the appropriate governmental body having authority to approve the Licensed Product, label, and package insert for marketing in Mexico) and (B) was not approved in advance by ANIKA;
- (d) any other act or omission of the OBI, its distributors, sublicensees or Affiliates, in connection with the marketing, promotion, and sale of Licensed Product, including the storage,

handling and distribution by OBI, its distributors, sublicensees or Affiliates of the Product, other than as contemplated by this Agreement or the provisions of the PMA;

(e) any product recall for which OBI is required to bear all costs and expenses pursuant to Section 6.9(d); and

(f) OBI's, its Affiliates', distributors' or sublicensees' use, sale or disposition of Licensed Products where such Licensed Products incorporate changes made by OBI, its Affiliates, distributors, or sublicensees, to the Specifications or packaging which ANIKA has not approved, or changes made by OBI, its Affiliates, distributors or sublicensees to any Regulatory Application with respect to Licensed Product which ANIKA has not approved.

13.3. The Parties agree that in the event of a loss for which it is determined under this Article XIII that both Parties bear a measure of responsibility, it is the intent of both Parties that the liability for the loss (including without limitation all damages, hard costs and expenses, together with reasonable attorney's fees) be apportioned among the Parties according to their respective measures of responsibility, as that responsibility is determined according to this Section 13.3. The Parties further agree that any portion of the loss not attributable to either party under this Section 13.3 (and not otherwise recoverable from a third party or its insurer) shall be borne equally among the Parties. For example, the Party determined to be 10% responsible under Article XIII pays 10% of the loss, the Party determined to be 60% responsible pays 60% of the loss, and each Party pays one-half of the remaining 30%. Within ten (10) business days after either Party so requests, the Steering Committee shall convene to develop an equitable apportionment of liability for the loss according to this Article XIII. If the Steering Committee fails to agree on an apportionment within twenty (20) days after meeting, either Party may submit the matter to arbitration under this Article XIV.

13.4. Notwithstanding anything contained in this Agreement to the contrary, the Parties expressly agree that ANIKA shall have no liability to OBI under this Article XIII for claims, losses, or liability of any kind based upon or related to:

(a) OBI's, its Affiliates', distributors', sublicensees' use, sale or disposition of Licensed Products where such Licensed Products incorporates changes made by OBI, its Affiliates, distributors or sublicensees to the Specifications or packaging which ANIKA has not approved, or changes made by OBI, its Affiliates, distributors or sublicensees, to any Regulatory Application with respect to Licensed Product which ANIKA has not approved;

(b) sale or disposition of Licensed Products by OBI, its Affiliates, distributors or sublicensees for any use other than the uses specified by the accompanying package inserts;

(c) use, sale or disposition of Licensed Products by OBI, its Affiliates, distributors or sublicensees in combination with devices or Licensed Products not purchased hereunder, where such combined sale or disposition is the sole cause of an infringement claim and whereas such Licensed Products would not themselves be infringing;

(d) sale or disposition of Licensed Products by OBI, its Affiliates, distributors or sublicensees in or for an application or environment for which such Licensed Products were not approved by the FDA or other applicable government or regulatory agency; or

(e) modifications of Licensed Products by OBI, its Affiliates, distributors or sublicensees ;

to the extent such uses, sales, dispositions or modifications give rise to the claim, loss or liability and have not been approved by ANIKA.

13.5. Notwithstanding anything contained in this Agreement to the contrary, the Parties expressly agree that OBI shall have no liability to ANIKA under this Section for claims, losses or liability of any kind based upon or related to:

(a) the design, manufacturing, packaging, sterilization, testing, warehousing and handling of the Product by ANIKA through delivery to the common carrier for shipment to the Shipping Point;

(b) ANIKA's use, sale or disposition of Licensed Products where such Licensed Products incorporate changes made by ANIKA to the Specifications which OBI has not approved;

(c) sale or disposition of Licensed Products by ANIKA for any use other than the uses specified by the accompanying package inserts;

(d) sale or disposition of Licensed Products by ANIKA in or for an application or environment for which such Licensed Products were not approved by the FDA or other applicable government or regulatory agency; or

(e) modification of Licensed Products by ANIKA which OBI has not approved and as to which OBI has the right to approve under this Agreement;

to the extent such activities, uses, sales, dispositions or modifications give rise to the claim, loss or liability and have not been reviewed or approved by ANIKA.

13.6. If OBI or ANIKA intends to claim indemnification under this Section, such Party (the "Claiming Party"), shall (i) promptly notify the other Party in writing of any claim or loss for which it intends to claim such indemnification, (ii) cooperate fully with the other Party and its legal representatives in the investigation of any claim or loss covered by this Section, and (iii) allow the other Party to control the defense and/or disposition of such suit or claim; provided that the Claiming Party shall have the right to participate at its own expense through counsel of its own choosing. Neither Party shall have any indemnification obligations hereunder to the extent that such Party's ability to defend such suit or redress such loss is prejudiced by the Claiming Party's failure to perform the obligations set forth in the preceding sentence. No claim shall be settled for which any Indemnifying Party shall be liable without the advance written consent of both the indemnifying Party and the Claiming Party, which consent shall not be unreasonably withheld.

ARTICLE XIV -ADDITIONAL APPLICATIONS AND INDICATIONS

14.1. OBI First Right of Refusal.

(a) ANIKA hereby grants to OBI a right of first refusal, as described in this Section 14.1, to obtain rights to any new HA-based products derived from ANIKA's R&D Pipeline, which are solely owned by ANIKA, acquired by or licensed to ANIKA (provided ANIKA has rights to sublicense to others thereunder) and developed for human use in the treatment of osteoarthritis, (collectively referred to as the "ANIKA Potential Products").

(b) If at any time during the development of ANIKA Potential Products, ANIKA determines in its sole discretion to seek a license, distribution and/or development partner, ANIKA shall promptly notify OBI and shall supply to OBI all available relevant information and data related thereto as is reasonably necessary for OBI to make an informed decision of its interest in obtaining license or distribution rights to the ANIKA Potential Product and to develop a proposal for the commercial terms for such rights. The date of such notification is hereinafter referred to as the "ANIKA Disclosure Date." OBI shall have sixty (60) days from the ANIKA Disclosure Date to review the ANIKA Potential Product and to determine if it wishes to negotiate distribution or licensing arrangements with respect to such ANIKA Potential Product. During such period, OBI may request that ANIKA provide OBI with additional information and data which OBI reasonably considers relevant to OBI's consideration of the ANIKA Potential Product, and ANIKA shall provide such additional information at OBI's expense, but only to the extent such information is in existence and easily accessed. If OBI does not wish to pursue negotiations for the distribution or license of such ANIKA Potential Product and OBI so notifies ANIKA, or if such sixty (60) day period expires without OBI notifying ANIKA as to its interest, then ANIKA shall be free to enter into an agreement with a Third Party as to that ANIKA Potential Product, as ANIKA shall determine at its sole discretion, without any further restriction or obligation to OBI.

(c) If prior to the expiration of the sixty (60) day period referred to in Section 14.1(b) OBI expresses in writing its interest in obtaining the right to distribute or license the ANIKA Potential Product, the Parties shall enter into good faith negotiations regarding the right to

distribute or license such ANIKA Potential Product within the one hundred eighty (180) day period immediately following the ANIKA Disclosure Date. If at the end of such one hundred eighty (180) day period the parties are unable to reach a definitive agreement, and ANIKA does not wish to continue the negotiations, as ANIKA shall determine at its sole discretion, ANIKA shall be free to enter into an agreement with any Third Party without any further restriction or obligation to OBI, except that it may not enter into an agreement with a Third Party on terms less favorable to ANIKA than those terms offered to ANIKA by OBI.

14.2. ANIKA First Right of Refusal.

(a) OBI (and its Affiliates) hereby grants to ANIKA a right of first refusal, as described in this Section 14.2, to manufacture any new HA-based products solely owned by OBI and/or its Affiliates or licensed to OBI and/or its Affiliates, provided, so long as, in the case of and such licensed products, OBI and/or its Affiliates has no obligations to use another manufacturer as part of its license obligations (collectively referred to as the "OBI Potential Products").

(b) If at any time during the development of OBI Potential Products, OBI or an Affiliate determines in its sole discretion to seek a supplier or manufactures for OBI Potential Products, OBI shall promptly notify ANIKA and shall supply to OBI all available relevant information and data related thereto as is reasonably necessary for ANIKA to make an informed decision of its interest in supplying and/or manufacturing the OBI Potential Product and to develop a proposal for the commercial terms for such supply rights. The date of such notification is hereinafter referred to as the "OBI Disclosure Date." ANIKA shall have sixty (60) days from the OBI Disclosure Date to review the OBI Potential Product and to determine if it wishes to negotiate supply and/or manufacturing arrangements with respect to such OBI Potential Product. During such period, ANIKA may request that OBI provide ANIKA with additional information and data which ANIKA reasonably considers relevant to ANIKA's consideration of the OBI Potential Product, and OBI and its Affiliates shall provide such additional information at ANIKA's expense, but only to the extent such information is in existence and easily accessed. If ANIKA does not wish to pursue negotiations for supply of such OBI Potential Product and ANIKA so notifies OBI, or if such sixty (60) day period expires without ANIKA notifying OBI as to its interest, then OBI or an Affiliate shall be free to enter into an agreement with a Third Party as to that OBI Potential Product, as OBI shall determine at its sole discretion, without any further restriction or obligation to ANIKA.

(c) If prior to the expiration of the sixty (60) day period referred to in Section 14.2(b) ANIKA expresses in writing its interest in obtaining the right to supply the OBI Potential Product, the Parties shall enter into good faith negotiations regarding the supply and/or manufacturing of such OBI Potential Product within the one hundred eighty (180) day period immediately following the OBI Disclosure Date. If at the end of such one hundred eighty (180) day period, the Parties are unable to reach a definitive agreement, and OBI does not wish to continue the negotiations, as OBI shall determine at its sole discretion, OBI or an Affiliate shall be free to enter into an agreement with any Third Party without any further restriction or obligation to ANIKA, except that it may not enter into an agreement with a Third Party on terms

less favorable to OBI and its Affiliates than those terms offered to OBI and its Affiliates by ANIKA.

ARTICLE XV -STEERING COMMITTEE

(a) OBI and ANIKA shall establish a Steering Committee (the "Steering Committee") consisting of four (4) members. Each of OBI and ANIKA shall appoint two (2) individuals to serve on the Steering Committee.

(b) Within thirty (30) days after the execution and delivery of this Agreement by both Parties, ANIKA and OBI shall each appoint its initial representatives to serve on the Steering Committee. Each Party may change its representatives upon notice to the other Party.

(c) The Steering Committee shall be chaired by one representative of either ANIKA or OBI for each successive twelve (12) month period during the Term of this Agreement, and the chair shall alternate between the Parties. During the first twelve (12) month period, the Steering Committee shall be chaired by a representative of OBI.

(d) The Steering Committee shall meet at least two (2) times each year during the Term of this Agreement, at such dates and times as agreed to by the Parties, with the intention that the meetings should occur at least once during each Calendar Quarter. Meetings in person shall alternate between the offices of the Parties or such other place as may be mutually agreed upon by the Parties. The Steering Committee may also convene or be polled or consulted from time to time by means of telecommunications or correspondence, and members will be deemed "present" at "meetings" for purposes of this Article 15 if participating by such means. All decisions made or actions taken by the Steering Committee shall require the affirmative vote of a majority of its entire membership. A quorum for a meeting shall require at least one ANIKA member and at least one OBI member.

(e) The duties and responsibilities of the Steering Committee shall include: (i) reviewing and commenting on any Development being conducted by OBI; (ii) reviewing and commenting on development relating to Ot1hovisc® being conducted by ANIKA outside the Territory; (iii) review and comment on marketing and sales activities being carried out by OBI in the Territory including trademark and website issues, including review of an annual marketing plan; (iv) review and comment on marketing and sales activities being conducted by ANIKA outside the Territory; (v) discussing issues concerning whether to file for Regulatory Approval and/or launch the Licensed Product in Mexico; and (vi) review and discuss any manufacture and supply issues that may arise. In connection with any meeting of the Steering Committee, the Parties will endeavor to provide to the other Party all materials in connection with this Article XV(e) at least five (5) Business Days in advance of such meeting.

ARTICLE XVI -DISPUTE RESOLUTION.

16.1. Dispute Resolution and Arbitration.

In the case of any Disputes (as defined below) between the Parties arising from this Agreement, and in case this Agreement does not provide a solution for how to resolve such disputes, the Parties shall endeavor to discuss and negotiate in good faith towards a solution acceptable to both Parties and in the spirit of this Agreement. If the Parties fail to reach agreement within sixty (60) days, then the President of ANIKA and the President of OBI shall discuss in good faith an appropriate resolution to the dispute. If these executives fail to reach an amicable agreement within sixty (60) days, then either Party may upon written notice to the other submit the dispute to binding arbitration pursuant to Section 16.2.

16.2. Arbitration.

Any claim, dispute or controversy arising out of or in connection with or relating to this Agreement, (including, without limitation, disputes with respect to the rights and obligations of the Parties following termination) (a "Dispute") not settled by the procedures set forth in Section 16.1 above shall be adjudicated by arbitration in accordance with the Arbitration Proceedings as set forth in Exhibit B attached hereto.

ARTICLE XVII -HSR FILING

17.1. To the extent, that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof in accordance with applicable Laws with any Governmental Authority with regulatory jurisdiction over enforcement of any applicable Competition Laws ("Governmental Antitrust Authority"), including without limitation the U.S. Federal Trade Commission Bureau of Competition ("FTC") and the U.S. Department of Justice Antitrust Division ("DOJ"), such Party may do so. Without limiting the foregoing, the Parties agree to make all necessary HSR Filings, if any, within seven (7) business days after the Effective Date. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any filing with any Governmental Antitrust Authority, including any HSR Filing.

17.2. Subject to appropriate confidentiality protections, the Parties shall work cooperatively in connection with obtaining the requisite approvals, consents or orders of each applicable Governmental Antitrust Authority necessary for the consummation of the transactions contemplated by this Agreement, and shall keep each other apprised of the status of matters relating to the obtainment of such approvals, consents or orders, including:

- (i) cooperating with each other in connection with HSR Filings and filings under any foreign investments Laws or any other Competition Laws;
- (ii) furnishing to the other Party all information within its possession that is required for any HSR Filing or any application or other filing to be made by the other

party pursuant to any foreign investment laws or any other Competition Laws in connection with the transactions contemplated by this Agreement;

(iii) promptly notifying each other of any communications from or with any Governmental Antitrust Authority with respect to the transactions contemplated by this Agreement;

(iv) promptly providing to the other Party copies of all communications with any Governmental Antitrust Authority relating to the transactions contemplated by this Agreement, or relating to any of the matters described in this Article XVII;

(v) not participating in any meeting or discussion with any Governmental Antitrust Authority in connection with proceedings under or relating to the HSR Act, any foreign investment laws or any other antitrust laws unless it consults with the other Party in advance, and, to the extent permitted by such Governmental Antitrust Authority, gives the other Party the opportunity to attend and participate thereat; and

(vi) consulting and cooperating with one another in connection with all analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any Party hereto in connection with proceedings under or relating to the HSR Act, any foreign investment laws or any other competition laws.

17.3. The Parties agree to request early termination of the applicable waiting period under the HSR Act in any HSR Filing. Each Party shall use its commercially reasonable best efforts to secure termination of any waiting periods under the HSR Act or other applicable law, to certify as soon as practicable its substantial compliance with any requests for additional information or documentary material that may be made under the HSR Act, and/or to obtain the approval of any Governmental Antitrust Authority of the transactions contemplated by this Agreement, including without limitation promptly providing information and documents requested by any Governmental Antitrust Authority and entering into good faith negotiations with any Governmental Antitrust Authority to enter into a consent decree or other arrangement to secure termination of such waiting periods or to obtain such approval (provided, however, that nothing in this Article XVII shall prevent, or be construed to prevent, either Party from agreeing to extend the waiting period under the HSR Act in connection with good faith settlement negotiations with the DOJ or FTC).

17.4. As used in this Article, the following terms have the following meanings:

(a) "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rule and regulations promulgated thereunder.

(b) "HSR Filing" means filings by ANIKA and OBI with the FTC and the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

- (c) "HSR Clearance Date" means the earlier of
 - (i) the date on which the FTC shall notify OBI and ANIKA of early termination of the applicable waiting period under the HSR Act, or
 - (ii) the day after the date on which the applicable waiting period under the HSR Act expires; or
 - (iii) the day after the date on which the seven (7) Business Day period referred to in Section 17.1 expires if no HSR Filings have been filed by that date.

17.5. The licenses granted pursuant to Articles III, IV and VIII shall not be effective until the HSR Clearance Date. In the event that an HSR Filing is required and either:

- (a) the FTC and/or the DOJ shall seek a preliminary injunction under the HSR Act against ANIKA and OBI to enjoin the transactions contemplated by this Agreement; or
- (b) the HSR Clearance Date shall not have occurred on or prior to June 1, 2004;

this Agreement may be terminated by either Party upon one (1) week written notice (such termination to be deemed a termination pursuant to Section 12.2).

ARTICLE XVIII -MISCELLANEOUS

18.1. Relationship of Parties.

For the purposes of this Agreement, each Party is an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized in writing.

18.2. Counterparts.

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

18.3. Headings.

All headings in this Agreement are for convenience only and shall not affect the meaning of any provision hereof.

18.4. Binding Effect.

This Agreement shall inure to the benefit of and be binding upon the Parties and their respective lawful successors and assigns.

18.5. Assignment.

Neither Party may assign or transfer this Agreement or its rights and obligations under this Agreement without the prior written consent of the other Party, except to its Affiliates, which consent may be given or withheld in its sole discretion, and any such assignment or transfer shall be null and void and entitle the non-assigning party to terminate this Agreement forthwith. Notwithstanding the foregoing, either Party must assign this Agreement (and shall be permitted to do so without the consent of the other Party) in connection with the sale of all or substantially all of its assets (whether by merger, consolidation or otherwise); provided, however, that in no event shall any such assignment release either Party from its responsibilities under this agreement unless the assignee has agreed in writing to assume all of the obligations of assignor hereunder.

18.6. Amendment and Waiver.

This Agreement may be amended, supplemented, or otherwise modified at any time, but only by means of a written instrument signed by both Parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

18.7. Governing Law.

This Agreement and the legal relations among the parties shall be governed by and construed in accordance with the laws of the State of New York, USA, irrespective of any choice of laws or conflict-of-law principles.

18.8. Severability.

In the event that any provision of this Agreement shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein.

18.9. Entire Agreement.

This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous oral and prior written agreements and understandings.

18.10. Advice of Counsel.

OBI and ANIKA have each consulted counsel of their choice regarding this Agreement, and each acknowledges and agrees that this Agreement shall not be deemed to have been drafted by one party or another and will be construed accordingly.

18.11. Force Majeure.

Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure or delay of performance by the defaulting Party if the failure or delay is occasioned by (i) any fire, explosion, unusually severe weather, natural disaster or Act of God (except for any fire or explosion that could reasonably have been prevented by ANIKA); (ii) epidemic; any nuclear, biological, chemical, or similar attack; any other public health or safety emergency; any act of terrorism; and any action reasonably taken in response to any of the foregoing; (iii) any act of declared or undeclared war or of a public enemy, or any riot or insurrection; (iv) any disruption in transportation, communications, electric power or other utilities, or other vital infrastructure; or any means of disrupting or damaging internet or other computer networks or facilities; (v) any strike, lockout or other labor dispute or action; (vi) any action taken in response to any of the foregoing events by any civil or military authority; or (vii) any other event beyond such Party's control, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance. Notwithstanding the foregoing, this Section 18.11 shall not operate to relieve either Party from performance of any obligation for more than ninety (90) days.

18.12. Further Actions.

Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

18.13. No Trademark Rights.

Except as otherwise explicitly provided herein, no right, express or implied, is granted by the Agreement to use in any manner the name "ANIKA" or "OBI", or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of the Agreement.

18.14. Notices.

All notices hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), email (receipt acknowledged), mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following address (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof).

Ifto ANIKA,

addressed to:

ANIKATHERAPEUTICS INC.
160 New Boston Street
Woburn, MA 01801
Attention: Chief Executive Officer
Facsimile: (781) 932-3360
Email: csherwood@anikatherapeutics.com

With a copy to:

Goodwin Procter LLP
Exchange Place
Boston, MA 02109
Attention: H. David Henken, P.C.
Facsimile: (617) 523-1231
Email: dhenken@goodwinprocter.com

Ifto OBI:

addressed to:

Ortho Biotech Products, L.P.
430 Route 22 East
P.O. Box 6914
Bridgewater, NJ 08807-0914
Attention: President
Facsimile: 908-529-4365
Email: jhjolms@obius.jnj.com

With a copy to:

Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Facsimile: 732-524-2788
Email: pjohnson@corus.jnj.com

Each of the Parties consent to the personal jurisdiction of the U.S. Federal Courts and agree to accept any legal process served upon such Party at the addresses specified above for such Party.

18.15. Waiver.

Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

18.16. Bankruptcy.

All rights and licenses granted under or pursuant to this Agreement by each Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101(60) of the Bankruptcy Code. The parties agree that OBI shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The licensor agrees, during the term of this Agreement, to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such intellectual property. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against it under the Bankruptcy Code, the licensee shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and all embodiments of such intellectual property, and same, if not already in its possession, shall promptly be delivered to licensee (a) upon such commencement of a bankruptcy proceeding upon written request therefore by licensee, unless licensor elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of licensor upon written request therefore by licensee.

18.17. Compliance with Environment, Safety And Industrial Hygiene .

With respect to all environmental, safety and industrial hygiene matters related to ANIKA's activities under this Agreement, ANIKA shall (i) comply with all applicable laws and regulations issued by national, state and local authorities, (ii) allow OBI to inspect ANIKA's facilities, such inspections to be at reasonable times and upon reasonable notice, and (iii) implement corrective action which may be reasonably requested by OBI to correct any violations of laws or regulations regarding environmental, safety and industrial hygiene

18.18. Child Labor Employment Practices.

ANIKA agrees to comply with the following PPC Corporate Policy relating to the Employment of Child Labor:

(a) No person under the age of 16 shall be employed, and no other young person (under age of 18) shall be employed unless such employment is in compliance with the International Labor Organizations Convention 138 Concerning Minimum Age;

(b) No young person (under age 18) shall be required to work more than 48 regular hours and 12 hours overtime per week nor more than six (6) days per week; and

(c) No young person (under age 18) shall be employed unless such employment is in compliance with all applicable laws and regulations concerning, age, hours, compensation, health and safety.

IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Agreement as a sealed instrument effective as of the date first above written.

ORTHO BIOTECH PRODUCTS, L.P.

BY: Ortho Biotech Inc., its general partner

BY: *Is/* John Johnson
John Johnson, President

DATE: December 20, 2003

ANIKA THERAPEUTICS, INC.

By: *Is/* Charles H. Sherwood
Charles H. Sherwood, Ph.D., President and CEO

DATE: December 20, 2003

EXHIBIT A PRODUCT SPECIFICATIONS

Orthovisc Specifications

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EXHIBIT B
ARBITRATION

Any controversy or claim arising out of or relating to this Agreement shall be resolved by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining (available at www.adr.org) except where those rules conflict with this provision, in which case this provision controls. Any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitrator shall be selected within twenty business days from commencement of the arbitration from the AAA's National Roster of Arbitrators pursuant to agreement or through selection procedures administered by the AAA. Within 45 days of initiation of arbitration, the parties shall reach agreement upon and thereafter follow procedures, including limits on discovery, assuring that the arbitration will be concluded and the award rendered within no more than six months from selection of the arbitrator or, failing agreement, procedures meeting such time limits will be designed by the AAA and adhered to by the parties. In connection with the arbitration proceeding, the arbitrator shall order the prompt exchange of relevant documents by each party; each party may take up to two depositions as of right, and the arbitrator may in his or her discretion allow additional depositions upon good cause shown by the moving party; however, the arbitrator shall not have the power to order the answering of interrogatories or the response to requests for admission. In connection with any arbitration, each party shall provide to the other, no later than fourteen (14) days before the date of the arbitration, the identity of all persons that may testify at the arbitration and a copy of all documents that may be introduced at the arbitration or considered or used by a party's witness or expert. The arbitration shall be held in Boston, MA and the arbitrator shall apply the substantive law of New York, except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. From the date of initiation of arbitration and until such time as any matter has been finally settled by arbitration, the running of the time periods contained in Article VII as to which Party must cure a breach of this Agreement shall be suspended as to the subject matter of the dispute. Prior to commencement of arbitration, emergency relief is available from any court to avoid irreparable harm. **THE ARBITRATOR SHALL NOT AWARD EITHER PARTY PUNITIVE, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES, OR ATTORNEYS FEES OR COSTS.**

Prior to commencement of arbitration, the parties must attempt to mediate their dispute using a professional mediator from AAA, the CPR Institute for Dispute Resolution, or like organization selected by agreement or, absent agreement, through selection procedures administered by the AAA. Within a period of 45 days after the request for mediation, the parties agree to convene with the mediator, with business representatives present, for at least one session to attempt to resolve the matter. In no event will mediation delay commencement of the arbitration for more than 45 days absent agreement of the parties or interfere with the availability of emergency relief.

EXHIBIT C

FORM OF PRESS RELEASE

DRAFT 12/18/03

FOR IMMEDIATE RELEASE

Contacts:

Anika Therapeutics, Inc.

Charles Sherwood, Ph.D., CEO
William Knight, CFO
(781) 932-6616

Pondei/Wilkinson Klein

Susan Klein (508) 358-4315
Rob Whetstone (323) 866-6050

ANIKA THERAPEUTICS ANNOUNCES U.S. ORTHOVISC® LICENSE AND SUPPLY AGREEMENT WITH ORTHO BIOTECH PRODUCTS, L.P.

WOBURN, MA- December 22, 2003- Anika Therapeutics, Inc. (NASDAQ:ANIK) today announced the signing of an exclusive, multi-year U.S. licensing and supply agreement with Ortho Biotech Products, L.P. for Anika's ORTHOVISC®, a highly purified, high molecular weight form of hyaluronic acid for treating pain in patients suffering from osteoarthritis of the knee.

Under the agreement, Anika will receive an initial payment of \$2 million and payments upon receipt of final marketing approval for ORTHOVISC from the U.S. Food and Drug Administration (FDA), and other milestones. Earlier this month, Anika announced that it had received a letter from the FDA stating that an approval order will be issued for ORTHOVISC subject to a successful inspection of Anika's manufacturing facility. In addition, Ortho Biotech will fund post-marketing clinical trials for ORTHOVISC and development of future products based on Anika's proprietary viscosupplementation technology. The agreement covers the U.S. and Mexico. The effectiveness of certain of the license provisions under the agreement may be subject to customary regulatory approvals, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

Anika Chief Executive Officer Charles H. Sherwood, Ph.D., said Anika selected Ortho Biotech as its U.S. marketing partner for ORTHOVISC due to its outstanding reputation for high quality products and customer service. "Ortho Biotech is known for its strategy aimed at becoming a leader in the markets it chooses to address. We

believe the company is an excellent partner for driving ORTHOVISC sales and penetrating the U.S. market for viscosupplementation."

Designed to relieve pain and stiffness and improve joint mobility, ORTHOVISC has been marketed outside of the United States since 1996. It is currently sold in Canada and various European and Middle Eastern nations. The U.S. market for viscosupplementation products is growing, with more than 10 million Americans suffering from osteoarthritis of the knee.

About Ortho Biotech Products, L.P. (www.orthobiotech.com)

In 1990, Ortho Biotech Products, L.P. was established in Raritan, N.J., as the first biotechnology subsidiary of Johnson & Johnson. Since that time, Ortho Biotech and its worldwide affiliates have earned a global reputation for researching, manufacturing and marketing innovative health care products that extend and enhance the quality of patients' lives. Ortho Biotech, the established market leader in Epoetin alfa therapy for anemia management across multiple indications, focuses its research and marketing efforts in four clinical areas: oncology, nephrology, immunology and critical care/surgery.

About Anika Therapeutics, Inc. (www.anikatherapeutics.com)

Headquartered in Woburn, Mass., Anika Therapeutics, Inc. develops, manufactures and commercializes therapeutic products and devices intended to promote the repair, protection and healing of bone, cartilage and soft tissue. These products are based on hyaluronic acid (HA), a naturally occurring, biocompatible polymer found throughout the body. In addition to ORTHOVISC®, a treatment for osteoarthritis of the knee (not approved for sale in the U.S.), Anika markets HYVISC® in the U.S. for the treatment of equine osteoarthritis through Boehringer Ingelheim Vetmedica, Inc. and manufactures AMVISC® and AMVISC® Plus, HA viscoelastic products for ophthalmic surgery, for Bausch & Lomb. It also produces CoEase™, which is marketed by Advanced Medical Optics, Inc., STAARVISC™11 distributed by STAAR Surgical Company and ShellGel™ for Cytosol Ophthalmics, Inc.

The statements made in this press release which are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements that may be identified by words such as "expectations," "remains," "focus," "expected," "prospective," "expanding," "building," "continue," "progress," "efforts," "hope," "believe," "objectives," "opportunities," "will," "seek," and other expressions which are predictions of or indicate future events and trends and which do not constitute historical matters identify forward-looking statements. The statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties. The Company's actual results could differ materially from any anticipated future results,

performance or achievements described in the forward-looking statements as a result of a number of factors, including: the results of its research and development efforts and timing of regulatory approvals; approval and commercialization of the Company's products, and, with respect to Orthovisc, risks relating to the ability of the Company to successfully address the requests of the FDA in the approvable seller and the timing of the Company's efforts to do so, as well as the timing of any approved order; and that the Company's new licensing and supply arrangements will not result in meaningful sales or will be terminated at an earlier date in accordance with its terms or that any of the milestones contained in the Company's new licensing and supply agreements will be achieved. There can be no assurances that the Company's increased unit sales will materially increase product revenue or improve gross margins. Certain other factors that might cause the Company's actual results to differ materially from those in the forward-looking statements include those set forth under the headings "Business," "Risk Factors and Certain Factors Affecting Future Operating Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in each of the Company's Annual Report on Form 10-K for the year ended December 31, 2002, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and Current Reports on Form 8-K, as well as those described in the Company's other press releases and SEC filings.

#

EXHIBITD

ANIKA's Insurance Requirements

1.0 Definitions

"ANIKA"

2.0 Insurance Requirements

ANIKA shall procure and maintain, at all times, and at its own expense, until final completion of the work covered by the contract, and during the time period following the final completion if ANIKA is required to return and perform additional work, for any reason whatsoever, the types of insurance(s) specified below.

A. Commercial General Liability

ANIKA shall provide coverage on a Commercial General Liability Occurrence Coverage Form (or equivalent) with limits of not less than \$1,000,000 each occurrence, \$1,000,000 products/completed operations aggregate, \$1,000,000 personal injury/advertising injury aggregate and \$2,000,000 general aggregate. ANIKA will endeavor to inform OBI of any exclusions or amendments to the policy form which would result in direct impact to OBI. ANIKA's policy shall be specifically endorsed with Chubb Form to include OBI, its subsidiaries, and its directors, officers and employees, as an Additional Insured, as respects negligence caused by ANIKA as a result of this Agreement. ANIKA shall supply OBI with the above proof of insurance and forms as required upon the signing of this Agreement, but OBI's failure to demand such proof or forms shall not waive OBI's rights to such coverage as specified herein.

B. Automobile Liability

ANIKA shall provide coverage on a Business Auto Policy Form (or equivalent) for hired and non-owned automobiles with a limit of liability in an amount no less than \$1,000,000 each accident.

C. Workers' Compensation

ANIKA shall provide Workers' Compensation Form (or equivalent) in accordance with the laws of the State of MA, and any other applicable jurisdiction, covering all employees who are to provide service under this Agreement. Employers' Liability coverage is required with limits of not less than the following:

Bodily Injury by Accident.....	\$500,000 Each Accident
Bodily Injury by Disease.....	\$500,000 Each Employee
Bodily Injury by Disease.....	\$500,000 Policy Limit

D. Excess Liability

ANIKA shall provide Umbrella Liability coverage with a limit of liability no less than \$5,000,000 each occurrence, \$5,000,000 aggregate.

E. Miscellaneous

All insurance companies must be authorized to do business in the States where business is being transacted covering all operations under this Agreement. All insurance companies must be rated A or better with a financial rating of VII or better in the most recent *A. M. Best's Rating Guide*.

All insurers will endeavor to provide for thirty (30) days' prior written notice to OBI of cancellation.

Certificates of insurance for all required coverages shall be provided to OBI prior to commencement of any work on the project.

EXHIBIT E
QUALITY AGREEMENT

QUALITY AGREEMENT

between

Pharmaceutical Sourcing Group Americas (PSGA),
A Johnson & Johnson Company,

and

Anika Therapeutics

EFFECTIVE DATE: mm/yy / REPLACES: New

QUALITY AGREEMENT

21 CFR Sec. 820.50 (Purchasing controls) of the Quality System Regulation states "Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements."

Toward this end, the purpose of this Agreement is to ensure a mutual understanding of key responsibilities to assure that those Pharmaceutical Sourcing Group Americas (PSGA) products manufactured by Anika Therapeutics, Inc., are produced according to specifications and comply with all governing regulations and corporate policies. *It is acknowledged that this will be a continuously evolving process.*

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1. Main Contacts:

PSGA:

Name: Joseph Crea

Title: Director, Quality Assurance, External Manufacturing

Telephone: (609) 730 2879

FAX: (609) 730 3591

e mail: jcrea@psgus.jnj.com

Name: Linda Bryant

Title: Vice President, Quality Assurance Pharmaceuticals

Telephone: (908)707 3330

FAX: (908) 725 4249

e mail: lbryant@psgus.jnj.com

Anika Therapeutics:

Name: Frank Luppino

Title: Vice President- Operations

Telephone: 781-932-6616 x136

FAX: 781-932-3360

e-mail: fluppino@anikatherapeutics.com

2. Objectives:

- 2.1 To document the responsibilities of Anika Therapeutics and Pharmaceutical Sourcing Group Americas (PSGA) associated with the manufacture, packaging, testing, storage, and release of product.
- 2.2 To ensure a mutual understanding of key responsibilities, to ensure PSGA products are produced according to agreed upon specifications, and to ensure compliance with all applicable governing regulations and corporate policies.
- 2.3 It is acknowledged that this will be a continuously evolving process and that this Quality Agreement may be amended with concuiTence from both parties as necessary.

3. Scope:

- 3.1 This agreement applies to the product(s) and locations listed below:

Product(s): ORTHOVISC®

Location(s): 236 West Cummings Park, Woburn, MA 01801

- 3.2 Any external manufacturing or packaging services provided for PSGA by an outside facility must conform at a minimum to the Quality Agreement terms and conditions. Anika Therapeutics is cunently being contracted to provide these services. This Quality Agreement is being implemented to delineate the PSGNAnika Therapeutics quality objectives and responsibilities.
- 3.3 This document constitutes a Quality Agreement only and is not intended to represent a purchase contract. The Quality Agreement does not represent or replace the Manufacturing and Supply Agreement or any other agreement and/or amendment(s) thereto between Anika Therapeutics and PSGA.

4. Definitions:

- 4.1 EDA: United States Food and Drug Administration or any successor entity (CBER-CDER).
- 4.2 PMA: Pre-market approval
- 4.3 QSR's: Quality System Regulation, covering medical device good manufacturing practices as defined in the regulations promulgated under the Food, Drug, & Cosmetic Act (FDCA) 21 CFR Part 820.

- 4.4 Products: Those products in Section 3.
- 4.5 Responsibility: These abbreviations will be used to identify the responsibilities outlined in Section 21.
 - 4.5.1 A= Audit
 - 4.5.2 R = Primary Responsibility
 - 4.5.3 D = Ultimate Decision Maker
 - 4.5.4 S = Shared Responsibility
- 4.6 Specifications:
 - 4.6.1 Master Formula
 - 4.6.2 Test Methods
 - 4.6.3 Product (WIP (Work in-process)/Finished) Requirements
 - 4.6.4 Standard Operating Procedures (SOPs)
 - 4.6.5 Labels & labelling
- 4.7 Product Terms:
 - 4.7.1 Bulk: Product stored in containers (dmms, vessels, portable kettles etc.)
 - 4.7.2 Work in Process (WIP): Product processed into its primary container needing further processing and/or packaging.
 - 4.7.3 Finished Product: Product completely packaged and in its final stage. No further processing and/or packaging is required.
- 4.8 Non-Conformance: Any deviation from a specification as defined in Section 4.6.

s. Regulatory / QSR:

- 5.1 Unless other wise specified, all information and documentation from Anika Therapeutics shall be provided to the PSGA QA contacts designated in Section 1 or their designee.
- 5.2 Anika Therapeutics shall manufacture, test, label, package, and store ORTHOVISC® in compliance with the QSR.
- 5.3 EMA:
 - 5.3.1 Anika Therapeutics shall provide PSGA with copy of the annual report to the FDA not later than thirty (30) days from established dates.
- 5.4 GMP Audits:

- 5.4.1 For auditing purposes, PSGA will be granted full access to the Anika Therapeutics facility (except restricted areas) used for manufacturing, filing, packaging, testing, and storage of ORTHOVISC®.
- 5.4.2 PSGA will provide Anika Therapeutics at least two weeks notification prior to scheduling an audit of the Anika Therapeutics facility.
- 5.4.3 The Anika Therapeutics response to any audit report findings must be received by PSGA within 30 days of receipt of an audit report unless otherwise agreed upon by the two companies.

5.5 Visits by the FDA:

- 5.5.1 Within 2 business days Anika Therapeutics shall notify PSGA of any FDA inspection, or notice of inspection, relating to the ORTHOVISC® product.
- 5.5.2 Anika Therapeutics will notify PSGA by the end of the audit, or more frequently if appropriate, of any issues found during the FDA inspection that may impact ORTHOVISC® operations.
- 5.5.3 Anika Therapeutics will provide PSGA with copies of FDA 483 reports or similar reports relating to ORTHOVISC® or the facility.
- 5.5.4 PSGA will participate in the development and approval of action plans which involve actions to be taken by PSGA.

6. **Materials:**

- 6.1 Raw Materials: Anika Therapeutics will be responsible for inspection/testing and acceptance of all raw materials.
- 6.2 Components: Anika Therapeutics will be responsible for all inspection/testing of components.

7. **Manufacturing / Packaging:**

- 7.1 Anika Therapeutics shall manufacture, package, test, and store the, bulk, WIP, and finished product in accordance with its approved specifications and current Good Manufacturing Practices.
- 7.2 The manufacture of any penicillin or steroid product will not be allowed in the same facility used for the manufacture of (PSGA product(s)).
- 7.3 Anika Therapeutics is responsible for releasing the finished product for PSGA review and the overall quality/compliance of the product (see Responsibilities – Section 21).

8. **Stability / Retain Samples:**

- 8.1 Anika Therapeutics will be responsible for withdrawing the required number of samples and performing annual product stability analysis in accordance with approved test methods and at test intervals identified in the stability specifications.
- 8.2 Anika Therapeutics will maintain the required amount of retain samples of finished goods to perform full testing from every commercial lot manufactured at Anika Therapeutics.
- 8.3 All stability results will be available to PSGA upon request.
- 8.4 Anika Therapeutics will provide a copy of their stability protocol to PSGA.

9. **Product Complaints:**

- 9.1 OBI shall promptly communicate to ANIKA by facsimile, telephone or email (and confirm any such telephone communication as instructed at the time) any complaint received from users of the Licensed Product, in the configuration supplied by ANIKA.
- 9.2 Each notification of a complaint shall contain, but not be limited to, the lot number, dosage size, expiration date, indication for actual use and description of circumstances involved in the failure of the Unit(s) in question.
- 9.3 Each complaint notification will contain all the information available to OBI at that time, including all information then available which is required in the ANIKA Complaint Form, and a summary of the proposed action to be taken by OBI to comply with its legal obligations. OBI will provide additional information promptly as it becomes available.
- 9.4 OBI acknowledges that complaint investigation is the responsibility of ANIKA, but OBI reserves the right to directly contact its customers.
- 9.5 Anika Therapeutics will make reasonable efforts to complete their investigation, in writing, to all complaints within 30 business days of receipt, although some complaint investigations, due to their nature, may take longer to complete.
- 9.6 Anika Therapeutics will provide PSGA with summary complaint data on a semi-annual basis.

tO. Expiration Dating / Lot Numbering:

- 10.1 Anika Therapeutics will be responsible for providing PSGA QA the formats, layouts and abbreviations for expiration dating and lot numbers. The assignment of expiration dates will be identified in the specifications.

10.2 The format, layout, and abbreviation for expiration date and lot number will be approved in writing by PSGA QA and be documented in the specification. All labels must comply with the PMA-approved labelling.

11. Non-Conformances:

11.1 Anika Therapeutics will be responsible for investigating and documenting any non-conformance to any process, material or product. (Reference Sections 4.6 and 4.8).

11.2 Anika Therapeutics will provide PSGA with non-conformance summary data on a quarterly basis.

12. Product Release:

12.1 Upon determination by Anika Therapeutics that the ORTHOVISC® meets the required specifications it is approved for shipment to PSGA. PSGA will disposition the shipment after review and receipt of Anika Therapeutics QA documentation:

12.1.1 Anika Therapeutics is responsible for the storage of product prior to its receipt by PSGA

12.1.2 Shipment will be made to the designated PSGA facility

12.1.3 PSGA will specify approved carrier(s).

12.1.4 Carriers not specified by PSGA must be initially approved by PSGA prior to use by Anika Therapeutics.

12.2 Anika Therapeutics will forward the required documentation to PSGA QA for release.

12.2.1 Certificate of Analysis (COA)

12.2.2 Certificate of Compliance (COC)

12.2.3 Copies of the completed manufacturing record

12.2.4

12.3 PSGA is responsible for its acceptance decisions on finished ORTHOVISC lots based on manufacturing site compliance with QSR's, including completed and approved batch record documentation and conformance to specifications.

12.4 Anika Therapeutics will maintain retain samples for each lot of raw materials for one (1) year past the expiration date.

12.5 Anika Therapeutics will not supply to PSGA product that has been reworked unless such rework is validated and approved within the PMA for the product.

13. Validation:

- 13.1 Anika Therapeutics will perform process, packaging, and cleaning validations as required by its procedures and in accordance with standard industry practice.
- 13.2 Anika Therapeutics will perform laboratory test method validations as required by its procedures and in accordance with standard industry practice.
- 13.3 Anika Therapeutics will develop protocols for required validations in accordance with standard industry practice.

14. Suppliers:

- 14.1 Anika Therapeutics will be responsible for conducting periodic audits of suppliers.
- 14.2 Anika Therapeutics will be responsible for qualification of new suppliers.
- 14.3 Anika Therapeutics will notify PSGA of any supplier-related quality issues impacting PSGA product(s).

15. Change Control:

- 15.1 Anika Therapeutics will notify PSGA QA in advance of any changes in processes, testing, and materials prior to implementation if such changes are significant enough to affect finished product specifications or require FDA pre-approval submission.
- 15.2 Anika Therapeutics will provide PSGA with a summary of Change Control activities on a semi annual basis. This depends upon the type of change.

16. Medical Device Reports:

- 16.1 ANIKA shall be responsible for notifying all applicable regulatory authorities of reportable events (including without limitation complaints) involving the Licensed Product for which ANIKA receives written notification, as required by applicable laws.
- 16.2 OBI shall notify ANIKA of potentially reportable events promptly but in no event later than twenty-four (24) hours after the event. In addition, all such notices by OBI shall be consistent with the requirements of law in the applicable jurisdictions.
- 16.3 Anika Therapeutics will provide PSGA with a summary of Medical Device Reports on a semi annual basis.
- 16.4 Anika Therapeutics and PSGA will work together to investigate reportable events and complaints, including gathering information from customers and end users.

17. Recalls:

17.1 Anika Therapeutics shall be responsible for coordinating any recall of product from PSGA

17.2 PSGA shall be responsible for recalling product from end users and notifying end users of any field alert activities.

17.3 Anika Therapeutics shall forward all required recall-related information to PSGA on request, within two (2) calendar days of the request.

18. Technical Support:

18.1 Technical support will be mutually agreed upon as situations arise.

19. Agreement Maintenance:

19.1 *This* agreement shall be reviewed and amended annually or as needed.

19.2 Modifications/addenda can be made as required; any such modifications or addenda must be in writing and approved by the Anika Therapeutics and PSGA.

19.3 Record Retention: Original signed copies of this Agreement must be maintained for ten (10) years from the date of approval.

20. Responsibilities:

GMP COMPLIANCE RESPONSIBILITIES

DUTIES	Anika	PS GA	N/ A	COMMENTS
<u>1. RAW MATERIAL AND COMPONENTS</u>				
-Specifications Development & Maintenance	R, D	A		
-Specifications Control in Plant/SOPs	R, D	A		
-Ordered from Approved Suppliers	R, D	A		
-Receipt/Warehousing/Segregation of Materials	R, D	A		
-Incoming inspection, sampling & testing	R, D	A		
-Retest as necessary for release	R, D	A		

-Retest for expiration	R,D	A	
-Inventory Management & Accountability - FIFO	R,D	A	
-Destruction of Waste Materials	R,D	A	
-Retain Samples (Active RM)	R,D	A	
-Labelling Control & Accountability	R, D	A	
-Disposition of Materials (Release/Reject)	R,D	A	
-Use of Materials out of Specifications- Deviations	R,D	A	
-Suppliers Audits	R,D	A	
-Supplier Audit (APO			X
GMP COMPLIANCE RESPONSIBILITIES (CONT.)			
2. BULK AND WORK-IN-PROGRESS			
-Specifications Development and Maintenance	R, D	A	
-Manufacturing Directions Development & Maint.	R,D	A	
-Specifications Control in Plant	R,D	A	
-Area/Equipment Set Up & Inspection	R,D	A	
-Sanitization - Manufacturing Areas	R, D	A	
-Filling Machinery & Equipment Sanitization	R, D	A	
-Line Clearance Procedure	R,D	A	
-Batch Records issuance & maintenance	R,D	A	
-Equipment -maintenance, integrity & calibration	R, D	A	
-Environmental & Personnel monitoring	R, D	A	
- Primb atch record review	R,D	A	
-Cleaning Records & Logs	R.D	A	
-Dispensing records & logs	R.D	A	
-In-Process Sampling analysis & testing	R,D	A	
-Deviations from Bulk Finished Parameters Specifications	S	S	
-Development of Bulk and WIP Parameters/Annual Rev.	R	A	
-Documentation System and SOPs/Int'l	R, D	A	
-Changes to Process Parameters*	S	S	

-Final Product Sampling and testing	R, D	A
-Disposition of Product (release/reject)	R	A
-Destruction of Waste Materials	R,D	A

•To the extent changes meet the threshold in the "Change Control" section of this agreement.

GMP COMPLIANCE RESPONSIBILITIES (cont.)

DUTIES	Anika	PS GA	N/ A	COMMENTS
3. PACKAGING				
-Specifications Development & Maintenance	R,D	A		
-Specifications Control in Plant	R, D	A		
-Line Clearance Procedure	R, D	A		
-Environmental & Personnel monitoring	R, D	A		
-Labelling controls & reconciliation (bottle,PI,carton)	R, D	A		
-Lot number, control	R,D	A		
-Expiration Date Control	R, D	A		
-Expiration Dating Development	S	A		
-Cartoning & Bundling	R, D	A		
-Palletizing and Storage	R,D	A		
-Quarantine and Storage SOPs	R,D	A		
-Deviations from Packaging Specifications	S	S		
-Product Sampling, Inspection and testing	R, D	A		
4. PRODUCT RELEASE				
-Specifications Development and Maintenance	R,D	A		
-Quarantine Release SOPs	R, D	A		
-Product Release SOPs	R, D	A		
-Standard Analytical & Microbiological Tests	R,D	A		
-Batch record review	R, D	A		
-Environmental monitoring review (air, water, steam, pressure)	R, D	A		
-Tests Problem Resolution procedures	R, D	A		
-Deviation(s) reporting, investigations & documentation	S	S		
-Finished Goods Re-testing	R	D		
-Disposition of Product (release/rejection)	R	D		
-Evaluation of Finished Product with deviations from specs	R	D		
-Destruction of Waste Materials	R,D	A		

-Quarantine & Quarantine Release procedures/Execute based on SOP	R,D	A
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GMP COMPLIANCE RESPONSIBILITIES (cont.)

DUTIES	Anika	PS GA	N/ A	COMMENTS
5. STABILITY PROGRAM				
-Stability Protocols/Documentation System	R,D	A		
-Documentation Systems/SOPs in Plant	R, D	A		
-Retain Sampling	R, D	A		
-Stability Testing	R, D	A		
-New test Methods Development { validation, transfer, documentation)	R,D	A		
-Test Methods Implementation	R, D	A		
-Equipment Records, calibrations, validations	R, D	A		
-Result Handling				
-Result Reporting to PSGA	R	A		
-Stability alert- OOS Results	R	A		
-Reporting (Internal, External)	R,D	A		
-FDA Field Alert	S	S		
6. CUSTOMER COMPLAINTS				
-Standard Operating Procedure-in plant	R, D	A		
-Logging/Receipt	RD	A		
-Retain Sampling, handling & testing	R,D	A		
-Analysis				
-in plant laboratory	R, D	A		
-outside laboratory	R	D		
-Synchrony on records with PSGA			X	
-Reporting (Internal & External)	R,D	A		
-FDA Field Alert	S	S		

GMP COMPLIANCE RESPONSIBILITIES (cont.)

DUTIES	Anika	PS GA	N/ A	COMMENTS
7. GENERAL & FACILITY				
-SOPs, Guidelines, Practices and Policies	R,D	A		
-Monitoring, Maintenance, Calibration of				
-Water Systems (DI, WFI)	R,D	A		
-Clean Air System	R,D	A		
-HVAC System	R, D	A		
-Steam System	R, D	A		
-Pressure System	R, D	A		
-Annual Product Review				
-Data Collection	R,D	A		
-Written Report (Process, Analytical & Complaint Data)	R,D	A		
-General Records Systems	R,D	A		
-Documentation System in Plant	R,D	A		
-Records Retention (Batch Records)	R,D	A		
-Change Control in Plant	R,D	A		
-Retain Samples Management	R,D	A		
-Training and Education	R, D	A		
-Process and Product Validation				
-Facilit' and Systems	R,D	A		
-Equipment	R, D	A		
-Product	R,D	A		
-Revalidation	R,D	A		
-New Products			X	
-Quality Alert System	R, D	A		
8. Compliance & PMA-related				
- Adverse Drug Experience Reporting	R,D	A		
- PMA compliance & Annual Report to FDA	R,D	A		
- Recall coordination	S	S		

A= Audits

R = Primary Responsible
D = Ultimate Decision Maker
S = Shared Responsibility/Agree

22. Approval Signatures

This Agreement has been reviewed and approved by:

Approved By:	Date:
Anika Therapeutics	
(Site QA Manager, PSGA)	
(QA Director Ext. Mfg., PSGA)	
(VPQA Pharmaceuticals, PSGA)	

EXHIBIT F

ANIKA COMPLAINT FORM

COMPLAINT FORM

Complaint File Number:	Complainant:
Date Complaint Received:	Address
Method of Communication of Complaint:	Address
	Phone number
Product Name:	Product Lot Number:
Complaint:	
Attach appropriate documentation to this form.	
1.	Date Complaint Receipt Acknowledged:
2.	Was there a death, serious injury or serious illness?
3.	Any relationship of the device/drug to the reported incident?
4.	Is the event described in product labeling?
5.	Description of specific medical intervention action taken or withheld:
6.	Physician name:
7.	Description of patient condition:
8.	ADE or MDR Reportable Event? YES: _____ NO: _____ (If yes, proceed to #4.) If NO state Rationale: _____
	Vigilance Reporting? YES: _____ NO: _____ Date Reported: _____
9.	Date Failure Investigation Initiated: If investigation was not initiated, state reason:
10.	CAPA#: If corrective action is not required, state rationale:
11.	Date Failure Investigation Closed:

Required Documentation Obtained and Complaint Closed:

Date of close-out to complainant: _____

QS/RA Signature: _____ *Date:* _____