UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2006

MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 000-51133 (Commission File Number) 33-0927979 (IRS Employer Identification No.)

4350 La Jolla Village Drive, Suite 950 San Diego, CA 92122 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (858) 373-1500

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry Into a Material Definitive Agreement

On October 31, 2006, MediciNova, Inc. (the "Company") and Meiji Seika Kaisha, Ltd. ("Meiji Seika") entered into two License Agreements (the "License Agreements") whereby the Company acquired licenses for two novel small molecule cardiovascular agents from Meiji Seika. The License Agreements provide the Company with licenses for global markets, with the exception of Japan and other selected Asian countries. The License Agreements are filed as exhibits to this Current Report.

Attached as Exhibit 99.1 hereto and incorporated herein by reference in its entirety is the press release issued by the Company on October 31, 2006.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1*	License Agreement, dated as of October 31, 2006, by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
10.2*	License Agreement, dated as of October 31, 2006, by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
99.1	Press Release issued October 31, 2006

* Certain confidential portions of these exhibits were omitted by means of redacting a portion of the text. Application has been made to the Securities and Exchange Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. These exhibits have been filed separately with the Securities and Exchange Commission without redactions in connection with MediciNova's confidential treatment request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 2, 2006.

MEDICINOVA, INC.

By: /s/ Shintaro Asako

Shintaro Asako Vice President, Accounting and Administration

EXHIBIT INDEX

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (hereinafter referred to as "Agreement") dated as of October 31, 2006 (hereinafter referred to as "Effective Date"), is entered into between **MediciNova, Inc.**, a Delaware corporation having a place of business located at 4350 La Jolla Village Drive, Ste 950, San Diego, California 92122, U.S.A. (hereinafter referred to as "MN"), and **Meiji Seika Kaisha, Ltd.**, a Japanese corporation having its principal business place at 4-16, Kyobashi 2chome, Chuo-ku, Tokyo 104-8002, Japan (hereinafter referred to as "MS").

WITNESSETH:

WHEREAS, MS is the owner of the MS Intellectual Property (as hereinafter defined) relating to a new chemical class of compounds of integrin alphaVbeta3 and GPIIbIIIa receptors dual antagonists, [***];

WHEREAS, MN desires to obtain an exclusive license, with a right to grant sublicenses, under the MS Intellectual Property, and MS desires to grant such license to MN, upon the terms and conditions set forth herein;

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

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, unless specifically set forth to the contrary herein, the terms defined in this ARTICLE 1 shall have the respective meanings set forth below, it being understood that words in the singular include the plural and vice versa:

1.1 "<u>Act</u>" shall mean the United States Food Drug and Cosmetic Act of 1938, as amended, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

1.2 "<u>Affiliate</u>" shall mean, (i) any corporation or business entity of which at least fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party or by any entity mentioned in (ii) hereinafter; or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds at least fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests

representing the equity, voting stock or general partnership interest of a Party. Further, if a joint venture is established pursuant to an agreement between a Third Party (as hereinafter defined) and MN, MS or their respective Affiliate (including, without limitation, an entity that manufactures, uses, purchases, sells, imports, exports, or acquires Compound and/or Product [as hereinafter respectively defined] for, to or from MN, MS or their respective Affiliate), where MN, MS or their respective such Affiliate has significant input regarding the management and operation of such joint venture (e.g., through board representation or specified veto rights) or a significant stake in the profits of such joint venture, such joint venture shall also be deemed as an Affiliate hereunder.

1.3 "ANDA" shall mean an abbreviated NDA (as hereinafter defined) in the United States according to applicable US laws and regulations.

1.4 "API" shall mean Compound in bulk form used as the active pharmaceutical ingredient in the manufacture of Product.

1.5 "<u>Business Day(s)</u>" shall mean any day that is not a Saturday, a Sunday, a national holiday in Japan and/or United States, or a day on which the New York Stock Exchange and/or the Tokyo Stock Exchange is closed.

1.6 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.7 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.8 "<u>Centralized Procedure</u>" shall mean the European Union Centralized Procedure for marketing authorization in accordance with Council Regulation n° 2309/93 of July 22, 1993 or any successor regulations.

1.9 "CFR" shall mean the United States Code of Federal Regulations.

1.10 "<u>cGMP</u>" shall mean then current good manufacturing practices as defined in regulations promulgated by the FDA (as hereinafter defined) under the Act and, if applicable, equivalent laws and regulations of other countries or jurisdictions in the MN Territory (as hereinafter defined) relating to the formulation, manufacture, testing prior to delivery, storage and delivery of Compound, API and Product.

1.11 "Commercially Reasonable Efforts" shall mean efforts and resources normally used by a licensee in the pharmaceutical industry that is similar in size to MN for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors.

1.12 "<u>Compound</u>" shall mean the chemical compound, [***], as diagrammed on **Schedule 1.12**, (ii) any other compounds claimed or covered by any of the MS Patent Assets (as hereinafter defined) listed on **Schedule 1.44**, (iii) [***].

1.13 "<u>Control</u>" shall mean possession of the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement with any Third Party.

1.14 "<u>Cost of Goods</u>" shall mean the actual and bona fide and verifiable manufacturing and supply costs calculated in accordance with GAAP (as hereinafter defined), including labor, material and factory costs, and including amounts payable to Third Party manufacturers, specifically associated with the manufacture and supply by MN or an MN Affiliate (as hereinafter defined) of API or Product supplied to an MN Sublicensee (as hereinafter defined).

1.15 "<u>Customer</u>" shall mean any purchaser of Products, provided, however, that any MN Affiliate or MN Sublicensee shall be deemed a Customer, with respect to a Sale (as hereinafter defined) thereto of a particular Product, only in the case where such party receives such Product for its own end-use or other internal commercialization and not for re-sale.

1.16 "Development Milestone" shall mean the milestone events set forth in Section 4.2.

1.17 "<u>Dominating Patent</u>" shall mean an unexpired patent which is owned or Controlled by a Third Party and as to which both Parties mutually agree in good faith and in writing would be infringed by activities associated with the commercialization of Product.

1.18 "<u>EMEA</u>" shall mean the European Agency for the Evaluation of Medicinal Products based in London (UK), as established by Council Regulation n° 2309/93 of July 22, 1993, as subsequently amended by Commission Regulation 649/98 of March 23, 1998, and any successor thereto having substantially the same functions.

1.19 "EMEA Authority" shall mean EMEA or the applicable Regulatory Authority (as hereinafter defined) in an EMEA Member State (as hereinafter defined).

1.20 "<u>EMEA Member State</u>" shall mean any country or jurisdiction where an MAA (as hereinafter defined) can be submitted under Centralized Procedure or Mutual Recognition Procedure (as hereinafter defined), including then current European Union member countries or jurisdictions and Norway, Iceland and Liechtenstein.

1.21 "FDA" shall mean the United States Food and Drug Administration and any successor thereto having substantially the same functions.

1.22 "Field" shall mean any use of Compound or Product in humans.

1.23 "First Commercial Sale" shall mean, on a country by country or jurisdiction by jurisdiction basis, the first commercial Sale of any Product to a Customer in each country or jurisdiction in the MN Territory by MN, MN Affiliates and/or MN Sublicensees after Regulatory Approval (as hereinafter defined) has been granted by the Regulatory Authority of such country or jurisdiction.

1.24 "GAAP" shall mean generally accepted accounting principles in the United States.

1.25 "<u>Generic Competition</u>" shall mean, on a country by country or jurisdiction by jurisdiction and Product by Product basis, (i) with respect to a country or jurisdiction in the MN Territory where IMS Statistical Data (or substantially equivalent data) are available, [***] or, (ii) in any particular country or jurisdiction in the MN Territory where IMS Statistical Data (or substantially equivalent data) are not available, [***].

1.26 "Generic Drug(s)" shall mean any pharmaceutical composition containing the same Compound as contained in Product Sold by MN, an MN Affiliate and/or an MN Sublicensee, in each case other than Product introduced in such country or jurisdiction by MN, an MN Affiliate and/or an MN Sublicensee.

1.27 "<u>Improvement</u>" shall mean any improvement or enhancement relating to Compound or Product including, without limitation, any change or modification to any method, process, composition, or any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage, administration, use, indication or packaging as well as the addition of other active ingredients.

1.28 "<u>IND</u>" shall mean an investigational new drug application, as defined in 21 CFR Section 312.3, and any amendments thereto, filed with the FDA or an equivalent application filed with an equivalent Regulatory Authority outside the United States, the filing of which is necessary to commence clinical testing of Product in such regulatory jurisdiction.

1.29 "Know-How" shall mean any and all unpatented information and materials, including but not limited to, discoveries, Improvements, processes, formulae, data, inventions, invention disclosures, know-how and trade secrets, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and nontechnical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any non-clinical, clinical, assay control, regulatory, and any other test results or information, that are necessary or useful for the development, manufacturing, Regulatory Approval and/or marketing of Compound or Product.

1.30 "Major European Countries" shall mean United Kingdom, France, Germany, Italy and Spain.

1.31 "<u>Market Exclusivity</u>" shall mean, with respect to any particular country or jurisdiction in the MN Territory, the situation or condition under which (i) the development, manufacture, use, offering for sale, sale, marketing, distribution, export and/or import of Compound and/or Product, but for the license granted in this Agreement, would infringe, or contribute to, or induce the infringement of, a Valid Patent Claim (as hereinafter defined) issued at the time of the infringing activity in such country(ies) or jurisdiction(s) and/or (ii) the exclusive right to market and sell Product is lawfully granted by the Regulatory Authority in such country(ies) or jurisdiction(s).

1.32 "<u>Marketing Authorization Application</u>" or "<u>MAA</u>" shall mean any new registration application or marketing authorization application, including any supplements or amendments thereto, such as a foreign counterpart or comparable to the NDA, which MN, MS, an MN Affiliate, an MN Sublicensee and/or an MS Licensee (as hereinafter defined) may file with the requisite Regulatory Authority in any country or jurisdiction other than the United States in the MN Territory or MS Territory (as hereinafter defined), as applicable, that is required to obtain Regulatory Approval of Product for a particular indication in such country or jurisdiction. For the avoidance of doubt, an application to EMEA Authority under the Centralized Procedure or Mutual Recognition Procedure shall be deemed as an MAA hereunder.

1.33 "<u>MN Affiliate</u>" shall mean any Affiliate of MN to which MN grants a sublicense in the MN Territory of the rights and licenses, whether in whole or in part, granted to MN by MS pursuant to Section 3.2 of this Agreement.

1.34 "<u>MN Development Costs</u>" shall mean the actual and bona fide and verifiable development costs, including but not limited to the costs for materials, full-time and part-time employees, overhead, payments made to Third Parties for manufacturing, formulation, non-clinical and clinical studies, specifically relating to Product which have been incurred by MN and/or an MN Affiliate prior to the effective date of the sublicense agreement between MN (or such MN Affiliate) and an MN Sublicensee, to the extent such development costs are reasonable and not excessive compared with the development costs of similarly situated development companies in the pharmaceutical industry under similar circumstances.

1.35 "<u>MN Intellectual Property</u>" shall mean any and all MN's and MN Affiliates' intellectual property and proprietary rights in any and all MN Patent Assets and MN Know-How (as hereinafter respectively defined).

1.36 "MN Know-How" shall mean any and all Know-How that becomes during the term of this Agreement owned or Controlled by MN or an MN Affiliate.

1.37 "<u>MN Patent Assets</u>" shall mean all Patent Assets (as hereinafter defined) that are necessary to develop, make, use, market, distribute, import, export, offer for sale and/or sell Compound or Product and that become during the term of this Agreement owned or Controlled by MN or an MN Affiliate.

1.38 "<u>MN Sublicensee</u>" shall mean any Third Party to which MN or an MN Affiliate grants a sublicense in the MN Territory of the rights and licenses, whether in whole or in part, granted to MN by MS pursuant to Section 3.2 of this Agreement.

1.39 "MN Territory" shall mean all countries or jurisdictions worldwide, except for those in the MS Territory.

1.40 "<u>MS Affiliate</u>" shall mean any Affiliate of MS to which MS grants the rights and licenses in the MS Territory to research, develop, make, have made, use, offer for sale, market, sell, import, export and/or distribute Compound and/or Product under the MS Intellectual Property.

1.41 "<u>MS Intellectual Property</u>" shall mean any and all MS's and MS Affiliates' intellectual property and proprietary rights in any and all MS Patent Assets and MS Know-How (as hereinafter defined).

1.42 "MS Know-How" shall mean any and all Know-How that is or becomes during the term of this Agreement owned or Controlled by MS or an MS Affiliate.

1.43 "<u>MS Licensee</u>" shall mean any Third Party to which MS grants the rights and licenses in the MS Territory to research, develop, make, have made, use, offer for sale, market, sell, import, export and/or distribute Compound and/or Product under the MS Intellectual Property.

1.44 "<u>MS Patent Assets</u>" shall mean (i) those Patent Assets listed on **Schedule 1.44** including any counterparts thereof which have been or may be filed in other countries or jurisdictions and (ii) all Patent Assets that become owned or Controlled by MS or MS Affiliates during the term of this Agreement which, absent the rights and license granted to MN hereunder, would be infringed by development, manufacture, use, importation, exportation, sale, offer for sale, market or distribution of Compound, API and/or Product.

1.45 "<u>MS Territory</u>" shall mean Japan, Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

1.46 "<u>Mutual Recognition Procedure</u>" shall mean the mutual recognition procedure for marketing authorization in accordance with Directive No. 2003/83/EC of November 6, 2001 or any successor regulations and/or directives.

1.47 "NDA" shall mean a new drug application as defined in the Act and applicable regulations promulgated thereunder that is submitted to the FDA to apply for Regulatory Approval of Product for a particular indication in the United States and any amendments and supplements thereto.

1.48 "<u>Net Sales</u>" shall mean the total gross amount invoiced by MN or MN Affiliates from Sales of Products, commencing upon the date of First Commercial Sale, whether invoiced under one or more separate agreements, after deducting any of the following to the extent actually paid or provided, not already deducted from the gross amount invoiced and allocated to Product, in accordance with GAAP, any (a) credits, allowances, samples, discounts and rebates to, and chargebacks from the account of, Customers; (b) freight and insurance costs; (c) trade discounts, cash discounts, quantity discounts, rebates; (d) retroactive price reductions; (e) recalls, credits and allowances on account of returned or rejected Product, including allowance for breakage or spoilage; (f) sales, value-added and other direct taxes incurred directly in connection with the Sale of Product; (g) rebates, chargebacks or similar payments or credits actually granted to managed health care organizations, wholesalers, distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, or other institutions or health care organizations or to any governmental or regulatory authority in respect of any state, provincial, local or federal Medicare, Medicaid or similar programs in any country or jurisdiction in the MN Territory; (h) write-offs for bad debts or allowances; and (i)

customs duties, custom broker charges and other surcharges and governmental charges incurred in connection with the exportation or importation of Product.

Sales or other transfers between or among MN, MN Affiliates and MN Sublicensees shall be excluded from the computation of Net Sales and no payments will be payable on such sales or transfers except where MN, such MN Affiliates or MN Sublicensees are Customers, but the computation of Net Sales shall include the subsequent Sales to Customers by MN or such MN Affiliates.

1.49 "<u>Net Sublicense Consideration</u>" shall mean (a) the total gross amount invoiced, received or otherwise charged and the value of any other consideration in the form of cash payments received or obtained, directly or indirectly, by MN or an MN Affiliate from any MN Sublicensee as consideration for the grant of the sublicense under Section 3.2, including, but not limited to, as royalties of any kind including royalties based on net sales of Product by such MN Sublicensee, flat fees, up-front license fee and payments based on the achievement of milestones relating to Product, whether received under one or more separate agreements, less MN Development Costs; and (b) the amount of any profit of MN (or MN Affiliates) derived from the supply of API or Product to MN Sublicensees (i.e. the transfer price from MN or such MN Affiliates to such MN Sublicensees, less Cost of Goods). Notwithstanding the foregoing, Net Sublicense Consideration shall not include any amounts received by MN or an MN Affiliate directly from MN Sublicensees attributable to any bona fide (i) funding by such MN Sublicensee of the costs for MN's (and/or such MN Affiliate's) development activities specifically relating to Product, including non-clinical and clinical studies associated with obtaining Regulatory Approval, which such MN Sublicensee contracts out on arms length terms to MN and/or an MN Affiliate on and after the effective date of the sublicense agreement between MN (or an MN Affiliate) and such MN Sublicensee, to the extent such costs do not exceed an amount which is reasonably typical under the similar circumstances in the pharmaceutical industry ; and (ii) arms length cash investments by such MN Sublicensee in securities of MN and/or an MN Affiliate not as part of consideration for sublicense set forth in Section 3.2.

1.50 "Party" shall mean MS or MN, and "Parties" shall mean MS and MN.

1.51 "<u>Patent Assets</u>" shall mean any patents and patent applications, including provisionals and priority filings, utility models and their applications (which shall be deemed to include certificates of invention and applications for certificates of invention and supplementary protection certificates) together in all cases with any continuations, continuations-in-part, divisions, patents of addition, reexaminations, reissues, renewals as well as extensions, supplementary protection certificates and any other patent term extensions of any of the foregoing.

1.52 "<u>Person</u>" shall mean an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.53 "<u>Phase 1 Clinical Trial</u>" shall mean that portion of the drug development process relating to Product which provides for the first introduction into humans of such Product including small scale clinical trial in healthy volunteers and/or patients to obtain information on such Product's safety, tolerability, pharmacological activity, pharmacokinetics and/or pharmacodynamics, and supporting Regulatory Approval of such Product in the Field, as more fully defined in 21 C.F.R. 312.21 (a) or the equivalent statute or regulation in a country or jurisdiction other than the United States.

1.54 "<u>Phase 2 Clinical Trial</u>" shall mean that portion of the drug development process relating to Product which provides for a well-controlled clinical trial conducted in patients, a principal purpose of which is to make a preliminary determination that such Product is safe for its intended use and to obtain sufficient information about such Product's efficacy, as well as to obtain an indication of the dosage regimen required, to permit the design of further clinical trials, and supporting Regulatory Approval of such Product in the Field, as more fully defined in 21 C.F.R. 312.21 (b) or the equivalent statute or regulation in a country or jurisdiction other than the United States.

1.55 "<u>Phase 3 Clinical Trial</u>" shall mean that portion of the drug development process relating to Product which provides for a large scale clinical trial conducted in a sufficient number of patients that is designed to establish that such Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, and supporting Regulatory Approval of such Product in the Field, as more fully defined in 21 C.F.R. 312.21 (c) or the equivalent statute or regulation in a country or jurisdiction other than the United States.

1.56 "<u>Product</u>" shall mean any pharmaceutical composition containing Compound as an active ingredient, in any formulation, delivery system or package configuration.

1.57 "<u>Proprietary Information</u>" shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned or Controlled and under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.

1.58 "<u>Regulatory Approval</u>" shall mean, in any country or jurisdiction in the MN Territory or the MS Territory, as applicable, all approvals (including pricing and reimbursement approvals required for marketing authorization), product and/or establishment licenses, registrations or authorizations of all regional, federal, state or local regulatory agencies, departments, bureaus or other Regulatory Authority, necessary for the manufacture, use, storage, import, export, transport, offer for sale and sale of Compound, API and/or Product in such country or jurisdiction. For the avoidance of doubt, an approval by the EMEA Authority under the Centralized Procedure or Mutual Recognition Procedure shall be deemed as a Regulatory Approval hereunder.

1.59 "<u>Regulatory Authority</u>" shall mean any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, domestic or foreign, that performs a function for such political subdivision similar to the function

performed by the FDA for the United States and the EMEA Authority for EMEA Member States with regard to the approval, licensing, registration or authorization to develop, test, manufacture, promote, market, distribute, use, store, import, export, transport, offer for sale or sell a pharmaceutical product intended for human use in the defined territory or political subdivisions, or with respect to the approval of pricing or reimbursement for such product.

1.60 "Royalty Term" shall mean the royalty term set forth in Section 4.3.4.

1.61 "<u>Royalty Year</u>" shall mean, during the Royalty Term (i) for the year in which the First Commercial Sale occurs (the "First Royalty Year"), the period commencing with the first day of the Calendar Quarter in which the First Commercial Sale occurs and expiring on the last day of the Calendar Year in which the First Commercial Sale occurs; and (ii) for each subsequent year, each successive Calendar Year.

1.62 "Sale" shall mean the act of selling, leasing, exchanging, or otherwise transferring, providing, furnishing, or disposing of Compound, API or Product for any consideration to a Customer. Correspondingly, "Sell" means to make or cause to be made a Sale, and "Sold" means to have made or caused to be made a Sale.

1.63 "Third Party" shall mean any Person other than MS, MN and their respective Affiliates.

1.64 "<u>Trademark</u>" shall mean any trademark, trade name or trade dress as MN or any MN Affiliate shall adopt for Product that is at any time during the term of this Agreement owned or Controlled by MN or such MN Affiliate.

1.65 "<u>Valid Patent Claim</u>" shall mean a claim of an issued and unexpired patent included within the MS Patent Assets, which (a) has not been held revoked, or held unenforceable or invalid by a court or other governmental agency of competent jurisdiction, in an unappealed or unappealable decision and (b) has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

ARTICLE 2

DEVELOPMENT; REGULATORY MATTERS; EXCHANGE OF INFORMATION

2.1 Development in the MN Territory.

2.1.1 MN shall select and develop Compound claimed or covered by any of the MS Patent Assets in the MN Territory. In the event that MN notifies MS in writing of its intention on reasonable grounds to select and develop Compound that is not claimed or covered by any of the MS Patent Assets in the MN Territory, MN may do so after having full consultation with and obtaining a written consent of MS.

2.1.2 <u>Development Plan.</u> MN shall prepare and submit to MS a projected plan for the development of Product (hereinafter referred to as "Development Plan"). The Development Plan shall be divided into the following phases of development: (a) pre-clinical development until the first IND filing, (b) until initiation of the first Phase 2 Clinical

Trial, (c) until initiation of the first Phase 3 Clinical Trial, and (d) until the first submission of either an NDA to the FDA or an MAA to an EMEA Authority. The Development Plan for (a) pre-clinical development until the first IND filing shall be prepared and submitted to MS by MN within one hundred twenty (120) days after the Effective Date and the Development Plan for its subsequent phase shall be prepared and submitted to MS by MN within ninety (90) days after the completion of the development activities in the Development Plan for each previous phase.

2.1.3 <u>Diligence and Information Exchange.</u> MN shall use Commercially Reasonable Efforts to develop and commercialize Product at its own costs and responsibilities. In addition, MN agrees to:

- (a) provide, at its own responsibilities, sufficient scientific, technical, clinical and regulatory personnel, equipment, time, funds and resources for the commercial development of Product to meet its obligations hereunder;
- (b) undertake the development in accordance with the Development Plan and in compliance with applicable laws and regulatory requirements;
- (c) maintain records with respect to the activities performed under the Development Plan in sufficient detail and good scientific manner appropriate for Regulatory Approval in the MN Territory;
- (d) provide MS, after API or Product for Phase 1 Clinical Trials in compliance with cGMP becomes available and upon MS's request, with the final version of the study protocol of any non-clinical and clinical study relating to Compound and Product to be conducted by or on behalf of MN, an MN Affiliate or, when applicable and available to MN, an MN Sublicensee;
- (e) submit to MS copies of all final reports of any non-clinical and clinical study relating to Compound and Product conducted by or on behalf of MN, an MN Affiliate or, when applicable and available to MN, an MN Sublicensee promptly after the completion of such studies;
- (f) semi-annually provide MS with a written report summarizing in reasonable detail the status of development activities of MN, any MN Affiliate and/or any MN Sublicensee relating to Compound and Product, including but not limited to, results of non-clinical and/or clinical studies conducted by or on behalf of MN, MN Affiliates and/or MN Sublicensees, with the delivery to MS of the summary of the annual report to an IND submitted by MN, MN Affiliates and/or MN Sublicensees to the FDA and/or EMEA Authority in connection with the periodic reporting requirements of the IND to be in satisfaction of the foregoing requirement;

- (g) [***]; and
- (h) [***];

provided, however, that the foregoing obligations of MN are expressly conditioned upon the absence of (i) any adverse conditions relating to the safety or efficacy of Compound or Product including the absence of any action by any Regulatory Authority limiting the development or commercialization of Compound or Product; (ii) *force majeure* (as more specifically described in Section 12.1) or other factors or reason(s) beyond MN's reasonable control, including, for example, the unavailability of drug supplies needed to conduct the clinical trial, including, without limitation, as a result of failure of stability or lack of a satisfactory formulation; an inability to conduct the clinical trial due to action on the part of any Regulatory Authority, including, without limitation, the placement of a clinical hold on such clinical trial; or if the conduct of such clinical trial would violate any applicable laws, rules or regulations; or (iii) a good faith determination on the part of MN, acting as a reasonable pharmaceutical company and after consultation with MS, that Product which is intended to be studied in the clinical trial is not safe or efficacious in its then current formulation or dosage form or dose level.

2.1.4 <u>Remedy.</u> Without prejudice to any other remedies as provided for hereunder or available under laws, in the event MN, an MN Affiliate and/or an MN Sublicensee ceases development activities of Compound and/or Product [***], and MN, such MN Affiliate and/or such MN Sublicensee does not demonstrate to MS's reasonable satisfaction that, despite Commercially Reasonable Efforts by MN, such MN Affiliate and/or such MN Sublicensee, such cessation was due to reason(s) beyond reasonable control by MN, such MN Affiliate and/or such MN Sublicensee, including, for example, situation(s) set forth in (i) to (iii) of the proviso of Section 2.1.3 above, MS shall have the right, at its sole discretion, to terminate this Agreement pursuant to Section 9.3.3.

2.1.5 MN shall, from time to time during the term of this Agreement, disclose, and shall cause any MN Affiliate to disclose, to MS all MN Intellectual Property subject to the license granted to MS under Section 3.3 and, when applicable and available to MN, all MN Sublicensee Intellectual Property (as defined in Section 3.3).

2.1.6 <u>Meeting</u>. Upon reasonable request and notice by one Party to the other Party, the Parties shall have a meeting at mutually agreed times and locations, a videoconference, or a teleconference up to twice a year to discuss the development of Product in the MN Territory and, if MS, an MS Affiliate or an MS Licensee is developing Product in the MS Territory, in the MS Territory. Each Party shall bear its own travel and related costs to attend the meeting.

2.1.7 <u>Regulatory Matters</u>. MN shall own, control and retain primary legal responsibility for, and shall be responsible for funding, preparing, filing and prosecuting all filing and regulatory applications required to obtain Regulatory Approval of Product in the

Field in the MN Territory. MS shall transfer free of charge to MN as soon as practicable after the Effective Date any IND or other regulatory filings or approvals in the MN Territory relating to Compound or Product owned or Controlled by MS and MS shall allow MN or its designees free of charge the right to cross reference any IND, MAA or other regulatory filing in the MS Territory relating to Compound or Product if owned or Controlled by MS or an MS Affiliate. It is understood between the Parties that MS shall not be required to conduct any additional studies which support Regulatory Approval of Product in the MN Territory.

2.2 <u>Development in the MS Territory</u>. In case that at any time during the term of this Agreement, MS decides to develop and commercialize Product in the MS Territory:

2.2.1 MS shall so advise MN in writing and, during any such development or commercialization by MS, an MS Affiliate and/or an MS Licensee, the Parties shall coordinate, review and assess the clinical development of Product necessary to receive Regulatory Approvals in the MS Territory, to harmonize worldwide objectives for Product and to facilitate the transfer of data and regulatory communications, including the handling and reporting of adverse events. In the event that MS, an MS Affiliate or an MS Licensee decides to develop Product in the MS Territory for an indication that is the same as or substantially similar to any indication for which MN, an MN Affiliate and/or an MN Sublicensee has developed or is developing in the MN Territory, MS shall so advise MN in writing and the Parties shall establish a joint committee for the purpose contemplated in this Section 2.2.1;

2.2.2 MS shall own, control and retain primary legal responsibility for, and shall be responsible for funding, preparing, filing and prosecuting all filings and regulatory applications required to obtain Regulatory Approval of Product in the Field in the MS Territory. MN shall provide MS as soon as practicable during the term of this Agreement with copies of any IND, NDA, MAA and other regulatory filings or approvals in the MN Territory relating to Compound and/or Product in the Field owned or Controlled by MN, an MN Affiliate or, when applicable and available to MN, an MN Sublicensee (hereinafter referred to as "MN Regulatory Filings"), and MN shall allow MS, an MS Affiliate and/or an MS Licensee free of charge the right to cross reference any MN Regulatory Filing, if owned or Controlled by MN, such MN Affiliate, or, if applicable and available to MN, such MN Sublicensee solely for use in obtaining Regulatory Approval of Product in the Field in the MS Territory; provided, however, that in case of a sublicense by MN or an MN Affiliate to an MN Sublicensee, Section 4.7 shall be applicable;

2.2.3 It is understood between the Parties that MS has no obligation to supply to MN Compound, API and Product for development and commercialization by MN, an MN Affiliate and/or an MN Sublicensee in the MN Territory. MN shall be responsible for conducting, at its own cost and expense, any and all research activities related to manufacturing Compound, API and Product and for supplying Compound, API and Product for development and commercialization in the MN Territory. MN may, at its sole discretion, entrust any Third Party, MN Affiliate and/or MN Sublicensee with such research and manufacturing activities relating to Compound, API and/or Product in whole or in part;

2.2.4 So long as MN or its designees (including an MN Affiliate and an MN Sublicensee) is then manufacturing Compound, API and/or Product for development and/or commercial use, upon reasonable written request by MS, MN shall supply MS with the Compound, API and/or Product that is then being manufactured by MN or its designee (including an MN Affiliate and an MN Sublicensee) solely for research, development and/or commercial use by MS, an MS Affiliate and/or an MS Licensee in the MS Territory. In such case, upon MS's request, MS and MN shall negotiate in good faith to enter into a supply agreement relating to such supply of Compound, API and/or Product to MS, solely for use in the MS Territory, containing such commercially reasonable terms and conditions as are typical for similar types of supply agreements.

2.2.5 In case that at any time during the term of this Agreement, MN or its designees (including an MN Affiliate and an MN Sublicensee) is then manufacturing Compound, API and/or Product for development and/or commercial use and MS decides to manufacture such Compound, API and/or Product that is then being manufactured by MN or its designee (including an MN Affiliate and an MN Sublicensee), solely for research, development and/or commercial use in the MS Territory, MS shall have the right to have transferred to MS solely for such use the manufacturing technology developed, owned and Controlled by MN, MN Affiliates and, when applicable and available to MN, MN Sublicensees (hereinafter referred to as "Manufacturing Technology"). Upon MS's request to have such Manufacturing Technology transferred to MS, MN then shall work with MS and/or its designees (including an MS Affiliate and an MS Licensee) in good faith and within a reasonable time frame to complete such technology transfer at MS's costs, enabling MS and/or its designees (including MS Affiliate and MS Licensee) to manufacture and/or have manufactured Compound, API and/or Product for research, development and/or commercial use by MS, an MS Affiliate and/or an MS Licensee in the MS Territory, provided, however that MN shall not be responsible for process and equipment validation required by applicable laws or regulations in the MS Territory or otherwise for MS's compliance necessary to pass inspection by any Regulatory Authority in the MS Territory. MS shall be free to perform, at its own costs and responsibilities, internal process chemistry research on the Manufacturing Technology independently of or in collaboration with MN and/or its designees (including an MN Affiliate and an MN Sublicensee);

2.2.6 MS and MN and/or their respective designees shall cooperate with respect to the exchange of adverse event and safety information associated with Compound and Product, provided that details of the cooperation in the handling of adverse event and safety information related to Compound and Product shall be the subject of a separate agreement to be negotiated in good faith between the Parties. Furthermore, the Parties shall cause their respective Affiliates and an MN Sublicensee and MS Licensee, as applicable, to cooperate with regard to the Parties' information exchange set forth in this Section 2.2.6.

2.3 <u>Exchange of Information</u>. MS shall disclose to MN in the language in which they are available (except that all information required to be submitted to any Regulatory Authority in connection with any Regulatory Approval shall be disclosed by MS to MN in English) and in writing, in electronic format, where available, and hard copies (or, upon MN's reasonable

request and MS's consent, originals), (a) within thirty (30) Business Days after the Effective Date, all MS Patent Assets and MS's in-house reports containing MS Know-How existing as of the Effective Date, not previously available or made available to MN, (b) upon MN's written request, MS Know-How which is not contained in MS's in-house reports set forth in (a) above but available in other form (such as laboratory notes) and (c) on an ongoing basis throughout the term of this Agreement, and in addition to the other communications required under this Agreement, all MS Intellectual Property that become owned or Controlled by MS, any MS Affiliate or, when applicable and available to MS, any MS Licensee during the term of this Agreement, and any and all additions or revisions thereto.

ARTICLE 3

LICENSES; SUBLICENSES

3.1 License Grant to MN. MS hereby grants to MN an exclusive (even as to MS) license, including the right to grant sublicenses, under the MS Intellectual Property to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound and/or Product in and throughout the MN Territory in the Field.

3.2 Sublicense Rights.

MN may grant sublicenses within the scope of the license granted to MN under this Agreement to any Affiliate of MN or any MN Sublicensee, provided, however, that (a) each MN Affiliate and MN Sublicensee is subject to a written sublicense agreement and is bound by all of the material terms, conditions, obligations, restrictions and other covenants of this Agreement that protect or benefit MS's rights and interests except for the cases in Sections 3.3, 4.3.3 and 4.7.1 where MN shall use Commercially Reasonable Efforts to obtain covenants from MN Sublicensee as provided for therein; (b) prior to granting each such sublicense, MN shall disclose to MS the proposed material terms and conditions of such sublicense; (c) MN shall advise MS of such sublicense and provide MS with a copy of the sublicense agreement; and (d) in the event of any sublicense by MN or an MN Affiliate to an MN Sublicensee, the provisions of Section 4.7 shall be applicable and MN shall, within thirty (30) days of the effective date of the sublicense agreement between MN (or such MN Affiliate) and such MN Sublicensee, submit MS a written report detailing MN Development Costs with certificates, vouchers and/or other documents related thereto in sufficient detail to the extent necessary for the verification of the accuracy and legitimacy of such MN Development Costs. MN covenants that it shall obtain appropriate reporting from MN Sublicensees to establish all amounts owed to MS hereunder, and shall make such reports available to MS.

In no event shall MS assume any obligations or liabilities, or be under any obligation or requirement of performance, under any such sublicense extending beyond MS' obligations and liabilities under this Agreement. Upon MN's reasonable request, at any time during the term of this Agreement, MS agrees to meet and confer in good faith with MN and any MN Sublicensee or potential MN Sublicensee to discuss mutually acceptable arrangements regarding the possibility of an extension of such MN Sublicensee's or potential MN Sublicensee's rights beyond any expiration or termination of this Agreement.

3.3 <u>Grant of license by MN.</u> MN hereby grants, subject to the terms and conditions of this Agreement to MS an exclusive (even as to MN) and royalty-free license, including the right to grant sublicenses to any Affiliate of MS or any MS Licensee under the MN Intellectual Property solely to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field, in and throughout the MS Territory. In the event MN or an MN Affiliate has sublicensed the rights granted by MS to MN under Section 3.1 to an MN Sublicensee, MN shall use Commercially Reasonable Efforts to cause such MN Sublicensee to grant to MN or MN's designee the right to grant MS an exclusive (even as to such MN Sublicensee) and royalty-free license, including the right to grant sublicenses to any Affiliate of MS or MS Licensees, under the Know-How and Patent Assets that are necessary to research, develop, make, have made, use, market, offer for sale, sell, distribute, import and export Compound, API and/or Product that become owned or Controlled by such MN Sublicensee during the term of this Agreement (hereinafter referred to as "MN Sublicensee Know-How" and "MN Sublicensee Patent Assets," respectively, and as "MN Sublicensee Intellectual Property", collectively) solely to research, develop, use, make, have made, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field in and throughout the MS Territory, and Section 4.7.1 shall be applicable. In case of a grant of such license, MN Sublicensee Know-How and MN Sublicensee Patent Assets shall be deemed to be MN Know-How and MN Patent Assets, respectively, and treated accordingly hereunder. If MS advises MN in writing that MS desires to use or sublicense the Trademark for Product in the MS Territory, MN shall grant MS a royalty-free, exclusive license, with a right to grant sublicenses to any Affiliate of MS or any MS Licensee, to use the Trademark solely in connection with the use, marketing,

3.4 <u>Retained Rights and Restrictions</u>. The licenses granted in Section 3.1 and 3.3, respectively, are limited to the rights expressly granted therein. The Parties agree and acknowledge that there are no implied licenses under this Agreement or with respect to all right, title and interest in and to either the MS Intellectual Property or the MN Intellectual Property, except as specifically set forth herein. MN shall have no right or license to the MS Intellectual Property under this Agreement outside the Field and MS shall retain the right to use the MS Intellectual Property outside the Field. MS shall have no right or license to the MN Intellectual Property under this Agreement outside the Field and MN shall retain the right to use the MN Intellectual Property outside the Field.

ARTICLE 4 PAYMENTS AND ROYALTIES

4.1 <u>Up-Front License Fee</u>. In consideration of the rights and licenses granted by MS to MN hereunder, and in addition to and not in lieu of any other amounts due hereunder, MN shall pay to MS the sum of [***].

4.2 <u>Milestone Payments</u>. Subject to the terms and conditions contained in this Agreement, in further consideration of the rights and licenses granted by MS to MN hereunder, MN shall pay MS the following milestone payments upon occurrence of the specified Development Milestone, irrespective of (i) whether such Development Milestones are achieved

by MN or an MN Affiliate, (ii) which indications are explored, and (iii) Product for which such Development Milestone may be achieved, with each milestone payment to be made no more than once with respect to the achievement of such Development Milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such Development Milestone, regardless of the number of Products for which such Development Milestone may be achieved (but payable on the first achievement of such Development Milestone):

- (a) **[***]**;
- (b) **[***]**;
- (C) **[***]**;
- (d) [***];
- (e) [***]; and
- (f) **[***]**.

MN shall notify MS in writing not later than thirty (30) Business Days after the achievement of each Development Milestone and each such notice shall be accompanied by the appropriate milestone payment. In no event shall the payments provided for in this Section 4.2 be refundable to MN or creditable or recoupable against future royalties or other payments payable to MS pursuant to Section 4.3 or any other provision of this Agreement.

4.3 Royalties Payable by MN.

4.3.1 <u>Royalty Rates-United States.</u> Subject to the terms and conditions of this Agreement, and in further consideration of the rights and licenses granted by MS to MN hereunder, MN shall pay to MS royalties equal to the applicable percentages set forth below of the sum of the annual Net Sales in the United States in each Royalty Year during the Royalty Term. For determination of applicable royalty rate, annual Net Sales in the United States shown below shall mean the sum of Net Sales in the United States in the applicable Royalty Year:

(a) in case that MN solely Sells Product in the United States;

Annual Net Sales in U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

(b) in case that MN Sells Product jointly with MN Sublicensee(s) in the United States;

Annual Net Sales in U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

Examples of the royalty calculation under this Section 4.3.1 are shown on Schedule 4.3.

4.3.2 <u>Royalty Rates-Outside the United States.</u> Subject to the terms and conditions of this Agreement, and in further consideration of the rights and licenses granted by MS to MN hereunder, MN shall pay to MS royalties equal to the applicable percentages set forth below of the aggregate annual Net Sales in all countries and jurisdictions in the MN Territory, other than the United States, in each Royalty Year during the Royalty Term. For determination of applicable royalty rate, aggregate annual Net Sales outside the United States shown below shall mean the sum of Net Sales in any country or jurisdiction in the MN Territory other than the United States shown below shall mean the sum of Net Sales in any country or jurisdiction in the MN Territory other than the United States in the applicable Royalty Year:

(a) in case that MN solely Sells Product outside the United States;

Aggregate Annual Net Sales outside U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

(b) in case that MN Sells Product jointly with MN Sublicensee(s) outside the United States;

Aggregate Annual Net Sales outside U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

Examples of the royalty calculation under this Section 4.3.2 are shown on Schedule 4.3.

4.3.3 MN shall make Commercially Reasonable Efforts to have the definition of net sales of Product sold by an MN Sublicensee in the sublicense agreement between MN or (an MN Affiliate) and such MN Sublicensee be substantially equivalent to the definition of Net Sales as defined hereunder.

4.3.4 <u>Royalty Term</u>. The Royalty Term shall, on a country by country or jurisdiction by jurisdiction basis, commence on the **[***]**; provided, however, that notwithstanding the foregoing, the following shall be applicable:

(a) in any country or jurisdiction in the MN Territory where no Market Exclusivity exists as of [***], then, notwithstanding the provisions of Sections 4.3.1 and 4.3.2, [***]; and

¹⁷

(b) in the event of Generic Competition in any country or jurisdiction at any time [***], notwithstanding the provisions of Sections 4.3.1, 4.3.2 and 4.3.4
 (a), MN shall instead pay MS royalties on Net Sales in such country or jurisdiction at rates equal to [***].

In the event MN or an MN Affiliate sells bulk Compound rather than a Product in packaged form to a Third Party other than an MN Sublicensee (and such Third Party shall not re-sell such bulk Compound or any product containing thereof), and is unable to determine Net Sales as defined in this Agreement, then the sale of such bulk Compound, less applicable Cost of Goods, shall be deemed as Net Sublicense Consideration and shared by MN and MS either in a [***] if the provisions of Section 4.7.1(a) apply or in a [***] if the provisions of Section 4.7.1(b) apply, as the case may be.

4.4 <u>Compulsory Licenses</u>. If a compulsory license is granted to a Third Party with respect to Product in any country or jurisdiction in the MN Territory with a royalty rate lower than the applicable royalty rates provided in Section 4.3, then the royalty rate to be paid to MS on Net Sales in such country or jurisdiction shall be reduced to the rate paid by the compulsory Third Party licensee.

4.5 <u>One Royalty</u>. No royalty shall be payable under this ARTICLE 4 with respect to sales of Products between or among MN, MN Affiliates and MN Sublicensees for re-sale, nor shall a royalty be payable under this ARTICLE 4 with respect to Products distributed for use in research and/or development, in clinical trials, training programs, educational programs, or as donations to non-profit institutions or government agencies or as promotional free samples.

4.6 <u>Combination Product</u>. Notwithstanding the provisions of Section 4.3, in the event Product is sold as a combination product with other product components including biologically active components (hereinafter referred to as "Product Component"), Net Sales, for purposes of royalty payments on the combination product, shall be calculated by **[***]**.

4.7 Sublicense Payments.

4.7.1 In the event MN or an MN Affiliate enters into a sublicense with an MN Sublicensee under Section 3.2 of this Agreement granting a sublicense of any rights licensed to MN by MS under Section 3.1 of this Agreement in any country or jurisdiction in the MN Territory , MN shall pay MS the following applicable percentages of Net Sublicense Consideration applicable to such country or jurisdiction subject to the sublicense (hereinafter referred to as "MN Sublicense Payments"), without depending on the stage of development of Product in the MN Territory achieved by MN or an MN Affiliate prior to the first sublicense with an MN Sublicensee in the countries or jurisdictions subject to such sublicense, for so long as MN or an MN Affiliate receives such Net Sublicense Consideration :

(a) **[***]**; or

(b) **[***]**.

MN and any MN Affiliate shall make Commercially Reasonable Efforts to receive consideration from an MN Sublicensee for the grant of the sublicense by MN or such MN Affiliate to such MN Sublicensee under Section 3.2 in the form of cash payment so that such consideration can be recorded as Net Sublicense Consideration.

4.7.2 [***]

The following are examples of the application of Section 4.7.2:

- (a) [***]; and
- (b) [***].

4.8 <u>Third Party Patent Licenses</u>. If MN, any MN Affiliate or any MN Sublicensee would be prevented from the use of MS Intellectual Property for developing, making, having made, using, offering for sale, selling, importing, exporting or distributing Product in any country or jurisdiction in the MN Territory on the grounds that by such use by MN or any MN Affiliate or MN Sublicensee would infringe a Dominating Patent in said country or jurisdiction, and MN or any MN Affiliate or MN Sublicensee, after a full consultation with MS, has entered into a license agreement with such Third Party (hereinafter referred to as "Third Party Patent License"), any royalties or other payments actually paid by MN, such MN Affiliate or such MN Sublicensee to such Third Party under such Third Party Patent License in such country or jurisdiction in any Calendar Quarter in any Royalty Year shall be creditable against the subsequent royalty payable to MS by MN under Section 4.3 (hereinafter referred to as "Section 4.3 Royalty Payments that would be payable by MN to MS under Section in question for such Calendar Quarter, provided, however, that in no event shall such Section 4.3 Royalty Payments and Section 4.7 Royalty Payments in such country or jurisdiction in any Calendar Quarter be **[***]** so long as MN's obligation to make Section 4.3 Royalty Payments or Section 4.7 Royal

ARTICLE 5 ROYALTY REPORTS AND ACCOUNTING

5.1 <u>Reports.</u> During the Royalty Term and for so long as MN Sublicense Payments are payable, MN shall furnish and shall cause MN Affiliates to furnish to MS a written report (hereinafter referred to as "Royalty Report") for each Calendar Quarter showing on a country by country or jurisdiction by jurisdiction and Product by Product basis, (a) the gross sales of all Products sold by MN and MN Affiliates in the MN Territory during such Calendar Quarter and the calculation of Net Sales from such gross sales; (b) the Section 4.3 Royalty Payments, payable in United States dollars, which shall have accrued hereunder based upon Net Sales; (c) the withholding taxes, if any, required by law to be deducted in respect of such royalties; (d) the date of the First Commercial Sale of each Product in each country or jurisdiction in the MN Territory;

(e) the exchange rates used in determining the amount of United States dollars, as more specifically provided in Section 6.2; (f) in the case of a sublicense by MN or an MN Affiliate to an MN Sublicensee, Net Sublicense Consideration and the amount of associated MN Sublicense Payments payable by MN to MS with certificates, vouchers and/or other documents related thereto in sufficient detail to the extent necessary for the verification of the accuracy and legitimacy of such Net Sublicense Consideration, including but not limited to details of Cost of Goods, MN Development Costs and net sales of Product sold by MN Sublicensees. Royalty Reports and payments shall be due forty-five (45) days following the close of each Calendar Quarter. MN shall keep, and shall cause MN Affiliates and MN Sublicensees to keep complete and accurate records in sufficient detail to properly reflect all gross sales of API and Product and Net Sales and net sales of Product sold by MN Sublicensees, and to enable the Section 4.3 Royalty Payments and Section 4.7 Royalty Payments payable hereunder to be determined.

5.2 Audits.

5.2.1 <u>Audit Rights</u>. Upon the written request of MS and not more than once in each Calendar Year, MN shall permit, and shall cause MN Affiliates and MN Sublicensees to permit an independent certified public accounting firm of nationally recognized standing, selected by MS and reasonably acceptable to MN, at MS's expense, to have access during normal business hours on at least ten (10) Business Days' prior written notice, to such of the records of MN, such MN Affiliates or MN Sublicensees, as applicable, as may be reasonably necessary to verify the accuracy of the Royalty Reports for any Royalty Year ending not more than thirty-six (36) months prior to the date of such request. It is understood between the Parties that MS shall have the right to audit the accuracy and legitimacy of the MN Development Costs and Costs of Goods in accordance with this ARTICLE 5.

5.2.2 <u>Audit Results</u>. In the event that such accounting firm concludes that additional royalties or other payments were owed to MS during such period, MN shall remit to MS, within thirty (30) days of receipt by MN of written notice from such accounting firm's conclusion, the amount of such royalties or other payments and interest thereon calculated pursuant to Section 6.5. In the event such accounting firm concludes that amounts were overpaid by MN during such period, MS shall return to MN the amount of such overpayment within thirty (30) days from receipt by MS of written notice from such accounting firm concludes that amounts were overpaid by MN during such period, MS shall return to MN the amount of such overpayment within thirty (30) days from receipt by MS of written notice from such accounting firm concluding that amounts were overpaid by MN. The fees and expenses charged by such accounting firm shall be paid by MS; provided, however, that in the event any such audit reveals an error in favor of MN (i.e. underpayment by MN) of more than **[***]** of the royalties or other payments due hereunder, MN shall pay the reasonable fees and expense charged by such accounting firm in connection with such audit. **[***]**, the calculation of royalties or other payments payable with respect to such Royalty Year shall be binding and conclusive upon MS and MN shall be released from any liability or accountability with respect to royalties or other payments for such Royalty Year.

5.2.3 <u>Confidential Financial Information</u>. MS shall treat all financial information subject to review under this ARTICLE 5 or under any sublicense agreement as

confidential, and shall cause its accounting firm to retain all such financial information in confidence.

ARTICLE 6 PAYMENTS

6.1 Payment Terms. Royalties shown to have accrued by each Royalty Report shall be due and payable on the date such Royalty Report is due. In order for MS to receive compensation on a quarterly basis, MN shall pay to MS, on a quarterly basis, royalties based on the cumulative Net Sales for the applicable Royalty Year through the end of such Calendar Quarter, less royalties previously paid to MS on account of Net Sales for the previous Calendar Quarters in such Royalty Year. MN shall notify MS in writing not later than ten (10) Business Days after the receipt of any Net Sublicense Consideration from any MN Sublicensee (other than the Section 4.7 Royalty Payments, which shall be reported in accordance with Section 5.1) and each such notice shall be accompanied by the appropriate MN Sublicense Payments.

6.2 <u>Payment Method.</u> All payments by MN to MS under this Agreement shall be paid in United States dollars through wire transfer at the bank(s) and to the account(s) designated by MS. Net Sales shall be first determined in the currency of the country or jurisdiction in which they are earned and then converted to its equivalent in United States Dollars. If any currency conversion shall be required in connection with the payment of any royalties or other payments due MS hereunder, such conversion shall be made unless otherwise agreed upon between the Parties by using the average of the exchange rates for the purchase and sale of United States dollars reported by the Wall Street Journal on the last Business Day of the Calendar Quarter to which such royalties or other payments relate. Except as otherwise set forth in this Agreement, any royalties and other payments to be made by MN to MS shall be without deduction of exchange, collection or other charges.

6.3 <u>Exchange Controls</u>. Notwithstanding any other provision of this Agreement, if at any time legal restrictions prevent the prompt remittance of part or all of the royalties or other payments due MS hereunder with respect to any country or jurisdiction in the MN Territory where the Sale takes place, payment shall be made through such lawful means or methods as MN may determine and reasonably acceptable to MS. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country or jurisdiction in the MN Territory where the Sale takes place, the royalty rate for Net Sales in such country or jurisdiction shall be adjusted to the highest legally permissible or government-approved rate.

6.4 <u>Withholding Taxes</u>. MN shall be entitled to deduct from any payment due MS under this Agreement the amount of any withholding taxes payable by MN or MN Affiliates, or any taxes required to be withheld by MN or MN Affiliates, to the extent MN or MN Affiliates pay to the appropriate governmental authority on behalf of MS such taxes, levies or charges. MN shall use Commercially Reasonable Efforts to minimize any such taxes, levies or charges required to be withheld on behalf of MS by MN or MN Affiliates. MN promptly shall deliver to MS proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto. Upon MN's written request, MS shall provide MN with all forms or documentation required by any

applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to, Form W-8BEN and any successor form).

6.5 <u>Late Payment</u>. Any sums not paid to MS by MN when due hereunder, shall accrue interest from the date when due until actually paid at a rate equal to the prime rate of Bank of America, N.A. on the Business Day immediately preceding the commencement of such interest period plus one percent (1%) per annum or the highest rate allowed by applicable law, whichever is less.

ARTICLE 7

CONFIDENTIALITY AND PUBLICITY

7.1 <u>Nondisclosure Obligations</u>. Except as otherwise provided in this ARTICLE 7, during the term of this Agreement and for a period of **[***]** thereafter, both Parties shall maintain in confidence and use only for purposes of this Agreement information and data resulting from or related to the research, development, manufacturing and commercialization of Compound, API and/or Products and other information and data supplied by the other Party under this Agreement and Confidential Disclosure Agreement executed on September 29, 2003. For purposes of this ARTICLE 7, information and data described in this Section 7.1 shall be deemed "Proprietary Information."

7.2 <u>Permitted Disclosures</u>. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, (a) a Party may disclose Proprietary Information of the other Party which is otherwise obligated not to disclose under this ARTICLE 7 to MN Affiliates, MN Sublicensees, and MS Licensees, as applicable, and each Party's consultants, outside contractors and clinical investigators, on a need-to-know basis on condition that such Persons agree to keep the Proprietary Information confidential for the same time periods and to the same extent as such Party is required to keep the Proprietary Information confidential; and (b) a Party (and MN Affiliates, MN Sublicensees or MS Licensees, as applicable) may disclose such Proprietary Information to government or other Regulatory Authorities to the extent that such disclosure is required by applicable law (including without limitation all applicable securities laws), regulation, agency or court order, or is reasonably necessary to obtain patents or authorizations to conduct clinical trials with, and to commercially market Product, provided that the disclosing Party shall provide prior written notice to the other Party and sufficient opportunity to object to such disclosure or to request confidential treatment thereof.

The obligation not to disclose or use Proprietary Information received from the other Party shall not apply to any part of such Proprietary Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts of the Party obligated not to disclose such Proprietary Information in contravention of this Agreement; (ii) the receiving Party can establish by competent written proof is lawfully disclosed to the receiving Party by a Third Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party on a confidential basis; (iii) the receiving Party can establish by competent written proof, prior to disclosure under this Agreement, was already in the possession of the receiving Party, provided such Proprietary

Information was not obtained directly or indirectly from the other Party; (iv) the receiving Party can establish by competent written proof is subsequently and independently developed by the receiving Party without the knowledge of the other Party's Proprietary Information; (v) is disclosed in a press release or other publication agreed to by both Parties, which agreement shall not be unreasonably withheld or delayed or (vi) the receiving Party has obtained prior written consent to disclose from the other Party.

ARTICLE 8

INTELLECTUAL PROPERTY AND INFRINGEMENT

8.1 <u>Ownership of Trademarks</u>. MN shall select, own and maintain Trademarks for Product in the MN Territory. The entire right and title in all Trademarks used by MN, MN Affiliates and, when applicable, MN Sublicensees, in the MN Territory shall be owned, as between MN and MS solely by MN or an MN Affiliate.

8.2 <u>Improvements by MN</u>. As between MS and MN, all rights and title to and interest in any Improvement conceived, developed, discovered and/or reduced to practice by MN, MN Affiliates, and/or MN Sublicensees in connection with the license granted to MN under Section 3.1 or activities by MN, MN Affiliates, and/or MN Sublicensees hereunder shall be vested in MN or an MN Affiliate subject to the license granted to MS under this Agreement.

8.3 Improvements by MS. As between MS and MN, all rights and title to and interest in any Improvement conceived, developed, discovered and/or reduced to practice by MS, MS Affiliates and/or MS Licensees or activities by MS, MS Affiliates and/or MS Licensees hereunder shall be vested in MS or an MS Affiliate, subject to the license granted to MN under this Agreement.

8.4 <u>Patent Prosecution and Maintenance of MS Patent Assets</u>. MS shall use Commercially Reasonable Efforts to prosecute the MS Patent Assets in the United States, Canada, Australia, and Major European Countries and in such other jurisdictions as are mutually agreed upon by the Parties. Subject to the terms of this Agreement, MS shall have the initial right to control the filing, prosecution and maintenance of the MS Patent Assets in the MN Territory and MS shall have the sole and unrestricted right to control the filing, prosecution and maintenance of the MS Patent Assets in the MS Territory. MS shall be responsible for the payment of all such patent prosecution and maintenance costs and expense incurred by MS in prosecution and maintenance of such MS Patent Assets. MS shall provide MN with a copy of draft patent application that MS has prepared for the filing in the MN Territory at least thirty (30) days prior to the targeted filing date (hereinafter referred to as "MS Target Filing Date"). MS shall notify MN of the MS Target Filing Date at the same time MS provides MN with the above draft patent application. MN may provide MS with its comments thereon within fifteen (15) days of the receipt of such draft and MS may revise the draft patent application taking MN's reasonable comments into account. In addition, MS shall provide a copy of material or important prosecution documents related to the MS Patent Assets in the MN Territory and correspondence received from the patent offices of or from MS's agents in the MN Territory

reasonably promptly after MS's receipt thereof. MN may provide MS with its comments thereon within the time reasonably requested by MS and MS may prepare a response to the patent office taking MN's reasonable comments into account. MS shall inform MN of any significant developments in the prosecution of pending patent applications included in the MS Patent Assets in the MN Territory, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If MS decides not to file, prosecute or maintain a Patent Asset included in the MS Patent Assets in any country or jurisdiction in the MN Territory, it shall provide MN with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) days prior written notice), and MN shall have the right, but not the obligation, at its sole expense, to file, prosecute or maintain such Patent Asset included in the MS Patent Assets and, if MN elects to do so, MS shall assign to MN all of MS's right, title and interest in and to such Patent Asset in the MN Territory and, thereafter, such Patent Asset shall be deemed to be MN Patent Assets and treated accordingly hereunder.

8.5 Patent Prosecution and Maintenance of MN Patent Assets. MN shall use, and cause any MN Affiliates to use, Commercially Reasonable Efforts to prosecute the MN Patent Assets in the United States, the major countries in the European Union, and Japan, Peoples Republic of China and South Korea and in such other jurisdictions as are mutually agreed upon by the Parties. MN and any MN Affiliates, as applicable, shall have the initial right to control the filing, prosecution and maintenance of the MN Patent Assets in the MS Territory and MN and any MN Affiliates, as applicable, shall have the sole and unrestricted right to control the filing, prosecution and maintenance of the MN Patent Assets in the MN Territory. MN shall be responsible, and cause any MN Affiliates to be responsible, for the payment of all such patent prosecution and maintenance costs and expense incurred by MN and/or such MN Affiliates in prosecution and maintenance of such MN Patent Assets. MN shall provide MS, and cause any MN Affiliates to provide MS, with a copy of draft patent application that MN and/or such MN Affiliates have prepared for the filing in the MN Territory and in the MS Territory at least thirty (30) days prior to the targeted filing date (hereinafter referred to as "MN Target Filing Date"). MN shall notify MS, and cause any MN Affiliates to notify MS, of the MN Target Filing Date at the same time MN and/or such MN Affiliates provide MS with the above draft patent application. MS may provide MN with its comments thereon within fifteen (15) days of the receipt of such draft and MN may revise, or cause such MN Affiliates to revise, the draft patent application taking MS's reasonable comments into account. In addition, MN shall provide MS, and cause any MN Affiliates to provide MS, with a copy of any material or important prosecution documents related to the MN Patent Assets in the MS Territory and correspondence received from the patent offices of and MN's agents in the MS Territory reasonably promptly after MN's receipt thereof by itself or through such MN Affiliates. MS may provide MN with its comments thereon within the time reasonably requested by MN and MN and/or MN Affiliates, as applicable, may prepare a response to the patent office taking reasonable comments from MS into account. MN shall inform MS, and cause any MN Affiliates to inform MS, of any significant developments in the prosecution of pending patent applications included in the MN Patent Assets, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If MN and/or any MN designee decide not to file, prosecute or maintain a Patent Asset included in the MN Patent

Assets in any country or jurisdiction in the MS Territory, MN shall provide MS with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) day prior written notice), and MS shall have the right, but not the obligation, at its sole costs and expense, to file, prosecute or maintain such Patent Asset included in the MN Patent Assets and, if MS elects to do so, MN shall assign to MS, and cause any MN Affiliates to assign to MS, any and all of the right, title and interest of MN and/or such MN Affiliates in and to such Patent Asset in the MS Territory and, thereafter, such Patent Asset shall be deemed to be MS Patent Assets and treated accordingly hereunder.

8.6 <u>Cooperation</u>. Each Party shall make available as far as possible to the other Party or to the other Party's authorized attorneys, agents, representatives, employees or consultants any documents necessary or appropriate to enable the other Party to file, prosecute and maintain patent applications and resulting patents, as set forth in Sections 8.4 and 8.5 above, for a period of time sufficient for the other Party to obtain the assistance it needs from the first Party. Where appropriate, each Party shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other Party.

8.7 <u>Enforcement of Patent Assets</u>. In the event either Party learns of significant and continuing or threatened significant infringement of the MS Patent Assets or the MN Patent Assets, it shall promptly provide written notice to the other Party of the fact and supply such other Party with all evidence it possesses pertaining to and establishing said infringement or threatened infringement.

8.7.1 MN shall have the first right to take legal action to enforce against the infringer of the MS Patent Assets in the MN Territory, and shall consult with MS both prior to and during said enforcement.

8.7.2 MS shall have the first right to take legal action to enforce against the infringer of the MN Patent Assets in the MS Territory, and shall consult with MN both prior to and during said enforcement.

8.8 Procedure for Enforcement of Patent Assets.

8.8.1 MN shall have six (6) months from the date of receipt of notice of request by MS to abate the infringement, or to file suit against the infringer of the MS Patent Assets in the MN Territory, at the sole expense of MN, following consultation with MS. If MN does not, within six (6) months of receipt of such notice, abate the infringement or file suit to enforce the MS Patent Assets against the infringer of the MS Patent Assets in the MN Territory, MS shall have the right to take whatever action it deems necessary or appropriate in its own name to enforce the MS Patent Assets in the MN Territory at sole expense of MS; provided, however, that, within thirty (30) days after receipt of notice of MS's intent to file such suit, MN shall have the right to jointly prosecute such suit at costs and expense to be equally shared by both Parties.

8.8.2 MS shall have six (6) months from the date of receipt of notice of request by MN to abate the infringement, or to file suit against the infringer of the MN

Patent Assets in the MS Territory, at the sole expense of MS, following consultation with MN. If MS does not, within six (6) months of receipt of such notice, abate the infringement or file suit to enforce the MN Patent Assets against the infringer of the MN Patent Assets in the MS Territory, MN shall have the right to take whatever action it deems necessary or appropriate in its own name to enforce the MN Patent Assets in the MS Territory at sole expense of MN; provided, however, that, within thirty (30) days after receipt of notice of MN's intent to file such suit, MS shall have the right to jointly prosecute such suit at costs and expense to be equally shared by both Parties.

8.9 <u>Settlements.</u> The Party controlling the action may not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. Notwithstanding the foregoing, MS and MN shall cooperate with each other in the planning and execution of any action to enforce the MS Patent Assets or the MN Patent Assets. Any recovery obtained by MN or MS shall be shared as follows:

(i) the Party that initiated and prosecuted, or maintained the defense of, the action shall recoup all of its costs and expense (including reasonable attorneys' fees) incurred in connection with the action, whether the recovery is by settlement or otherwise;

(ii) the other Party then shall, to the extent possible, recover its costs and expense (including reasonable attorneys' fees) incurred in connection with the action;

(iii) if MS initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining then shall be retained by MS; and

(iv) if MN initiated and prosecuted, or maintained the defense of, the action relating to the MN Patent Assets, the amount of any recovery remaining shall be retained by MN; if MN initiated and prosecuted, or maintained the defense of, the action relating to the MS Patent Assets, the amount of any recovery remaining shall be retained by MN, except that MS shall receive a portion equivalent to the Section 4.3 Royalty Payments it would have received in accordance with the terms of this Agreement as if the amount of any remaining recovery had been Net Sales.

8.10 Notification of Patent Term Restoration. The Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country or jurisdiction where applicable to the MS Patent Assets in the MN Territory and the MS Territory. Each Party shall notify the other if it becomes aware of (a) the issuance of a patent included within the MS Patent Assets, giving the date of issue and patent number for each such patent, and (b) each notice pertaining to any patent included within the MS Patent Assets pursuant to the United States Drug Price Competition and Patent Term Restoration Act of 1984 (hereinafter referred to as "1984 Act"), including notices pursuant to §§ 101 and 103 of the 1984 Act from Persons who have filed an ANDA. Such notices shall be given promptly, but in any event within five (5) days of each Party's becoming aware of such patent's issue or receipt of each such notice pursuant to the 1984 Act, whichever is applicable. MS shall notify MN of each filing for patent term restoration under the 1984 Act, and all awards of patent term

restoration (extensions) with respect to the MS Patent Assets. Likewise, MS or MN, as the case may be, shall inform the other Party of patent extensions and periods of data exclusivity in the rest of the world regarding any Patent Assets included in the MS Patent Assets and MN Patent Assets.

8.11 Infringement Actions by Third Parties. If MN or any of MN Affiliates shall be sued by a Third Party in a country or jurisdiction in the MN Territory for infringement of a patent held by such Third Party because of the use of MS Intellectual Property for the development, manufacture, importation, exportation, use, offer for sale, sale, market or distribution of Compound, API or Products, MN shall promptly notify MS in writing of the institution of such suit. MN shall have the first right, in its sole discretion, to control the defense of such suit at its own expense, in which event MS shall have the right to be represented by advisory counsel of its own selection, at its own expense, and shall cooperate fully in the defense of such suit and furnish to MN all evidence and assistance in MS's control. If MN does not elect within thirty (30) days after such notice from MN to MS to so control the defense of such suit, MS shall have the right, but not the obligation, to undertake such control at its own expense, and MN shall then have the right to be represented by advisory counsel of its own selection and at its own expense, and MN shall then have the right to be represented by advisory counsel of its own selection and at its own expense, and MN shall not settle the suit or otherwise consent to an adverse judgment in such suit that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. In the event that royalty or other payments are required to be paid by MN or any MA Affiliates to such Third Party as the result of a judgment or settlement under this Section 8.11, such royalty Payments and/or Section 4.7 Royalty Payments in such country or jurisdiction in any Calendar Quarter of such Calendar Quarter be **[***]** so long as MN's obligation to make payment of Section 4.3 Royalty Payments and Section 4.7 Royalty Payments in such country or jurisdiction in any Calendar Quarter or jurisdiction in any colendar Quarter or jurisdiction in any cale

ARTICLE 9 TERM AND TERMINATION

9.1 Expiration. Unless terminated earlier pursuant to Sections 9.2 or 9.3 below, this Agreement shall commence as of the Effective Date and expire on a country by country or jurisdiction by jurisdiction and Product by Product basis on the expiration of the last to expire Royalty Term applicable to such Product in such country or jurisdiction. Notwithstanding the foregoing, in case that MN or an MN Affiliate enters into a sublicense with an MN Sublicensee, MN's payment obligation relating to MN Sublicense Payments pursuant to Section 4.7 shall continue for so long as MN or an MN Affiliate receives Net Sublicense Consideration from such MN Sublicensee. Expiration of this Agreement in a particular country or jurisdiction in the MN Territory relating to a particular Product under this Section 9.1 shall not preclude MN and/or an MN Affiliate from continuing to develop, make, have made, use, sell, offer for sale, market, import, export and distribute such Product in such country or jurisdiction without further

remuneration to MS. Any expiration of this Agreement under this Section 9.1 shall not affect the license granted by MN to MS under Section 3.3, which license shall survive any expiration of this Agreement. Nevertheless, such a surviving license shall be governed by the provisions of Section 9.5, below.

9.2 Termination by MN. MN shall have the right, in its sole discretion, to terminate this Agreement as follows:

9.2.1 with respect to the entire Agreement or with respect to any country or jurisdiction in the MN Territory in the event that (i) a Third Party claims that an activity associated with the commercialization of Compound or Product infringes such Third Party's intellectual property in any country or jurisdiction in the MN Territory, (ii) MN and MS mutually agree in writing that such Third Party's intellectual property includes a Dominating Patent, (iii) either MN has failed, after a reasonable period of time and use of good faith and Commercially Reasonable Efforts, to enter into a Third Party License or MN has opted, from a reasonable pharmaceutical company's point of view and after full consultation with MS, not to enter into such Third Party License, and (iv) after all of the foregoing (i) to (iii), MN provides not less than thirty (30) days prior written notice of such termination to MS with respect to the entire Agreement or any such country or jurisdiction in the MN Territory;

9.2.2 with respect to the entire Agreement or, upon the mutual agreement of the Parties, with respect to the United States, the EMEA Member States or the rest of the MN Territory (each, a "MN Sub-Territory"), by providing not less than ninety (90) days written notice to MS, if in MN's reasonable opinion, from a reasonable pharmaceutical company's point of view, after full consultation with MS, the safety, patient tolerability, efficacy, or the profile or the commercial viability of Product does not justify continued development by MN, an MN Affiliate and/or an MN Sublicensee;

9.2.3 with respect to the entire Agreement, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against MS, and MN provides not less than thirty (30) days prior written notice of such termination to MS, provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if MS consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof;

9.2.4 with respect to the entire Agreement, upon or after the breach of any material provision of this Agreement by MS, if MS has not cured such breach within ninety (90) days after written notice thereof from MN; provided, however, that if the breach is not capable of being cured within ninety (90) days of such written notice, this Agreement may not be terminated so long as MS commences and is taking commercially reasonable actions to cure such breach as promptly as practicable; or

9.2.5 with respect to the entire Agreement, in the event that any delay by MS in fulfilling or performing any term of this Agreement for any of the reasons set forth in Section 12.1 extends longer than twelve (12) months, by providing a written notice of such termination to MS.

9.3 Termination by MS. MS shall have the right, in its sole discretion, to terminate this Agreement as follows:

9.3.1 with respect to the entire Agreement, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against MN, and MS provides not less than thirty (30) days prior written notice of such termination to MN, provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if MN consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof;

9.3.2 with respect to the entire Agreement, upon or after the breach of any material provision of this Agreement by MN, including without limitation, MN's failure to purchase, obtain, keep in force and maintain the insurance as set forth in Section 11.4, if MN has not cured such breach within ninety (90) days after written notice thereof from MS; provided, however, that if the breach is not capable of being cured within ninety (90) days of such written notice, this Agreement may not be terminated so long as MN commences and is taking commercially reasonable actions to cure such breach as promptly as practicable;

9.3.3 with respect to the entire Agreement or any particular country or jurisdiction, at the option and sole discretion of MS, in accordance with Section 2.1.4, by providing written notice of such termination to MN; or

9.3.4 with respect to the entire Agreement, in the event that any delay by MN in fulfilling or performing any term of this Agreement for any of the reasons set forth in Section 12.1 extends longer than twelve (12) months, by providing written notice of such termination to MN.

9.4 <u>Rights Not Affected</u>. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of 11 U.S.C. §101 et seq. (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that MN and MS shall retain and may fully exercise all of their respective rights, remedies and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy or reorganization case by or against a Party under the Bankruptcy Code, the other Party shall be entitled to all applicable rights under Section 365 (including 365(n)) of the Bankruptcy Code. Upon rejection of this Agreement by a Party or a trustee in bankruptcy for such Party, pursuant

to Section 365(n) of the Bankruptcy Code, the other Party may elect (i) to treat this Agreement as terminated by such rejection or (ii) to retain its rights (including any right to enforce any exclusivity provision of this Agreement) to intellectual property (including any embodiment of such intellectual property) under this Agreement and under any agreement supplementary to this Agreement for the duration of this Agreement and any period for which this Agreement could have been extended by such other Party, subject, however, to the continued payment of all amounts owing under this Agreement, all of which amounts shall be deemed to be royalties for purposes of Section 365(n) of the Bankruptcy Code. Upon written request to the trustee in bankrupt yor bankrupt Party, the trustee or Party, as applicable, shall (i) provide to the other Party any intellectual property (including any embodiment of such intellectual property) held by the trustee or the bankrupt Party and shall provide to the other Party a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property and all in ot interfere with the rights of the other Party to such intellectual property as provided in this Agreement or any agreement supplementary to this Agreement, including any right to obtain such intellectual property (or such embodiment or duplicates thereof) from a Third Party.

9.5 Effect of Expiration and Termination.

9.5.1 Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing on or prior to such expiration or termination.

9.5.2 Subject to the provisions of this Section 9.5, all rights, licenses and obligations of MS and of MN with respect to and under this Agreement, in its entirety or with respect to the terminated country, jurisdiction or the MN Sub-Territory in the MN Territory, as applicable, shall terminate in the event of a termination pursuant to Section 9.2 or 9.3, provided, however, that in the event of a partial termination by MN under Section 9.2, this Agreement shall continue in full force and effect with respect to the countries, jurisdictions or MN Sub-Territory in the MN Territory unaffected by such partial termination, and such terminated country, jurisdiction or MN Sub-Territory shall be excluded from the countries or jurisdictions in the MN Territory and thereafter shall be deemed a country or jurisdiction in the MS Territory and treated accordingly hereunder.

9.5.3 In the event of any termination of this Agreement by MN under Section 9.2 or by MS under Section 9.3., MS shall, if requested by any then MN Sublicensee, accept assignment of the sublicense agreement as of the effective date of termination of this Agreement, provided that (a) the MN Sublicensee is not in breach of its sublicense agreement at the effective date of termination of this Agreement; and (b) the MN Sublicensee acquires no rights from or obligations on the part of MS, other than those that are specifically granted in this Agreement, and the MN Sublicensee assumes all obligations to MS required of MN by this Agreement, including past due obligations existing at the time of assumption of the sublicense with such MN Sublicensee.

9.5.4 In case of any termination of this Agreement, MN, MN Affiliates and MN Sublicensees shall, for a period of six (6) months from the effective date of such termination, have the right to sell or otherwise dispose of the stock of any Product then on

hand or in process of manufacture or supply, subject to MN's obligation under this Agreement to pay to MS pursuant to Section 4.3 or Section 4.7, as applicable.

9.5.5 In the event that this Agreement is terminated in its entirety by MN under Section 9.2.1, 9.2.2 or 9.2.5, (i) all rights and licenses granted by one Party to the other Party under this Agreement shall revert to the first Party; and (ii) if MS so requests of MN in writing, MN shall grant to MS in any country or jurisdiction in the MS Territory and/or MN Territory an exclusive (even to MN) license, including the right to grant sublicenses, to and under the MN Intellectual Property, including all right, title and interest in and to MN Regulatory Filings pertaining to Compound and Product, solely to research, develop, make, have made, use, offer for sale, market, sell, import, export, and distribute Compound, API and Product in the Field; provided, however, that such license [***]; and (iii) with the exception of the termination of this Agreement in its entirety under Section 9.2.1, if MS so requests of MN in writing, MN shall, at MS's expense, render MS assistance for implementation of MS's rights granted under this Section 9.5.5, including, if MN or its designee (including an MN Affiliate and an MN Sublicensee) is then manufacturing API or Product for development and/or commercial use prior to the effective date of such termination, providing MS with assistance in transfer of Manufacturing Technology.

9.5.6 In the event that this Agreement is terminated in its entirety by MN under Section 9.2.4, MN shall have an irrevocable, perpetual and exclusive (even to MS) license under MS Intellectual Property to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound and Product in the MN Territory. In consideration for such license, MN shall pay MS an amount **[***]**; provided, however, that ARTICLES 4 and 5 and any other provision required to interpret and enforce the Parties' rights and obligations under this Section 9.5.6 shall survive such termination, but only to the extent required for the full observation and performance of this Section 9.5.6.

9.5.7 In the event that this Agreement is terminated by MS under Section 9.3.2 and 9.3.3, (i) all rights and licenses granted by one Party to the other Party hereunder shall revert to the first Party; (ii) if MS so requests of MN in writing, MN shall grant to MS in any country or jurisdiction in the MS Territory and in the MN Territory an irrevocable, perpetual, fully paid-up, exclusive (even to MN) license, including the right to grant sublicenses, to and under the MN Intellectual Property including all right, title and interest in and to MN Regulatory Filings pertaining to Compound, API and Product, solely to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field; and (iii) if MS so requests of MN in writing, MN shall, at MN's expense, render MS assistance for implementation of MS's rights granted under this Section 9.5.7, including, if MN or its designee (including an MN Affiliate and an MN Sublicensee) is then manufacturing API or Product for development and/or commercial use prior to the effective date of such termination, providing MS with assistance in transfer of Manufacturing Technology.

9.5.8 In the event that this Agreement is terminated by MS under Section 9.3. 4, (i) all rights and licenses granted by one Party to the other Party hereunder shall revert to the first Party; (ii) if MS so requests of MN in writing, MN shall grant to MS

in any country or jurisdiction in the MS Territory and/or MN Territory an exclusive (even to MN) license, including the right to grant sublicenses, to and under the MN Intellectual Property including all right, title and interest in and to MN Regulatory Filings pertaining to Compound, API and Product, solely to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field; provided, however, that such license shall be **[***]**; and (iii) if MS so requests of MN in writing, MN shall, at MS's expense, render MS assistance for implementation of MS's rights granted under this Section 9.5.8, including, if MN or its designee (including an MN Affiliate and an MN Sublicensee) is then manufacturing API or Product for development and/or commercial use prior to the effective date of such termination, providing MS with assistance in transfer of Manufacturing Technology.

9.5.9 In addition to any other provision of this Agreement which by their terms continue after the expiration or termination of this Agreement, the following provisions shall survive the expiration or termination of this Agreement and shall continue in full force and effect: ARTICLE 1, ARTICLES 4, 5 and 6 (solely with respect to any amounts that have accrued or are owing and not paid), ARTICLE 7, ARTICLE 8, ARTICLE 9, ARTICLE 10, and ARTICLE 11. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.

9.5.10 Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

ARTICLE 10 REPRESENTATIONS AND WARRANTIES

10.1 Each Party hereby represents and warrants to the other Party as follows:

10.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

10.1.2 Such Party has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and the execution, delivery and performance by such Party of this Agreement have been duly authorized by all necessary corporate action. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except as enforceability may be limited by (A) any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor's rights generally, or (B) general principles of equity, whether considered in a proceeding in equity or at law;

10.1.3 All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained; and

10.1.4 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations or any judgment, injunction, decree, determination or award presently in effect having applicability to it, and (b) do not conflict with, or constitute a default under, any agreement of such Party.

10.2 Additional MS Representations and Warranties. MS hereby represents and warrants that: (a) the MS Intellectual Property in the MN Territory are owned or Controlled solely and exclusively by MS free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental or university entity or subdivision thereof, has any valid claim of ownership with respect to the MS Intellectual Property in the MN Territory, whatsoever; (b) MS has not previously granted, and will not grant during the term of this Agreement, any right, license or interest in and to the MS Intellectual Property, or any portion thereof, inconsistent with the license granted to MN herein; (c) as of the Effective Date, MS is aware of no reason why MS Patent Assets listed on Schedule 1.44 could be held invalid or unenforceable; (d) as of the Effective Date, there are no pending or, to the best knowledge of MS, threatened actions, suits, investigations, claims or proceedings in any way relating to the MS Intellectual Property in the MN Territory; (e) as of the Effective Date, there are no pending or, to the best knowledge of MS, threatened actions, suits, or claims by any Third Party alleging that use of the MS Intellectual Property in the MN Territory and the contemplated research, development, importation or exportation, manufacture, use, offer for sale and sale of any Compound or Product in the Field in the MN Territory would infringe any patent rights owned or possible by Ratent Assets in the MN Territory (including all material information received by MS concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification, or any official proceeding involving a MS Patent Asset in the MN Territory) and will continue such disclosure with respect to new events during the term of the Agreement; and (g) Schedule 1.44 contains a complete and accurate list of all MS Patent Assets in the MN Territory which are owned or Controlled by M

10.3 <u>Additional MN Covenant.</u> MN agrees that it will not grant during the term of this Agreement and thereafter, any right, license or interest in and to the MN Intellectual Property, or any portion thereof, that would prohibit or materially adversely affect the ability of MN to grant MS the license granted to MS herein in the MS Territory and, when applicable, in the MN Territory.

10.4 <u>Effect of Representations and Warranties</u>. It is understood that if the representations and warranties made by a Party under this ARTICLE 10 are not true and accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, the Party making such representations and warranties shall indemnify and hold the other Party harmless from and against any such damages, liabilities, costs or other expenses incurred as a

result. Notwithstanding the foregoing, if the representations and warranties made by MS under Section 10.2 (e) are not true and accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, Section 8.11 shall operate to indemnify MN and MS shall have no further obligation to compensate MN for such damages, liabilities, costs or other expenses incurred as a result.

10.5 <u>MS Warranty Disclaimer</u>. Except for the warranties expressly provided under Sections 10.1 and 10.2, the rights granted to MN by MS under this Agreement and the associated MS Intellectual Property are provided WITHOUT ANY OTHER WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED OR STATUTORY, AND MS HEREBY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, TITLE, AND ANY WARRANTY THAT MAY ARISE FROM COURSE OF DEALING, COURSE OF PERFORMANCE OR USAGE OF TRADE. MS DOES NOT MAKE, AND HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY THAT COMPOUND, API, PRODUCT OR THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, OFFER FOR SALE, SALE, MARKETING, DISTRIBUTION, IMPORT OR EXPORT THEREOF DO NOT INFRINGE OR VIOLATE ANY PATENT OR ANY OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY OR THAT ANY PATENTS WITHIN THE MS PATENT ASSETS ARE VALID OR ENCORCEABLE OR THAT ANY PATENTS WILL ISSUE UPON ANY PATENT APPLICATIONS WITHIN THE MS PATENT ASSETS.

10.6 <u>MN Warranty Disclaimer</u>. Except for the warranties expressly provided under Section 10.1 and 10.3, the rights granted to MS by MN under this Agreement and the associated MN Intellectual Property are provided WITHOUT ANY OTHER WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED OR STATUTORY, AND MN HEREBY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, TITLE, AND ANY WARRANTY THAT MAY ARISE FROM COURSE OF DEALING, COURSE OF PERFORMANCE OR USAGE OF TRADE. MN DOES NOT MAKE, AND HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY THAT COMPOUND, API, PRODUCT OR THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, OFFER FOR SALE, SALE, MARKETING, DISTRIBUTION, IMPORT OR EXPORT THEREOF DO NOT INFRINGE OR VIOLATE ANY PATENT OR ANY OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY OR THAT ANY PATENTS WITHIN THE MN PATENT ASSETS ARE VALID OR ENCORCEABLE OR THAT ANY PATENTS WILL ISSUE UPON ANY PATENT APPLICATIONS WITHIN THE MN PATENT ASSETS.

10.7 Without limiting the generality of the foregoing, this Agreement does not:

10.7.1 obligate MS or MN to bring or prosecute actions or suits against Third Parties for patent infringement except as provided in ARTICLE 8;

10.7.2 confer by implication, estoppel or otherwise any license or rights under any patents or know-how of MS or MN other than MS Intellectual Property or MN Intellectual Property, as defined in this Agreement, regardless of whether those patents are dominant or subordinate to MS Patent Assets or MN Patent Assets, respectively; or

10.7.3 obligate MS or MN to furnish any know-how or other information except as expressly set forth herein.

ARTICLE 11 INDEMNIFICATION

11.1 MN's Obligation. MN shall defend, indemnify, and hold harmless MS, MS Affiliates and their respective directors, officers, shareholders, employees and agents (hereinafter referred to as "MS Indemnitees"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expense, including, but not limited to the amount of any judgment or settlement and reasonable attorney's fees (hereinafter referred to as "Damages") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against the MS Indemnitee that is due to, arising from or based upon:

- (a) any breach of a representation, warranty, covenant or obligation of MN under this Agreement,
- (b) any negligent or more culpable act or omission of MN under this Agreement, or
- (c) the research, development, manufacture, use, offer for sale, sale, importation, exportation, distribution, or other commercialization or exploitation of Compound, API and/or Products by MN, MN Affiliates or MN Sublicensees in the MN Territory.

However, MN shall not be required to indemnify or hold harmless the MS Indemnitees from Damages to the extent that such Damages are determined to have resulted from the negligent or more culpable acts or omissions of an MS Indemnitee.

11.2 <u>MS's Obligation</u>. MS shall defend, indemnify, and hold harmless MN, MN Affiliates and their respective directors, officers, shareholders, employees and agents (hereinafter referred to as "MN Indemnitees"), from and against any and all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against the MN Indemnitee that is due to, arising from or based upon:

- (a) any breach of a representation, warranty, covenant or obligation of MS under this Agreement,
- (b) any negligent or more culpable act or omission of MS under this Agreement, or

(c) the research, development, manufacture, use, offer for sale, sale, importation, exportation, distribution, or other commercialization or exploitation of Compound, API and/or Products by MS, MS Affiliates or MS Licensees in the MS Territory.

However, MS shall not be required to indemnify or hold harmless the MN Indemnitees from Damages to the extent that such Damages are determined to have resulted from the negligent or more culpable acts or omissions of an MN Indemnitee.

11.3 <u>Indemnification Procedure</u>. Each Party shall promptly notify the other Party in writing of any claim for which such Party intends to seek indemnification hereunder. Concurrent with the provision of notice pursuant to this Section 11.3, such Party shall provide to the other Party copies of any complaint, summons, praecipe, subpoena or other court filings or correspondence related to such claim and will give such other information with respect thereto as the other Party shall reasonably request. A Party seeking indemnification hereunder will cooperate with the indemnitor at the indemnitor's expense in the defense of any suit.

11.4 Insurance. MN shall maintain and keep in force during the term of this Agreement and for a period of at least five (5) years after it has ceased commercial distribution, Sale or use of any Compound and/or Product comprehensive general liability insurance, including Products/Completed Operations, Contractual and Broad Form Property Damage, in such amount as MN customarily maintains with respect to its other products and which is reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities at the respective place of business of MN but in any event with the coverage of [***] per occurrence or series of occurrences, combined single limit for Bodily Injury and Property Damage. It is understood that such insurance shall not be construed to limit MN's liability with respect to such indemnification obligations. Such insurance shall be placed with a first class insurance carrier with at least BBB rating by Standard & Poor's. Upon MS's request, MN shall furnish a certificate of such insurance to MS (or provide MS with a written affirmation of the adequacy of an existing certificate) evidencing the foregoing endorsements, coverage and limits, and MN shall provide MS with notice prior to any cancellation, non-renewal or material change in such insurance, to the extent MN receives advance notice of such matters from its insurer.

ARTICLE 12

MISCELLANEOUS

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, earthquakes, embargoes, power shortage or failure, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; provided, however, that, in the event any such delay extends longer than twelve (12) months, the other Party may terminate this Agreement in accordance with ARTICLE 9. As soon as practicable after the occurrence of any such event the

affected Party shall (a) notify the other Party thereof, (b) provide to such other Party as much detail as possible with respect to such event and shall keep the other Party informed of any further development and results of such event, and (c) use its Commercially Reasonable Efforts to limit the resulting delay in its performance. Immediately after such event ceases or is removed, the affected Party shall perform its obligation suspended by such events.

12.2 <u>Assignment</u>. Except as expressly provided hereunder, this Agreement shall not be assigned or otherwise transferred, nor shall any right or obligations hereunder be assigned or transferred by MN without the prior written consent of MS, which consent shall not be unreasonably withheld by MS; provided, however, that MN may, without such consent, assign this Agreement and its rights and obligations hereunder to an MN Affiliate or in connection with (i) a merger in which MN is not the surviving entity, (ii) a consolidation or division of MN, (iii) a sale of all or substantially all of the assets or the business(es) of MN, (iv) a change of control resulting from a sale or repurchase of shares or similar transaction (whether in one or more related transactions) involving MN, or (v) any similar transaction. Any purported assignment or other disposition by MN or MS, except as permitted herein, shall be null and void. For the avoidance of doubt, MS may assign this Agreement and its rights and obligations hereunder to any Person at MS's sole discretion. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Subject to the foregoing, this Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assignees.

12.3 <u>Severability</u>. In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the original purposes of this Agreement.

12.4 <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered by hand or by facsimile or email (and promptly confirmed by personal delivery, U.S. or international first class mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated in the first paragraph of this Agreement, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

12.5 <u>Applicable Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to the conflicts of law principles thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Assets in question.

12.6 Dispute Resolution.

(a) The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (hereinafter referred to as "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within thirty (30) days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within thirty (30) days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers are unable to settle the Dispute between themselves within thirty (30) days, they shall so report to the Parties in writing. The Dispute shall then be referred to arbitration as set forth in the following subsection (b).

(b) Any dispute which could not be settled by the Chief Executive Officers pursuant to subsection (a) above shall be finally settled by arbitration, which shall be conducted in New York, U.S.A in accordance with the rules of the American Arbitration Association (hereinafter referred to as "AAA") then in force, if initiated by MS, or in Tokyo, Japan in accordance with the rules of the Japan Commercial Arbitration Association (hereinafter referred to as "JCAA") then in force, if initiated by MN, and the language of the arbitration shall be English. The arbitration shall be conducted by a panel of three arbitrators with experience in the pharmaceutical industry: one arbitrator shall be appointed by each of MN and MS and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two-Party appointed arbitrators.

The tribunal shall issue its award within forty-five (45) days after the date on which the arbitration proceedings have closed. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the arbitration levied by the AAA or JCAA, as the case may be.

12.7 <u>Injunctive Relief</u>. Each party acknowledges and agrees that, due to the unique and valuable nature of Proprietary Information and materials of the other Party, there may be no adequate remedy at law for any breach by such Party of Section 3.1, 3.3 and/or ARTICLE 7 of this Agreement, that any such breach may result in irreparable harm to the non-breaching Party for which monetary damages would be inadequate to compensate the non-breaching Party, and that the non-breaching Party shall have the right, in addition to any other rights available under applicable law, to obtain from any court of competent jurisdiction injunctive relief to restrain any breach or threatened breach of, or otherwise to specifically enforce, any covenant or obligation of such Party under such Section 3.1, 3.3 and/or ARTICLE 7.

12.8 <u>LIMITATION OF LIABILITY</u>. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

12.9 <u>Further Assurances</u>. At any time or from time to time on and after the Effective Date, each Party shall at the request of the other (i) deliver to the other such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as such Party or the other Party may reasonably deem necessary or desirable in order for the other Party to obtain the full benefits of this Agreement and the transactions contemplated herein.

12.10 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made including Confidential Disclosure Agreement executed on September 29, 2003 and Letter of Intent executed on September 22, 2004, are expressly superseded by this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

12.11 <u>Headings</u>. The captions to the several ARTICLES and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several ARTICLES and Sections hereof.

12.12 <u>Independent Contractors</u>. It is expressly agreed that MS and MN shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MS nor MN shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

12.13 <u>Waiver</u>. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

12.14 <u>Counterparts</u>. This Agreement may be executed in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

MediciNova, Inc.

By: /s/ Yuichi Iwaki, MD., Ph. D. Name: Yuichi Iwaki, MD., Ph. D. Title: Chairman of the Board, Chief Executive Officer

Meiji Seika Kaisha, Ltd.

By: /s/ Akinobu Otsubo

Name: Akinobu Otsubo

Title: Executive Vice President, President of Pharmaceutical Company

SCHEDULE 1.12

COMPOUND DIAGRAM

[***]

SCHEDULE 1.44

MS PATENT ASSETS

[***]

SCHEDULE 4.3

EXAMPLES OF ROYALTY CALCULATION

For the purpose of calculation of Section 4.3 Royalty Payments payable by MN to MS hereunder:

"Patent/Exclusivity Net Sales" shall mean Net Sales during the Royalty Term set forth in Sections 4.3.1 and 4.3.2;

"Non-Patent/Exclusivity Net Sales" shall mean Net Sales during the Royalty Term set forth in Section 4.3.4 (a);

"Generic Competition Net Sales" shall mean Net Sales during the Royalty Term set forth in Section 4.3.4 (b);

"Tier 1", "Tier 2" and "Tier 3" shall mean as follows; and

Annual Net Sales in U.S.:	Royalty Rate:
Tier 1; Up to [***]	[***]
Tier 2; From [***]	[***]
Tier 3; From and over [***]	[***]
Aggregate Annual Net Sales outside U.S.:	Royalty Rate:
	Royalty Rate: [***]
Aggregate Annual Net Sales outside U.S.: Tier 1; Up to [***] Tier 2; From [***]	

"<u>\$</u>" shall mean United States dollar.

Case 1) When Product is Sold solely by MN in U.S.

In the event that in a particular Royalty Year there are Net Sales of [***] (Patent/Exclusivity Net Sales);

of such Net Sales, in accordance with Section 4.3.1, [***]

Tier 1 Royalty: [***]	= [***]
Tier 2 Royalty: [***]	= [***]
Tier 3 Royalty: [***]	= [***]
Total Section 4.3 Milestone Payments	[***]

Case 2) When Product is Sold solely by MN in all countries and jurisdictions other than U.S. in MN Territory

In the event that in a particular Royalty Year there are Net Sales of [***] in the MN Territory, broken down as follows;

Patent/Exclusivity Net Sales:	[***]
Non-Patent Exclusivity Net Sales:	[***]
Generic Competition Net Sales:	[***]
Net Sales:	[***]

A) In order to calculate Section 4.3 Royalty Payments on such Net Sales [***], one must first calculate what percentage of such Net Sales will be subject to Tier 1, Tier 2 and Tier 3:

Tier 1; [***]	= [***]
Tier 2; [***]	= [***]
Tier 3; [***]	= [***]

B) Then MN shall pay MS royalties based on Patent/Exclusivity Net Sales

STEP 1: calculate portion of Patent/Exclusivity Net Sales [***] applicable to each Tier

Tier 1 Patent/Exclusivity Net Sales:	[***] = [***]
Tier 2 Patent/Exclusivity Net Sales:	[***] = [***]
Tier 3 Patent/Exclusivity Net Sales:	[***] = [***]

STEP 2: apply appropriate royalty rate to portion of Patent/Exclusivity Net Sales calculated in STEP 1 above

Tier 1 Royalty: [***]	= [***]
Tier 2 Royalty: [***]	= [***]
Tier 3 Royalty: [***]	=[***]
Total:	[***]

C) Then MN shall pay MS royalties based on Non-Patent/Exclusivity Net Sales

STEP 1: calculate portion of Non-Patent/Exclusivity Net Sales [***] applicable to each Tier

Tier 1 Non-Patent/Exclusivity Net Sales:	[***] = [***]
Tier 2 Non-Patent/Exclusivity Net Sales:	[***] = [***]
Tier 3 Non-Patent/Exclusivity Net Sales:	[***] = [***]

STEP 2: apply appropriate royalty rate to portion of Non-Patent/Exclusivity Net Sales calculated in STEP1 above (Note: royalty rates are [***] of those set forth in Section 4.3.2)

Tier 1 Royalty: [***]	=[***]
Tier 2 Royalty: [***]	=[***]
Tier 3 Royalty: [***]	=[***]
Total:	[***]

D) Then MN shall pay MS royalties based on Generic Competition Net Sales

STEP 1: calculate portion of Generic Competition Net Sales [***] applicable to each Tier

Tier 1 Generic Competition Net Sales:	[***]	=[***]
Tier 2 Generic Competition Net Sales:	[***]	=[***]
Tier 3 Generic Competition Net Sales:	[***]	=[***]

STEP 2: apply appropriate royalty rate to portion of Generic Competition Net Sales calculated in STEP 1 above (Note: royalty rates are [***] of those set forth in Section 4.3.2)

Tier 1 Royalty: [***]	=[***]
Tier 2 Royalty: [***]	=[***]
Tier 3 Royalty: [***]	=[***]
Total:	[***]

E) Then total Section 4.3 Royalty Payments shall be summed:

Royalties based on Patent/Exclusivity Net Sales:	[***]
Royalties based on Non-Patent/Exclusivity Net Sales:	[***]
Royalties based on Generic Competition Net Sales:	[***]
Total Section 4.3 Royalty Payments:	[***]

[*** Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. Application has been made to the Securities and Exchange Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. This exhibit has been filed separately with the Securities and Exchange Commission without redactions in connection with MediciNova's confidential treatment request.]

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (hereinafter referred to as "Agreement") dated as of October 31, 2006 (hereinafter referred to as "Effective Date"), is entered into between **MediciNova, Inc.**, a Delaware corporation having a place of business located at 4350 La Jolla Village Drive, Ste 950, San Diego, California 92122, U.S.A. (hereinafter referred to as "MN"), and **Meiji Seika Kaisha, Ltd.**, a Japanese corporation having its principal business place at 4-16, Kyobashi 2chome, Chuo-ku, Tokyo 104-8002, Japan (hereinafter referred to as "MS").

WITNESSETH:

WHEREAS, MS is the owner of the MS Intellectual Property (as hereinafter defined) relating to a new chemical class of compounds of plasma carboxypeptidase B inhibitor, [***];

WHEREAS, MN desires to obtain an exclusive license, with a right to grant sublicenses, under the MS Intellectual Property, and MS desires to grant such license to MN, upon the terms and conditions set forth herein;

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

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, unless specifically set forth to the contrary herein, the terms defined in this ARTICLE 1 shall have the respective meanings set forth below, it being understood that words in the singular include the plural and vice versa:

1.1 "<u>Act</u>" shall mean the United States Food Drug and Cosmetic Act of 1938, as amended, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

1.2 "<u>Affiliate</u>" shall mean, (i) any corporation or business entity of which at least fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party or by any entity mentioned in (ii) hereinafter; or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds at least fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests

representing the equity, voting stock or general partnership interest of a Party. Further, if a joint venture is established pursuant to an agreement between a Third Party (as hereinafter defined) and MN, MS or their respective Affiliate (including, without limitation, an entity that manufactures, uses, purchases, sells, imports, exports, or acquires Compound and/or Product [as hereinafter respectively defined] for, to or from MN, MS or their respective Affiliate), where MN, MS or their respective such Affiliate has significant input regarding the management and operation of such joint venture (e.g., through board representation or specified veto rights) or a significant stake in the profits of such joint venture, such joint venture shall also be deemed as an Affiliate hereunder.

1.3 "ANDA" shall mean an abbreviated NDA (as hereinafter defined) in the United States according to applicable US laws and regulations.

1.4 "API" shall mean Compound in bulk form used as the active pharmaceutical ingredient in the manufacture of Product.

1.5 "Business Day(s)" shall mean any day that is not a Saturday, a Sunday, a national holiday in Japan and/or United States, or a day on which the New York Stock Exchange and/or the Tokyo Stock Exchange is closed.

1.6 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.7 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.8 "<u>Centralized Procedure</u>" shall mean the European Union Centralized Procedure for marketing authorization in accordance with Council Regulation n° 2309/93 of July 22, 1993 or any successor regulations.

1.9 "CFR" shall mean the United States Code of Federal Regulations.

1.10 "<u>cGMP</u>" shall mean then current good manufacturing practices as defined in regulations promulgated by the FDA (as hereinafter defined) under the Act and, if applicable, equivalent laws and regulations of other countries or jurisdictions in the MN Territory (as hereinafter defined) relating to the formulation, manufacture, testing prior to delivery, storage and delivery of Compound, API and Product.

1.11 "Commercially Reasonable Efforts" shall mean efforts and resources normally used by a licensee in the pharmaceutical industry that is similar in size to MN for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors.

1.12 "Compound" shall mean the chemical compound, [***], as diagrammed on Schedule 1.12, (ii) any other compounds claimed or covered by any of the MS Patent Assets (as hereinafter defined) listed on Schedule 1.44, (iii) [***].

1.13 "<u>Control</u>" shall mean possession of the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement with any Third Party.

1.14 "<u>Cost of Goods</u>" shall mean the actual and bona fide and verifiable manufacturing and supply costs calculated in accordance with GAAP (as hereinafter defined), including labor, material and factory costs, and including amounts payable to Third Party manufacturers, specifically associated with the manufacture and supply by MN or an MN Affiliate (as hereinafter defined) of API or Product supplied to an MN Sublicensee (as hereinafter defined).

1.15 "<u>Customer</u>" shall mean any purchaser of Products, provided, however, that any MN Affiliate or MN Sublicensee shall be deemed a Customer, with respect to a Sale (as hereinafter defined) thereto of a particular Product, only in the case where such party receives such Product for its own end-use or other internal commercialization and not for re-sale.

1.16 "Development Milestone" shall mean the milestone events set forth in Section 4.2.

1.17 "<u>Dominating Patent</u>" shall mean an unexpired patent which is owned or Controlled by a Third Party and as to which both Parties mutually agree in good faith and in writing would be infringed by activities associated with the commercialization of Product.

1.18 "<u>EMEA</u>" shall mean the European Agency for the Evaluation of Medicinal Products based in London (UK), as established by Council Regulation n° 2309/93 of July 22, 1993, as subsequently amended by Commission Regulation 649/98 of March 23, 1998, and any successor thereto having substantially the same functions.

1.19 "EMEA Authority" shall mean EMEA or the applicable Regulatory Authority (as hereinafter defined) in an EMEA Member State (as hereinafter defined).

1.20 "<u>EMEA Member State</u>" shall mean any country or jurisdiction where an MAA (as hereinafter defined) can be submitted under Centralized Procedure or Mutual Recognition Procedure (as hereinafter defined), including then current European Union member countries or jurisdictions and Norway, Iceland and Liechtenstein.

1.21 "FDA" shall mean the United States Food and Drug Administration and any successor thereto having substantially the same functions.

1.22 "Field" shall mean any use of Compound or Product in humans.

1.23 "First Commercial Sale" shall mean, on a country by country or jurisdiction by jurisdiction basis, the first commercial Sale of any Product to a Customer in each country or jurisdiction in the MN Territory by MN, MN Affiliates and/or MN Sublicensees after Regulatory Approval (as hereinafter defined) has been granted by the Regulatory Authority of such country or jurisdiction.

1.24 "GAAP" shall mean generally accepted accounting principles in the United States.

1.25 "<u>Generic Competition</u>" shall mean, on a country by country or jurisdiction by jurisdiction and Product by Product basis, (i) with respect to a country or jurisdiction in the MN Territory

where IMS Statistical Data (or substantially equivalent data) are available, [***] or, (ii) in any particular country or jurisdiction in the MN Territory where IMS Statistical Data (or substantially equivalent data) are not available, [***].

1.26 "Generic Drug(s)" shall mean any pharmaceutical composition containing the same Compound as contained in Product Sold by MN, an MN Affiliate and/or an MN Sublicensee, in each case other than Product introduced in such country or jurisdiction by MN, an MN Affiliate and/or an MN Sublicensee.

1.27 "<u>Improvement</u>" shall mean any improvement or enhancement relating to Compound or Product including, without limitation, any change or modification to any method, process, composition, or any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage, administration, use, indication or packaging as well as the addition of other active ingredients.

1.28 "<u>IND</u>" shall mean an investigational new drug application, as defined in 21 CFR Section 312.3, and any amendments thereto, filed with the FDA or an equivalent application filed with an equivalent Regulatory Authority outside the United States, the filing of which is necessary to commence clinical testing of Product in such regulatory jurisdiction.

1.29 "Know-How" shall mean any and all unpatented information and materials, including but not limited to, discoveries, Improvements, processes, formulae, data, inventions, invention disclosures, know-how and trade secrets, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and nontechnical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any non-clinical, clinical, assay control, regulatory, and any other test results or information, that are necessary or useful for the development, manufacturing, Regulatory Approval and/or marketing of Compound or Product.

1.30 "Major European Countries" shall mean United Kingdom, France, Germany, Italy and Spain.

1.31 "<u>Market Exclusivity</u>" shall mean, with respect to any particular country or jurisdiction in the MN Territory, the situation or condition under which (i) the development, manufacture, use, offering for sale, sale, marketing, distribution, export and/or import of Compound and/or Product, but for the license granted in this Agreement, would infringe, or contribute to, or induce the infringement of, a Valid Patent Claim (as hereinafter defined) issued at the time of the infringing activity in such country(ies) or jurisdiction(s) and/or (ii) the exclusive right to market and sell Product is lawfully granted by the Regulatory Authority in such country(ies) or jurisdiction(s).

1.32 "<u>Marketing Authorization Application</u>" or "<u>MAA</u>" shall mean any new registration application or marketing authorization application, including any supplements or amendments thereto, such as a foreign counterpart or comparable to the NDA, which MN, MS, an MN Affiliate, an MN Sublicensee and/or an MS Licensee (as hereinafter defined) may file with the requisite Regulatory Authority in any country or jurisdiction other than the United States in the MN Territory or MS Territory (as hereinafter defined), as applicable, that is required to obtain

Regulatory Approval of Product for a particular indication in such country or jurisdiction. For the avoidance of doubt, an application to EMEA Authority under the Centralized Procedure or Mutual Recognition Procedure shall be deemed as an MAA hereunder.

1.33 "<u>MN Affiliate</u>" shall mean any Affiliate of MN to which MN grants a sublicense in the MN Territory of the rights and licenses, whether in whole or in part, granted to MN by MS pursuant to Section 3.2 of this Agreement.

1.34 "<u>MN Development Costs</u>" shall mean the actual and bona fide and verifiable development costs, including but not limited to the costs for materials, full-time and part-time employees, overhead, payments made to Third Parties for manufacturing, formulation, non-clinical and clinical studies, specifically relating to Product which have been incurred by MN and/or an MN Affiliate prior to the effective date of the sublicense agreement between MN (or such MN Affiliate) and an MN Sublicensee, to the extent such development costs are reasonable and not excessive compared with the development costs of similarly situated development companies in the pharmaceutical industry under similar circumstances.

1.35 "<u>MN Intellectual Property</u>" shall mean any and all MN's and MN Affiliates' intellectual property and proprietary rights in any and all MN Patent Assets and MN Know-How (as hereinafter respectively defined).

1.36 "MN Know-How" shall mean any and all Know-How that becomes during the term of this Agreement owned or Controlled by MN or an MN Affiliate.

1.37 "<u>MN Patent Assets</u>" shall mean all Patent Assets (as hereinafter defined) that are necessary to develop, make, use, market, distribute, import, export, offer for sale and/or sell Compound or Product and that become during the term of this Agreement owned or Controlled by MN or an MN Affiliate.

1.38 "<u>MN Sublicensee</u>" shall mean any Third Party to which MN or an MN Affiliate grants a sublicense in the MN Territory of the rights and licenses, whether in whole or in part, granted to MN by MS pursuant to Section 3.2 of this Agreement.

1.39 "MN Territory." shall mean all countries or jurisdictions worldwide, except for those in the MS Territory.

1.40 "<u>MS Affiliate</u>" shall mean any Affiliate of MS to which MS grants the rights and licenses in the MS Territory to research, develop, make, have made, use, offer for sale, market, sell, import, export and/or distribute Compound and/or Product under the MS Intellectual Property.

1.41 "<u>MS Intellectual Property</u>" shall mean any and all MS's and MS Affiliates' intellectual property and proprietary rights in any and all MS Patent Assets and MS Know-How (as hereinafter defined).

1.42 "MS Know-How" shall mean any and all Know-How that is or becomes during the term of this Agreement owned or Controlled by MS or an MS Affiliate.

1.43 "<u>MS Licensee</u>" shall mean any Third Party to which MS grants the rights and licenses in the MS Territory to research, develop, make, have made, use, offer for sale, market, sell, import, export and/or distribute Compound and/or Product under the MS Intellectual Property.

1.44 "<u>MS Patent Assets</u>" shall mean (i) those Patent Assets listed on **Schedule 1.44** including any counterparts thereof which have been or may be filed in other countries or jurisdictions and (ii) all Patent Assets that become owned or Controlled by MS or MS Affiliates during the term of this Agreement which, absent the rights and license granted to MN hereunder, would be infringed by development, manufacture, use, importation, exportation, sale, offer for sale, market or distribution of Compound, API and/or Product.

1.45 "<u>MS Territory</u>" shall mean Japan, Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

1.46 "Mutual Recognition Procedure" shall mean the mutual recognition procedure for marketing authorization in accordance with Directive No. 2003/83/EC of November 6, 2001 or any successor regulations and/or directives.

1.47 "NDA" shall mean a new drug application as defined in the Act and applicable regulations promulgated thereunder that is submitted to the FDA to apply for Regulatory Approval of Product for a particular indication in the United States and any amendments and supplements thereto.

1.48 "Net Sales" shall mean the total gross amount invoiced by MN or MN Affiliates from Sales of Products, commencing upon the date of First Commercial Sale, whether invoiced under one or more separate agreements, after deducting any of the following to the extent actually paid or provided, not already deducted from the gross amount invoiced and allocated to Product, in accordance with GAAP, any (a) credits, allowances, samples, discounts and rebates to, and chargebacks from the account of, Customers; (b) freight and insurance costs; (c) trade discounts, cash discounts, quantity discounts, rebates; (d) retroactive price reductions; (e) recalls, credits and allowances on account of returned or rejected Product, including allowance for breakage or spoilage; (f) sales, value-added and other direct taxes incurred directly in connection with the Sale of Product; (g) rebates, chargebacks or similar payments or credits actually granted to managed health care organizations, wholesalers, distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, or other institutions or health care organizations or to any governmental or regulatory authority in respect of any state, provincial, local or federal Medicare, Medicaid or similar programs in any country or jurisdiction in the MN Territory; (h) write-offs for bad debts or allowances; and (i) customs duties, custom broker charges and other surcharges and governmental charges incurred in connection with the exportation or importation of Product.

Sales or other transfers between or among MN, MN Affiliates and MN Sublicensees shall be excluded from the computation of Net Sales and no payments will be payable on such sales or transfers except where MN, such MN Affiliates or MN Sublicensees are Customers, but the computation of Net Sales shall include the subsequent Sales to Customers by MN or such MN Affiliates.

1.49 "Net Sublicense Consideration" shall mean (a) the total gross amount invoiced, received or otherwise charged and the value of any other consideration in the form of cash payments received or obtained, directly or indirectly, by MN or an MN Affiliate from any MN Sublicensee as consideration for the grant of the sublicense under Section 3.2, including, but not limited to, as royalties of any kind including royalties based on net sales of Product by such MN Sublicensee, flat fees, up-front license fee and payments based on the achievement of milestones relating to Product, whether received under one or more separate agreements, less MN Development Costs; and (b) the amount of any profit of MN (or MN Affiliates) derived from the supply of API or Product to MN Sublicensees (i.e. the transfer price from MN or such MN Affiliates to such MN Sublicensees, less Cost of Goods). Notwithstanding the foregoing, Net Sublicense Consideration shall not include any amounts received by MN or an MN Affiliate directly from MN Sublicensees attributable to any bona fide (i) funding by such MN Sublicensee of the costs for MN's (and/or such MN Affiliate's) development activities specifically relating to Product, including non-clinical and clinical studies associated with obtaining Regulatory Approval, which such MN Sublicensee contracts out on arms length terms to MN and/or an MN Affiliate on and after the effective date of the sublicense agreement between MN (or an MN Affiliate) and such MN Sublicensee, to the extent such costs do not exceed an amount which is reasonably typical under the similar circumstances in the pharmaceutical industry ; and (ii) arms length cash investments by such MN Sublicensee in securities of MN and/or an MN Affiliate not as part of consideration for sublicense set forth in Section 3.2.

1.50 "Party" shall mean MS or MN, and "Parties" shall mean MS and MN.

1.51 "Patent Assets" shall mean any patents and patent applications, including provisionals and priority filings, utility models and their applications (which shall be deemed to include certificates of invention and applications for certificates of invention and supplementary protection certificates) together in all cases with any continuations, continuations-in-part, divisions, patents of addition, reexaminations, reissues, renewals as well as extensions, supplementary protection certificates and any other patent term extensions of any of the foregoing.

1.52 "<u>Person</u>" shall mean an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.53 "<u>Phase 1 Clinical Trial</u>" shall mean that portion of the drug development process relating to Product which provides for the first introduction into humans of such Product including small scale clinical trial in healthy volunteers and/or patients to obtain information on such Product's safety, tolerability, pharmacological activity, pharmacokinetics and/or pharmacodynamics, and supporting Regulatory Approval of such Product in the Field, as more fully defined in 21 C.F.R. 312.21 (a) or the equivalent statute or regulation in a country or jurisdiction other than the United States.

1.54 "<u>Phase 2 Clinical Trial</u>" shall mean that portion of the drug development process relating to Product which provides for a well-controlled clinical trial conducted in patients, a principal purpose of which is to make a preliminary determination that such Product is safe for its intended

use and to obtain sufficient information about such Product's efficacy, as well as to obtain an indication of the dosage regimen required, to permit the design of further clinical trials, and supporting Regulatory Approval of such Product in the Field, as more fully defined in 21 C.F.R. 312.21 (b) or the equivalent statute or regulation in a country or jurisdiction other than the United States.

1.55 "<u>Phase 3 Clinical Trial</u>" shall mean that portion of the drug development process relating to Product which provides for a large scale clinical trial conducted in a sufficient number of patients that is designed to establish that such Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, and supporting Regulatory Approval of such Product in the Field, as more fully defined in 21 C.F.R. 312.21 (c) or the equivalent statute or regulation in a country or jurisdiction other than the United States.

1.56 "<u>Product</u>" shall mean any pharmaceutical composition containing Compound as an active ingredient, in any formulation, delivery system or package configuration.

1.57 "<u>Proprietary Information</u>" shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned or Controlled and under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.

1.58 "<u>Regulatory Approval</u>" shall mean, in any country or jurisdiction in the MN Territory or the MS Territory, as applicable, all approvals (including pricing and reimbursement approvals required for marketing authorization), product and/or establishment licenses, registrations or authorizations of all regional, federal, state or local regulatory agencies, departments, bureaus or other Regulatory Authority, necessary for the manufacture, use, storage, import, export, transport, offer for sale and sale of Compound, API and/or Product in such country or jurisdiction. For the avoidance of doubt, an approval by the EMEA Authority under the Centralized Procedure or Mutual Recognition Procedure shall be deemed as a Regulatory Approval hereunder.

1.59 "<u>Regulatory Authority</u>" shall mean any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, domestic or foreign, that performs a function for such political subdivision similar to the function performed by the FDA for the United States and the EMEA Authority for EMEA Member States with regard to the approval, licensing, registration or authorization to develop, test, manufacture, promote, market, distribute, use, store, import, export, transport, offer for sale or sell a pharmaceutical product intended for human use in the defined territory or political subdivisions, or with respect to the approval of pricing or reimbursement for such product.

1.60 "Royalty Term" shall mean the royalty term set forth in Section 4.3.4.

1.61 "<u>Royalty Year</u>" shall mean, during the Royalty Term (i) for the year in which the First Commercial Sale occurs (the "First Royalty Year"), the period commencing with the first day of the Calendar Quarter in which the First Commercial Sale occurs and expiring on the last day of

the Calendar Year in which the First Commercial Sale occurs; and (ii) for each subsequent year, each successive Calendar Year.

1.62 "<u>Sale</u>" shall mean the act of selling, leasing, exchanging, or otherwise transferring, providing, furnishing, or disposing of Compound, API or Product for any consideration to a Customer. Correspondingly, "Sell" means to make or cause to be made a Sale, and "Sold" means to have made or caused to be made a Sale.

1.63 "Third Party" shall mean any Person other than MS, MN and their respective Affiliates.

1.64 "<u>Trademark</u>" shall mean any trademark, trade name or trade dress as MN or any MN Affiliate shall adopt for Product that is at any time during the term of this Agreement owned or Controlled by MN or such MN Affiliate.

1.65 "<u>Valid Patent Claim</u>" shall mean a claim of an issued and unexpired patent included within the MS Patent Assets, which (a) has not been held revoked, or held unenforceable or invalid by a court or other governmental agency of competent jurisdiction, in an unappealed or unappealable decision and (b) has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

ARTICLE 2 DEVELOPMENT; REGULATORY MATTERS; EXCHANGE OF INFORMATION

2.1 Development in the MN Territory.

2.1.1 MN shall select and develop Compound claimed or covered by any of the MS Patent Assets in the MN Territory. In the event that MN notifies MS in writing of its intention on reasonable grounds to select and develop Compound that is not claimed or covered by any of the MS Patent Assets in the MN Territory, MN may do so after having full consultation with and obtaining a written consent of MS.

2.1.2 <u>Development Plan</u>. MN shall prepare and submit to MS a projected plan for the development of Product (hereinafter referred to as "Development Plan"). The Development Plan shall be divided into the following phases of development: (a) pre-clinical development until the first IND filing, (b) until initiation of the first Phase 2 Clinical Trial, (c) until initiation of the first Phase 3 Clinical Trial, and (d) until the first submission of either an NDA to the FDA or an MAA to an EMEA Authority. The Development Plan for (a) pre-clinical development until the first IND filing shall be prepared and submitted to MS by MN within one hundred twenty (120) days after the Effective Date and the Development Plan for its subsequent phase shall be prepared and submitted to MS by MN within ninety (90) days after the completion of the development activities in the Development Plan for each previous phase.

2.1.3 <u>Diligence and Information Exchange</u>. MN shall use Commercially Reasonable Efforts to develop and commercialize Product at its own costs and responsibilities. In addition, MN agrees to:

- (a) provide, at its own responsibilities, sufficient scientific, technical, clinical and regulatory personnel, equipment, time, funds and resources for the commercial development of Product to meet its obligations hereunder;
- (b) undertake the development in accordance with the Development Plan and in compliance with applicable laws and regulatory requirements;
- (c) maintain records with respect to the activities performed under the Development Plan in sufficient detail and good scientific manner appropriate for Regulatory Approval in the MN Territory;
- (d) provide MS, after API or Product for Phase 1 Clinical Trials in compliance with cGMP becomes available and upon MS's request, with the final version of the study protocol of any non-clinical and clinical study relating to Compound and Product to be conducted by or on behalf of MN, an MN Affiliate or, when applicable and available to MN, an MN Sublicensee;
- (e) submit to MS copies of all final reports of any non-clinical and clinical study relating to Compound and Product conducted by or on behalf of MN, an MN Affiliate or, when applicable and available to MN, an MN Sublicensee promptly after the completion of such studies;
- (f) semi-annually provide MS with a written report summarizing in reasonable detail the status of development activities of MN, any MN Affiliate and/or any MN Sublicensee relating to Compound and Product, including but not limited to, results of non-clinical and/or clinical studies conducted by or on behalf of MN, MN Affiliates and/or MN Sublicensees, with the delivery to MS of the summary of the annual report to an IND submitted by MN, MN Affiliates and/or MN Sublicensees to the FDA and/or EMEA Authority in connection with the periodic reporting requirements of the IND to be in satisfaction of the foregoing requirement;
- (g) [***]; and
- (h) [***];

provided, however, that the foregoing obligations of MN are expressly conditioned upon the absence of (i) any adverse conditions relating to the safety or efficacy of Compound or Product including the absence of any action by any Regulatory Authority limiting the development or commercialization of Compound or Product; (ii) *force majeure* (as more specifically described in Section 12.1) or other factors or reason(s) beyond MN's reasonable control, including, for example, the unavailability of drug supplies needed to conduct the clinical trial, including, without limitation, as a result of failure of stability or lack of a satisfactory formulation; an inability to conduct the clinical trial due to action on the part of any Regulatory Authority, including, without limitation, the placement of a clinical hold on such clinical trial; or if the conduct of such clinical trial would violate any

¹⁰

applicable laws, rules or regulations; or (iii) a good faith determination on the part of MN, acting as a reasonable pharmaceutical company and after consultation with MS, that Product which is intended to be studied in the clinical trial is not safe or efficacious in its then current formulation or dosage form or dose level.

2.1.4 <u>Remedy</u>. Without prejudice to any other remedies as provided for hereunder or available under laws, in the event MN, an MN Affiliate and/or an MN Sublicensee ceases development activities of Compound and/or Product for [***], and MN, such MN Affiliate and/or such MN Sublicensee does not demonstrate to MS's reasonable satisfaction that, despite Commercially Reasonable Efforts by MN, such MN Affiliate and/or such MN Sublicensee, such cessation was due to reason(s) beyond reasonable control by MN, such MN Affiliate and/or such MN Sublicensee, including, for example, situation(s) set forth in (i) to (iii) of the proviso of Section 2.1.3 above, MS shall have the right, at its sole discretion, to terminate this Agreement pursuant to Section 9.3.3.

2.1.5 MN shall, from time to time during the term of this Agreement, disclose, and shall cause any MN Affiliate to disclose, to MS all MN Intellectual Property subject to the license granted to MS under Section 3.3 and, when applicable and available to MN, all MN Sublicensee Intellectual Property (as defined in Section 3.3).

2.1.6 <u>Meeting</u>. Upon reasonable request and notice by one Party to the other Party, the Parties shall have a meeting at mutually agreed times and locations, a videoconference, or a teleconference up to twice a year to discuss the development of Product in the MN Territory and, if MS, an MS Affiliate or an MS Licensee is developing Product in the MS Territory, in the MS Territory. Each Party shall bear its own travel and related costs to attend the meeting.

2.1.7 <u>Regulatory Matters</u>. MN shall own, control and retain primary legal responsibility for, and shall be responsible for funding, preparing, filing and prosecuting all filing and regulatory applications required to obtain Regulatory Approval of Product in the Field in the MN Territory. MS shall transfer free of charge to MN as soon as practicable after the Effective Date any IND or other regulatory filings or approvals in the MN Territory relating to Compound or Product owned or Controlled by MS and MS shall allow MN or its designees free of charge the right to cross reference any IND, MAA or other regulatory filing in the MS Territory relating to Compound or Product if owned or Controlled by MS or an MS Affiliate. It is understood between the Parties that MS shall not be required to conduct any additional studies which support Regulatory Approval of Product in the MN Territory.

2.2 <u>Development in the MS Territory</u>. In case that at any time during the term of this Agreement, MS decides to develop and commercialize Product in the MS Territory:

2.2.1 MS shall so advise MN in writing and, during any such development or commercialization by MS, an MS Affiliate and/or an MS Licensee, the Parties shall coordinate, review and assess the clinical development of Product necessary to receive

Regulatory Approvals in the MS Territory, to harmonize worldwide objectives for Product and to facilitate the transfer of data and regulatory communications, including the handling and reporting of adverse events. In the event that MS, an MS Affiliate or an MS Licensee decides to develop Product in the MS Territory for an indication that is the same as or substantially similar to any indication for which MN, an MN Affiliate and/or an MN Sublicensee has developed or is developing in the MN Territory, MS shall so advise MN in writing and the Parties shall establish a joint committee for the purpose contemplated in this Section 2.2.1;

2.2.2 MS shall own, control and retain primary legal responsibility for, and shall be responsible for funding, preparing, filing and prosecuting all filings and regulatory applications required to obtain Regulatory Approval of Product in the Field in the MS Territory. MN shall provide MS as soon as practicable during the term of this Agreement with copies of any IND, NDA, MAA and other regulatory filings or approvals in the MN Territory relating to Compound and/or Product in the Field owned or Controlled by MN, an MN Affiliate or, when applicable and available to MN, an MN Sublicensee (hereinafter referred to as "MN Regulatory Filings"), and MN shall allow MS, an MS Affiliate and/or an MS Licensee free of charge the right to cross reference any MN Regulatory Filing, if owned or Controlled by MN, such MN Affiliate, or, if applicable and available to MN, such MN Sublicensee solely for use in obtaining Regulatory Approval of Product in the Field in the MS Territory; provided, however, that in case of a sublicense by MN or an MN Affiliate to an MN Sublicensee, Section 4.7 shall be applicable;

2.2.3 It is understood between the Parties that MS has no obligation to supply to MN Compound, API and Product for development and commercialization by MN, an MN Affiliate and/or an MN Sublicensee in the MN Territory. MN shall be responsible for conducting, at its own cost and expense, any and all research activities related to manufacturing Compound, API and Product and for supplying Compound, API and Product for development and commercialization in the MN Territory. MN may, at its sole discretion, entrust any Third Party, MN Affiliate and/or MN Sublicensee with such research and manufacturing activities relating to Compound, API and/or Product in whole or in part;

2.2.4 So long as MN or its designees (including an MN Affiliate and an MN Sublicensee) is then manufacturing Compound, API and/or Product for development and/or commercial use, upon reasonable written request by MS, MN shall supply MS with the Compound, API and/or Product that is then being manufactured by MN or its designee (including an MN Affiliate and an MN Sublicensee) solely for research, development and/or commercial use by MS, an MS Affiliate and/or an MS Licensee in the MS Territory. In such case, upon MS's request, MS and MN shall negotiate in good faith to enter into a supply agreement relating to such supply of Compound, API and/or Product to MS, solely for use in the MS Territory, containing such commercially reasonable terms and conditions as are typical for similar types of supply agreements.

2.2.5 In case that at any time during the term of this Agreement, MN or its designees (including an MN Affiliate and an MN Sublicensee) is then manufacturing Compound, API and/or Product for development and/or commercial use and MS decides to manufacture such Compound, API and/or Product that is then being manufactured by MN or

its designee (including an MN Affiliate and an MN Sublicensee), solely for research, development and/or commercial use in the MS Territory, MS shall have the right to have transferred to MS solely for such use the manufacturing technology developed, owned and Controlled by MN, MN Affiliates and, when applicable and available to MN, MN Sublicensees (hereinafter referred to as "Manufacturing Technology"). Upon MS's request to have such Manufacturing Technology transferred to MS, MN then shall work with MS and/or its designees (including an MS Affiliate and an MS Licensee) in good faith and within a reasonable time frame to complete such technology transfer at MS's costs, enabling MS and/or its designees (including MS Affiliate and MS Licensee) to manufacture and/or have manufactured Compound, API and/or Product for research, development and/or commercial use by MS, an MS Affiliate and/or an MS Licensee in the MS Territory, provided, however that MN shall not be responsible for process and equipment validation required by applicable laws or regulations in the MS Territory or otherwise for MS's compliance necessary to pass inspection by any Regulatory Authority in the MS Territory. MS shall be free to perform, at its own costs and responsibilities, internal process chemistry research on the Manufacturing Technology independently of or in collaboration with MN and/or its designees (including an MN Affiliate and an MN Sublicensee);

2.2.6 MS and MN and/or their respective designees shall cooperate with respect to the exchange of adverse event and safety information associated with Compound and Product, provided that details of the cooperation in the handling of adverse event and safety information related to Compound and Product shall be the subject of a separate agreement to be negotiated in good faith between the Parties. Furthermore, the Parties shall cause their respective Affiliates and an MN Sublicensee and MS Licensee, as applicable, to cooperate with regard to the Parties' information exchange set forth in this Section 2.2.6.

2.3 Exchange of Information. MS shall disclose to MN in the language in which they are available (except that all information required to be submitted to any Regulatory Authority in connection with any Regulatory Approval shall be disclosed by MS to MN in English) and in writing, in electronic format, where available, and hard copies (or, upon MN's reasonable request and MS's consent, originals), (a) within thirty (30) Business Days after the Effective Date, all MS Patent Assets and MS's in-house reports containing MS Know-How existing as of the Effective Date, not previously available or made available to MN, (b) upon MN's written request, MS Know-How which is not contained in MS's in-house reports set forth in (a) above but available in other form (such as laboratory notes) and (c) on an ongoing basis throughout the term of this Agreement, and in addition to the other communications required under this Agreement, all MS Intellectual Property that become owned or Controlled by MS, any MS Affiliate or, when applicable and available to MS, any MS Licensee during the term of this Agreement, and any and all additions or revisions thereto.

ARTICLE 3 LICENSES; SUBLICENSES

3.1 License Grant to MN. MS hereby grants to MN an exclusive (even as to MS) license, including the right to grant sublicenses, under the MS Intellectual Property to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound and/or Product in and throughout the MN Territory in the Field.

3.2 Sublicense Rights.

MN may grant sublicenses within the scope of the license granted to MN under this Agreement to any Affiliate of MN or any MN Sublicensee, provided, however, that (a) each MN Affiliate and MN Sublicensee is subject to a written sublicense agreement and is bound by all of the material terms, conditions, obligations, restrictions and other covenants of this Agreement that protect or benefit MS's rights and interests except for the cases in Sections 3.3, 4.3.3 and 4.7.1 where MN shall use Commercially Reasonable Efforts to obtain covenants from MN Sublicensee as provided for therein; (b) prior to granting each such sublicense, MN shall disclose to MS the proposed material terms and conditions of such sublicense; (c) MN shall advise MS of such sublicense and provide MS with a copy of the sublicense agreement; and (d) in the event of any sublicense by MN or an MN Affiliate to an MN Sublicensee, the provisions of Section 4.7 shall be applicable and MN shall, within thirty (30) days of the effective date of the sublicense agreement between MN (or such MN Affiliate) and such MN Sublicensee, submit MS a written report detailing MN Development Costs with certificates, vouchers and/or other documents related thereto in sufficient detail to the extent necessary for the verification of the accuracy and legitimacy of such MN Development Costs. MN covenants that it shall obtain appropriate reporting from MN Sublicensees to establish all amounts owed to MS hereunder, and shall make such reports available to MS.

In no event shall MS assume any obligations or liabilities, or be under any obligation or requirement of performance, under any such sublicense extending beyond MS' obligations and liabilities under this Agreement. Upon MN's reasonable request, at any time during the term of this Agreement, MS agrees to meet and confer in good faith with MN and any MN Sublicensee or potential MN Sublicensee to discuss mutually acceptable arrangements regarding the possibility of an extension of such MN Sublicensee's or potential MN Sublicensee's rights beyond any expiration or termination of this Agreement.

3.3 <u>Grant of license by MN</u>. MN hereby grants, subject to the terms and conditions of this Agreement to MS an exclusive (even as to MN) and royalty-free license, including the right to grant sublicenses to any Affiliate of MS or any MS Licensee under the MN Intellectual Property solely to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field, in and throughout the MS Territory. In the event MN or an MN Affiliate has sublicensed the rights granted by MS to MN under Section 3.1 to an MN Sublicensee, MN shall use Commercially Reasonable Efforts to cause such MN Sublicensee to grant to MN or MN's designee the right to grant MS an exclusive (even as to such MN Sublicensee) and royalty-free license, including the right to grant sublicenses to any Affiliate of MS or MS Licensees, under the Know-How and Patent Assets that are necessary to research, develop, make, have made, use, market, offer for sale, sell, distribute, import and export Compound, API and/or Product that become owned or Controlled by such MN Sublicensee during the term of this Agreement (hereinafter referred to as "MN Sublicensee Know-How" and "MN Sublicensee Patent Assets," respectively, and as "MN Sublicensee Intellectual Property", collectively) solely to research, develop, use, make, have made, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field in and throughout the MS Territory, and Section 4.7.1 shall be applicable. In case of a grant of such license, MN Sublicensee Know-How and MN Sublcensee Patent Assets shall be deemed to be MN Know-How and MN Patent Assets, respectively, and treated accordingly hereunder. If MS

advises MN in writing that MS desires to use or sublicense the Trademark for Product in the MS Territory, MN shall grant MS a royalty-free, exclusive license, with a right to grant sublicenses to any Affiliate of MS or any MS Licensee, to use the Trademark solely in connection with the use, marketing, promotion, distribution, sale and other commercialization of Product in the MS Territory.

3.4 <u>Retained Rights and Restrictions</u>. The licenses granted in Section 3.1 and 3.3, respectively, are limited to the rights expressly granted therein. The Parties agree and acknowledge that there are no implied licenses under this Agreement or with respect to all right, title and interest in and to either the MS Intellectual Property or the MN Intellectual Property, except as specifically set forth herein. MN shall have no right or license to the MS Intellectual Property under this Agreement outside the Field and MS shall retain the right to use the MS Intellectual Property outside the Field. MS shall have no right or license to the MN Intellectual Property under this Agreement outside the Field and MN shall retain the right to use the MN Intellectual Property outside the Field.

ARTICLE 4

PAYMENTS AND ROYALTIES

4.1 <u>Up-Front License Fee</u>. In consideration of the rights and licenses granted by MS to MN hereunder, and in addition to and not in lieu of any other amounts due hereunder, MN shall pay to MS the sum of **[***]**.

4.2 <u>Milestone Payments</u>. Subject to the terms and conditions contained in this Agreement, in further consideration of the rights and licenses granted by MS to MN hereunder, MN shall pay MS the following milestone payments upon occurrence of the specified Development Milestone, irrespective of (i) whether such Development Milestones are achieved by MN or an MN Affiliate, (ii) which indications are explored, and (iii) Product for which such Development Milestone may be achieved, with each milestone payment to be made no more than once with respect to the achievement of such Development Milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such Development Milestone, regardless of the number of Products for which such Development Milestone may be achieved (but payable on the first achievement of such Development Milestone):

- (a) **[***];**
- (b) **[***];**
- (C) [***];
- (d) [***];
- (e) **[***]**; and
- (f) **[***]**.

MN shall notify MS in writing not later than thirty (30) Business Days after the achievement of each Development Milestone and each such notice shall be accompanied by the

appropriate milestone payment. In no event shall the payments provided for in this Section 4.2 be refundable to MN or creditable or recoupable against future royalties or other payments payable to MS pursuant to Section 4.3 or any other provision of this Agreement.

4.3 Royalties Payable by MN.

4.3.1 <u>Royalty Rates-United States.</u> Subject to the terms and conditions of this Agreement, and in further consideration of the rights and licenses granted by MS to MN hereunder, MN shall pay to MS royalties equal to the applicable percentages set forth below of the sum of the annual Net Sales in the United States in each Royalty Year during the Royalty Term. For determination of applicable royalty rate, annual Net Sales in the United States shown below shall mean the sum of Net Sales in the United States in the applicable Royalty Year:

(a) in case that MN solely Sells Product in the United States;

Annual Net Sales in U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

(b) in case that MN Sells Product jointly with MN Sublicensee(s) in the United States;

Annual Net Sales in U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

Examples of the royalty calculation under this Section 4.3.1 are shown on Schedule 4.3.

4.3.2 <u>Royalty Rates-Outside the United States</u>. Subject to the terms and conditions of this Agreement, and in further consideration of the rights and licenses granted by MS to MN hereunder, MN shall pay to MS royalties equal to the applicable percentages set forth below of the aggregate annual Net Sales in all countries and jurisdictions in the MN Territory, other than the United States, in each Royalty Year during the Royalty Term. For determination of applicable royalty rate, aggregate annual Net Sales outside the United States shown below shall mean the sum of Net Sales in any country or jurisdiction in the MN Territory other than the United States shown below shall mean the sum of Net Sales in any country or jurisdiction in the MN Territory other than the United States in the applicable Royalty Year:

(a) in case that MN solely Sells Product outside the United States;

Aggregate Annual Net Sales outside U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

(b) in case that MN Sells Product jointly with MN Sublicensee(s) outside the United States;

Aggregate Annual Net Sales outside U.S.:	Royalty Rate:
Up to US[***]	[***]
From US[***]	[***]
From and over US[***]	[***]

Examples of the royalty calculation under this Section 4.3.2 are shown on Schedule 4.3.

4.3.3 MN shall make Commercially Reasonable Efforts to have the definition of net sales of Product sold by an MN Sublicensee in the sublicense agreement between MN or (an MN Affiliate) and such MN Sublicensee be substantially equivalent to the definition of Net Sales as defined hereunder.

4.3.4 <u>Royalty Term</u>. The Royalty Term shall, on a country by country or jurisdiction by jurisdiction basis, commence on the **[***]**; provided, however, that notwithstanding the foregoing, the following shall be applicable:

- (a) in any country or jurisdiction in the MN Territory where no Market Exclusivity exists as of [***], then, notwithstanding the provisions of Sections 4.3.1 and 4.3.2, [****]; and
- (b) in the event of Generic Competition in any country or jurisdiction at any time [***], notwithstanding the provisions of Sections 4.3.1, 4.3.2 and 4.3.4
 (a), MN shall instead pay MS royalties on Net Sales in such country or jurisdiction at rates equal to [***].

In the event MN or an MN Affiliate sells bulk Compound rather than a Product in packaged form to a Third Party other than an MN Sublicensee (and such Third Party shall not re-sell such bulk Compound or any product containing thereof), and is unable to determine Net Sales as defined in this Agreement, then the sale of such bulk Compound, less applicable Cost of Goods, shall be deemed as Net Sublicense Consideration and shared by MN and MS either in a [***] if the provisions of Section 4.7.1(a) apply or in a [***] if the provisions of Section 4.7.1(b) apply, as the case may be.

4.4 <u>Compulsory Licenses</u>. If a compulsory license is granted to a Third Party with respect to Product in any country or jurisdiction in the MN Territory with a royalty rate lower than the applicable royalty rates provided in Section 4.3, then the royalty rate to be paid to MS on Net Sales in such country or jurisdiction shall be reduced to the rate paid by the compulsory Third Party licensee.

4.5 <u>One Royalty</u>. No royalty shall be payable under this ARTICLE 4 with respect to sales of Products between or among MN, MN Affiliates and MN Sublicensees for re-sale, nor shall a royalty be payable under this ARTICLE 4 with respect to Products distributed for use in

research and/or development, in clinical trials, training programs, educational programs, or as donations to non-profit institutions or government agencies or as promotional free samples.

4.6 <u>Combination Product</u>. Notwithstanding the provisions of Section 4.3, in the event Product is sold as a combination product with other product components including biologically active components (hereinafter referred to as "Product Component"), Net Sales, for purposes of royalty payments on the combination product, shall be calculated by [***].

4.7 Sublicense Payments.

4.7.1 In the event MN or an MN Affiliate enters into a sublicense with an MN Sublicensee under Section 3.2 of this Agreement granting a sublicense of any rights licensed to MN by MS under Section 3.1 of this Agreement in any country or jurisdiction in the MN Territory , MN shall pay MS the following applicable percentages of Net Sublicense Consideration applicable to such country or jurisdiction subject to the sublicense (hereinafter referred to as "MN Sublicense Payments"), without depending on the stage of development of Product in the MN Territory achieved by MN or an MN Affiliate prior to the first sublicense with an MN Sublicensee in the countries or jurisdictions subject to such sublicense, for so long as MN or an MN Affiliate receives such Net Sublicense Consideration :

- (a) **[***]**; or
- (b) **[***]**.

MN and any MN Affiliate shall make Commercially Reasonable Efforts to receive consideration from an MN Sublicensee for the grant of the sublicense by MN or such MN Affiliate to such MN Sublicensee under Section 3.2 in the form of cash payment so that such consideration can be recorded as Net Sublicense Consideration.

4.7.2 [***].

The following are examples of the application of Section 4.7.2:

- (a) [***]; and
- (b) **[***]**.

4.8 <u>Third Party Patent Licenses</u>. If MN, any MN Affiliate or any MN Sublicensee would be prevented from the use of MS Intellectual Property for developing, making, having made, using, offering for sale, selling, importing, exporting or distributing Product in any country or jurisdiction in the MN Territory on the grounds that by such use by MN or any MN Affiliate or MN Sublicensee would infringe a Dominating Patent in said country or jurisdiction, and MN or any MN Affiliate or MN Sublicensee, after a full consultation with MS, has entered into a license agreement with such Third Party (hereinafter referred to as "Third Party Patent License"), any royalties or other payments actually paid by MN, such MN Affiliate or such MN Sublicensee to such Third Party under such Third Party Patent License in such country or jurisdiction in any Calendar Quarter in any Royalty Year shall be creditable against the

subsequent royalty payable to MS by MN under Section 4.3 (hereinafter referred to as "Section 4.3 Royalty Payments") or the MN Sublicense Payments that would be payable by MN to MS under Section 4.7.1 based on royalties on net sales of Product from MN Sublicensees (hereinafter referred to as "Section 4.7 Royalty Payments") in the country or jurisdiction in question for such Calendar Quarter, provided, however, that in no event shall such Section 4.3 Royalty Payments and Section 4.7 Royalty Payments in such country or jurisdiction in any Calendar Quarter be **[***]** so long as MN's obligation to make Section 4.3 Royalty Payments or Section 4.7 Royalty Payments continues in such country or jurisdiction.

ARTICLE 5 ROYALTY REPORTS AND ACCOUNTING

5.1 <u>Reports</u>. During the Royalty Term and for so long as MN Sublicense Payments are payable, MN shall furnish and shall cause MN Affiliates to furnish to MS a written report (hereinafter referred to as "Royalty Report") for each Calendar Quarter showing on a country by country or jurisdiction by jurisdiction and Product by Product basis, (a) the gross sales of all Products sold by MN and MN Affiliates in the MN Territory during such Calendar Quarter and the calculation of Net Sales from such gross sales; (b) the Section 4.3 Royalty Payments, payable in United States dollars, which shall have accrued hereunder based upon Net Sales; (c) the withholding taxes, if any, required by law to be deducted in respect of such royalties; (d) the date of the First Commercial Sale of each Product in each country or jurisdiction in the MN Territory; (e) the exchange rates used in determining the amount of United States dollars, as more specifically provided in Section 6.2; (f) in the case of a sublicense by MN or an MN Affiliate to an MN Sublicensee, Net Sublicense Consideration and the amount of associated MN Sublicense Payments payable by MN to MS with certificates, vouchers and/or other documents related thereto in sufficient detail to the extent necessary for the verification of the accuracy and legitimacy of such Net Sublicense Consideration, including but not limited to details of Cost of Goods, MN Development Costs and net sales of Product sold by MN Sublicensees. Royalty Reports and payments shall be due forty-five (45) days following the close of each Calendar Quarter. MN shall keep, and shall cause MN Affiliates and MN Sublicensees to keep complete and accurate records in sufficient detail to properly reflect all gross sales of API and Product and Net Sales and net sales of Product sold by MN Sublicensees to keep complete and accurate records in sufficient detail to properly reflect all gross sales of API and Product and Net Sales and net sales of Product sold by MN Sublicensees, and to enable the Section 4.3 Royalt

5.2 Audits.

5.2.1 <u>Audit Rights</u>. Upon the written request of MS and not more than once in each Calendar Year, MN shall permit, and shall cause MN Affiliates and MN Sublicensees to permit an independent certified public accounting firm of nationally recognized standing, selected by MS and reasonably acceptable to MN, at MS's expense, to have access during normal business hours on at least ten (10) Business Days' prior written notice, to such of the records of MN, such MN Affiliates or MN Sublicensees, as applicable, as may be reasonably necessary to verify the accuracy of the Royalty Reports for any Royalty Year ending not more than thirty-six (36) months prior to the date of such request. It is understood between the Parties that MS shall have the right to audit the accuracy and

legitimacy of the MN Development Costs and Costs of Goods in accordance with this ARTICLE 5.

5.2.2 <u>Audit Results</u>. In the event that such accounting firm concludes that additional royalties or other payments were owed to MS during such period, MN shall remit to MS, within thirty (30) days of receipt by MN of written notice from such accounting firm's conclusion, the amount of such royalties or other payments and interest thereon calculated pursuant to Section 6.5. In the event such accounting firm concludes that amounts were overpaid by MN during such period, MS shall return to MN the amount of such overpayment within thirty (30) days from receipt by MS of written notice from such accounting firm concluding that amounts were overpaid by MN. The fees and expenses charged by such accounting firm shall be paid by MS; provided, however, that in the event any such audit reveals an error in favor of MN (i.e. underpayment by MN) of more than **[***]** of the royalties or other payments due hereunder, MN shall pay the reasonable fees and expense charged by such accounting firm in connection with such audit. **[***]**, the calculation of royalties or other payments payable with respect to such Royalty Year shall be binding and conclusive upon MS and MN shall be released from any liability or accountability with respect to royalties or other payments for such Royalty Year.

5.2.3 <u>Confidential Financial Information</u>. MS shall treat all financial information subject to review under this ARTICLE 5 or under any sublicense agreement as confidential, and shall cause its accounting firm to retain all such financial information in confidence.

ARTICLE 6 PAYMENTS

6.1 Payment Terms. Royalties shown to have accrued by each Royalty Report shall be due and payable on the date such Royalty Report is due. In order for MS to receive compensation on a quarterly basis, MN shall pay to MS, on a quarterly basis, royalties based on the cumulative Net Sales for the applicable Royalty Year through the end of such Calendar Quarter, less royalties previously paid to MS on account of Net Sales for the previous Calendar Quarters in such Royalty Year. MN shall notify MS in writing not later than ten (10) Business Days after the receipt of any Net Sublicense Consideration from any MN Sublicensee (other than the Section 4.7 Royalty Payments, which shall be reported in accordance with Section 5.1) and each such notice shall be accompanied by the appropriate MN Sublicense Payments.

6.2 <u>Payment Method</u>. All payments by MN to MS under this Agreement shall be paid in United States dollars through wire transfer at the bank(s) and to the account(s) designated by MS. Net Sales shall be first determined in the currency of the country or jurisdiction in which they are earned and then converted to its equivalent in United States Dollars. If any currency conversion shall be required in connection with the payment of any royalties or other payments due MS hereunder, such conversion shall be made unless otherwise agreed upon between the Parties by using the average of the exchange rates for the purchase and sale of United States dollars reported by the Wall Street Journal on the last Business Day of the Calendar Quarter to which such royalties or other payments relate. Except as otherwise set forth in this Agreement,

any royalties and other payments to be made by MN to MS shall be without deduction of exchange, collection or other charges.

6.3 <u>Exchange Controls</u>. Notwithstanding any other provision of this Agreement, if at any time legal restrictions prevent the prompt remittance of part or all of the royalties or other payments due MS hereunder with respect to any country or jurisdiction in the MN Territory where the Sale takes place, payment shall be made through such lawful means or methods as MN may determine and reasonably acceptable to MS. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country or jurisdiction in the MN Territory where the Sale takes place, the royalty rate for Net Sales in such country or jurisdiction shall be adjusted to the highest legally permissible or government-approved rate.

6.4 <u>Withholding Taxes</u>. MN shall be entitled to deduct from any payment due MS under this Agreement the amount of any withholding taxes payable by MN or MN Affiliates, or any taxes required to be withheld by MN or MN Affiliates, to the extent MN or MN Affiliates pay to the appropriate governmental authority on behalf of MS such taxes, levies or charges. MN shall use Commercially Reasonable Efforts to minimize any such taxes, levies or charges required to be withheld on behalf of MS by MN or MN Affiliates. MN promptly shall deliver to MS proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto. Upon MN's written request, MS shall provide MN with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to, Form W-8BEN and any successor form).

6.5 <u>Late Payment</u>. Any sums not paid to MS by MN when due hereunder, shall accrue interest from the date when due until actually paid at a rate equal to the prime rate of Bank of America, N.A. on the Business Day immediately preceding the commencement of such interest period plus one percent (1%) per annum or the highest rate allowed by applicable law, whichever is less.

ARTICLE 7 CONFIDENTIALITY AND PUBLICITY

7.1 <u>Nondisclosure Obligations</u>. Except as otherwise provided in this ARTICLE 7, during the term of this Agreement and for a period of **[***]** thereafter, both Parties shall maintain in confidence and use only for purposes of this Agreement information and data resulting from or related to the research, development, manufacturing and commercialization of Compound, API and/or Products and other information and data supplied by the other Party under this Agreement and Confidential Disclosure Agreement executed on September 29, 2003. For purposes of this ARTICLE 7, information and data described in this Section 7.1 shall be deemed "Proprietary Information."

7.2 <u>Permitted Disclosures</u>. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, (a) a Party may disclose Proprietary Information of the other Party which is otherwise obligated not to disclose under this ARTICLE 7 to MN Affiliates, MN Sublicensees, and MS Licensees, as applicable, and each Party's consultants, outside contractors and clinical investigators, on a need-to-know basis on

condition that such Persons agree to keep the Proprietary Information confidential for the same time periods and to the same extent as such Party is required to keep the Proprietary Information confidential; and (b) a Party (and MN Affiliates, MN Sublicensees or MS Licensees, as applicable) may disclose such Proprietary Information to government or other Regulatory Authorities to the extent that such disclosure is required by applicable law (including without limitation all applicable securities laws), regulation, agency or court order, or is reasonably necessary to obtain patents or authorizations to conduct clinical trials with, and to commercially market Product, provided that the disclosing Party shall provide prior written notice to the other Party and sufficient opportunity to object to such disclosure or to request confidential treatment thereof.

The obligation not to disclose or use Proprietary Information received from the other Party shall not apply to any part of such Proprietary Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts of the Party obligated not to disclose such Proprietary Information in contravention of this Agreement; (ii) the receiving Party can establish by competent written proof is lawfully disclosed to the receiving Party by a Third Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party on a confidential basis; (iii) the receiving Party can establish by competent written proof is lawfully disclosed to the receiving Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party on a confidential basis; (iii) the receiving Party can establish by competent written proof is lawfully disclosed to the receiving Party, provided such Proprietary Information was not obtained directly or indirectly from the other Party; (iv) the receiving Party can establish by competent written proof is subsequently and independently developed by the receiving Party without the knowledge of the other Party's Proprietary Information; (v) is disclosed in a press release or other publication agreed to by both Parties, which agreement shall not be unreasonably withheld or delayed or (vi) the receiving Party has obtained prior written consent to disclose from the other Party.

ARTICLE 8

INTELLECTUAL PROPERTY AND INFRINGEMENT

8.1 <u>Ownership of Trademarks</u>. MN shall select, own and maintain Trademarks for Product in the MN Territory. The entire right and title in all Trademarks used by MN, MN Affiliates and, when applicable, MN Sublicensees, in the MN Territory shall be owned, as between MN and MS solely by MN or an MN Affiliate.

8.2 <u>Improvements by MN</u>. As between MS and MN, all rights and title to and interest in any Improvement conceived, developed, discovered and/or reduced to practice by MN, MN Affiliates, and/or MN Sublicensees in connection with the license granted to MN under Section 3.1 or activities by MN, MN Affiliates, and/or MN Sublicensees hereunder shall be vested in MN or an MN Affiliate subject to the license granted to MS under this Agreement.

8.3 Improvements by MS. As between MS and MN, all rights and title to and interest in any Improvement conceived, developed, discovered and/or reduced to practice by MS, MS Affiliates and/or MS Licensees or activities by MS, MS Affiliates and/or MS Licensees

hereunder shall be vested in MS or an MS Affiliate, subject to the license granted to MN under this Agreement.

8.4 Patent Prosecution and Maintenance of MS Patent Assets. MS shall use Commercially Reasonable Efforts to prosecute the MS Patent Assets in the United States, Canada, Australia, and Major European Countries and in such other jurisdictions as are mutually agreed upon by the Parties. Subject to the terms of this Agreement, MS shall have the initial right to control the filing, prosecution and maintenance of the MS Patent Assets in the MN Territory and MS shall have the sole and unrestricted right to control the filing, prosecution and maintenance of the MS Patent Assets in the MS Territory. MS shall be responsible for the payment of all such patent prosecution and maintenance costs and expense incurred by MS in prosecution and maintenance of such MS Patent Assets. MS shall provide MN with a copy of draft patent application that MS has prepared for the filing in the MN Territory at least thirty (30) days prior to the targeted filing date (hereinafter referred to as "MS Target Filing Date"). MS shall notify MN of the MS Target Filing Date at the same time MS provides MN with the above draft patent application. MN may provide MS with its comments thereon within fifteen (15) days of the receipt of such draft and MS may revise the draft patent application taking MN's reasonable comments into account. In addition, MS shall provide a copy of material or important prosecution documents related to the MS Patent Assets in the MN Territory and correspondence received from the patent offices of or from MS's agents in the MN Territory reasonably promptly after MS's receipt thereof. MN may provide MS with its comments thereon within the time reasonably requested by MS and MS may prepare a response to the patent office taking MN's reasonable comments into account. MS shall inform MN of any significant developments in the prosecution of pending patent applications included in the MS Patent Assets in the MN Territory, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If MS decides not to file, prosecute or maintain a Patent Asset included in the MS Patent Assets in any country or jurisdiction in the MN Territory, it shall provide MN with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) days prior written notice), and MN shall have the right, but not the obligation, at its sole expense, to file, prosecute or maintain such Patent Asset included in the MS Patent Assets and, if MN elects to do so, MS shall assign to MN all of MS's right, title and interest in and to such Patent Asset in the MN Territory and, thereafter, such Patent Asset shall be deemed to be MN Patent Assets and treated accordingly hereunder.

8.5 Patent Prosecution and Maintenance of MN Patent Assets. MN shall use, and cause any MN Affiliates to use, Commercially Reasonable Efforts to prosecute the MN Patent Assets in the United States, the major countries in the European Union, and Japan, Peoples Republic of China and South Korea and in such other jurisdictions as are mutually agreed upon by the Parties. MN and any MN Affiliates, as applicable, shall have the initial right to control the filing, prosecution and maintenance of the MN Patent Assets in the MS Territory and MN and any MN Affiliates, as applicable, shall have the sole and unrestricted right to control the filing, prosecution and maintenance of the MN Patent Assets in the MS Territory. MN shall be responsible, and cause any MN Affiliates to be responsible, for the payment of all such patent prosecution and maintenance costs and expense incurred by MN and/or such MN Affiliates in prosecution and maintenance of such MN Patent Assets. MN shall provide MS, and cause any MN Affiliates to provide MS, with a copy of draft patent application that MN and/or such MN

Affiliates have prepared for the filing in the MN Territory and in the MS Territory at least thirty (30) days prior to the targeted filing date (hereinafter referred to as "MN Target Filing Date"). MN shall notify MS, and cause any MN Affiliates to notify MS, of the MN Target Filing Date at the same time MN and/or such MN Affiliates provide MS with the above draft patent application. MS may provide MN with its comments thereon within fifteen (15) days of the receipt of such draft and MN may revise, or cause such MN Affiliates to revise, the draft patent application taking MS's reasonable comments into account. In addition, MN shall provide MS, and cause any MN Affiliates to provide MS, with a copy of any material or important prosecution documents related to the MN Patent Assets in the MS Territory and correspondence received from the patent offices of and MN's agents in the MS Territory reasonably promptly after MN's receipt thereof by itself or through such MN Affiliates. MS may provide MN with its comments thereon within the time reasonably requested by MN and MN and/or MN Affiliates, as applicable, may prepare a response to the patent office taking reasonable comments from MS into account. MN shall inform MS, and cause any MN Affiliates to foreign patent applications included in the MN Patent Assets, including the issuance of any domestic or foreign patent based thereon. If MN and/or any MN designee decide not to file, prosecute or maintain a Patent Asset included in the MN Patent Assets in any country or jurisdiction in the MS Territory, MN shall provide MS with written obligation, at its sole costs and expense, to file, prosecute or maintain such Patent Asset sint any country or such days prior to the MN shall have the right, but not the obligation, at its sole costs and expense, to file, prosecute or maintain such Patent Asset included in the MN Patent Assets and, if MS elects to do so, MN shall assign to MS, and cause any MN Affiliates to assign to MS, any and all of the right, title and interest of MN

8.6 <u>Cooperation</u>. Each Party shall make available as far as possible to the other Party or to the other Party's authorized attorneys, agents, representatives, employees or consultants any documents necessary or appropriate to enable the other Party to file, prosecute and maintain patent applications and resulting patents, as set forth in Sections 8.4 and 8.5 above, for a period of time sufficient for the other Party to obtain the assistance it needs from the first Party. Where appropriate, each Party shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other Party.

8.7 <u>Enforcement of Patent Assets</u>. In the event either Party learns of significant and continuing or threatened significant infringement of the MS Patent Assets or the MN Patent Assets, it shall promptly provide written notice to the other Party of the fact and supply such other Party with all evidence it possesses pertaining to and establishing said infringement or threatened infringement.

8.7.1 MN shall have the first right to take legal action to enforce against the infringer of the MS Patent Assets in the MN Territory, and shall consult with MS both prior to and during said enforcement.

8.7.2 MS shall have the first right to take legal action to enforce against the infringer of the MN Patent Assets in the MS Territory, and shall consult with MN both prior to and during said enforcement.

8.8 Procedure for Enforcement of Patent Assets.

8.8.1 MN shall have six (6) months from the date of receipt of notice of request by MS to abate the infringement, or to file suit against the infringer of the MS Patent Assets in the MN Territory, at the sole expense of MN, following consultation with MS. If MN does not, within six (6) months of receipt of such notice, abate the infringement or file suit to enforce the MS Patent Assets against the infringer of the MS Patent Assets in the MN Territory, MS shall have the right to take whatever action it deems necessary or appropriate in its own name to enforce the MS Patent Assets in the MN Territory at sole expense of MS; provided, however, that, within thirty (30) days after receipt of notice of MS's intent to file such suit, MN shall have the right to jointly prosecute such suit at costs and expense to be equally shared by both Parties.

8.8.2 MS shall have six (6) months from the date of receipt of notice of request by MN to abate the infringement, or to file suit against the infringer of the MN Patent Assets in the MS Territory, at the sole expense of MS, following consultation with MN. If MS does not, within six (6) months of receipt of such notice, abate the infringement or file suit to enforce the MN Patent Assets against the infringer of the MN Patent Assets in the MS Territory, MN shall have the right to take whatever action it deems necessary or appropriate in its own name to enforce the MN Patent Assets in the MS Territory at sole expense of MN; provided, however, that, within thirty (30) days after receipt of notice of MN's intent to file such suit, MS shall have the right to jointly prosecute such suit at costs and expense to be equally shared by both Parties.

8.9 <u>Settlements</u>. The Party controlling the action may not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. Notwithstanding the foregoing, MS and MN shall cooperate with each other in the planning and execution of any action to enforce the MS Patent Assets or the MN Patent Assets. Any recovery obtained by MN or MS shall be shared as follows:

(i) the Party that initiated and prosecuted, or maintained the defense of, the action shall recoup all of its costs and expense (including reasonable attorneys' fees) incurred in connection with the action, whether the recovery is by settlement or otherwise;

(ii) the other Party then shall, to the extent possible, recover its costs and expense (including reasonable attorneys' fees) incurred in connection with the action;

(iii) if MS initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining then shall be retained by MS; and

(iv) if MN initiated and prosecuted, or maintained the defense of, the action relating to the MN Patent Assets, the amount of any recovery remaining shall be retained by MN; if MN initiated and prosecuted, or maintained the defense of, the action relating to the MS Patent

Assets, the amount of any recovery remaining shall be retained by MN, except that MS shall receive a portion equivalent to the Section 4.3 Royalty Payments it would have received in accordance with the terms of this Agreement as if the amount of any remaining recovery had been Net Sales.

8.10 Notification of Patent Term Restoration. The Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country or jurisdiction where applicable to the MS Patent Assets in the MN Territory and the MS Territory. Each Party shall notify the other if it becomes aware of (a) the issuance of a patent included within the MS Patent Assets, giving the date of issue and patent number for each such patent, and (b) each notice pertaining to any patent included within the MS Patent Assets pursuant to the United States Drug Price Competition and Patent Term Restoration Act of 1984 (hereinafter referred to as "1984 Act"), including notices pursuant to §§ 101 and 103 of the 1984 Act from Persons who have filed an ANDA. Such notices shall be given promptly, but in any event within five (5) days of each Party's becoming aware of such patent's issue or receipt of each such notice pursuant to the 1984 Act, whichever is applicable. MS shall notify MN of each filing for patent term restoration under the 1984 Act, and all awards of patent term restoration (extensions) with respect to the MS Patent Assets. Likewise, MS or MN, as the case may be, shall inform the other Party of patent extensions and periods of data exclusivity in the rest of the world regarding any Patent Assets included in the MS Patent Assets and MN Patent Assets.

8.11 Infringement Actions by Third Parties. If MN or any of MN Affiliates shall be sued by a Third Party in a country or jurisdiction in the MN Territory for infringement of a patent held by such Third Party because of the use of MS Intellectual Property for the development, manufacture, importation, exportation, use, offer for sale, sale, market or distribution of Compound, API or Products, MN shall promptly notify MS in writing of the institution of such suit. MN shall have the first right, in its sole discretion, to control the defense of such suit at its own expense, in which event MS shall have the right to be represented by advisory counsel of its own selection, at its own expense, and shall cooperate fully in the defense of such suit and furnish to MN all evidence and assistance in MS's control. If MN does not elect within thirty (30) days after such notice from MN to MS to so control the defense of such suit, MS shall have the right, but not the obligation, to undertake such control at its own expense, and MN shall then have the right to be represented by advisory counsel of its own selection and at its own expense, and MN shall then have the right to be represented by advisory counsel of its own selection and at its own expense, and MN shall not settle the suit or otherwise consent to an adverse judgment in such suit that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. In the event that royalty or other payments are required to be paid by MN or any MN Affiliates to such Third Party as the result of a judgment or settlement under this Section 8.11, such royalty or other payments add/or Section 4.7 Royalty Payments in such country or jurisdiction in any Calendar Quarter of such Calendar Quarter, provided, however, that in no event shall such Section 4.3 Royalty Payments and Section 4.7 Royalty Payments or Section 4.7 Royalty Payments or Section 4.7 Royalty Payments or Section 4.7 Royalty Payments continues in such country o

ARTICLE 9 TERM AND TERMINATION

9.1 Expiration. Unless terminated earlier pursuant to Sections 9.2 or 9.3 below, this Agreement shall commence as of the Effective Date and expire on a country by country or jurisdiction by jurisdiction and Product by Product basis on the expiration of the last to expire Royalty Term applicable to such Product in such country or jurisdiction. Notwithstanding the foregoing, in case that MN or an MN Affiliate enters into a sublicense with an MN Sublicensee, MN's payment obligation relating to MN Sublicense Payments pursuant to Section 4.7 shall continue for so long as MN or an MN Affiliate receives Net Sublicense Consideration from such MN Sublicensee. Expiration of this Agreement in a particular country or jurisdiction in the MN Territory relating to a particular Product under this Section 9.1 shall not preclude MN and/or an MN Affiliate from continuing to develop, make, have made, use, sell, offer for sale, market, import, export and distribute such Product in such country or jurisdiction without further remuneration to MS. Any expiration of this Agreement under this Section 9.1 shall not affect the license granted by MN to MS under Section 3.3, which license shall survive any expiration of this Agreement. Nevertheless, such a surviving license shall be governed by the provisions of Section 9.5, below.

9.2 Termination by MN. MN shall have the right, in its sole discretion, to terminate this Agreement as follows:

9.2.1 with respect to the entire Agreement or with respect to any country or jurisdiction in the MN Territory in the event that (i) a Third Party claims that an activity associated with the commercialization of Compound or Product infringes such Third Party's intellectual property in any country or jurisdiction in the MN Territory, (ii) MN and MS mutually agree in writing that such Third Party's intellectual property includes a Dominating Patent, (iii) either MN has failed, after a reasonable period of time and use of good faith and Commercially Reasonable Efforts, to enter into a Third Party License or MN has opted, from a reasonable pharmaceutical company's point of view and after full consultation with MS, not to enter into such Third Party License, and (iv) after all of the foregoing (i) to (iii), MN provides not less than thirty (30) days prior written notice of such termination to MS with respect to the entire Agreement or any such country or jurisdiction in the MN Territory;

9.2.2 with respect to the entire Agreement or, upon the mutual agreement of the Parties, with respect to the United States, the EMEA Member States or the rest of the MN Territory (each, a "MN Sub-Territory"), by providing not less than ninety (90) days written notice to MS, if in MN's reasonable opinion, from a reasonable pharmaceutical company's point of view, after full consultation with MS, the safety, patient tolerability, efficacy, or the profile or the commercial viability of Product does not justify continued development by MN, an MN Affiliate and/or an MN Sublicensee;

9.2.3 with respect to the entire Agreement, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against MS, and MN provides not less than thirty (30) days prior written notice of such termination

to MS, provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if MS consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof;

9.2.4 with respect to the entire Agreement, upon or after the breach of any material provision of this Agreement by MS, if MS has not cured such breach within ninety (90) days after written notice thereof from MN; provided, however, that if the breach is not capable of being cured within ninety (90) days of such written notice, this Agreement may not be terminated so long as MS commences and is taking commercially reasonable actions to cure such breach as promptly as practicable; or

9.2.5 with respect to the entire Agreement, in the event that any delay by MS in fulfilling or performing any term of this Agreement for any of the reasons set forth in Section 12.1 extends longer than twelve (12) months, by providing a written notice of such termination to MS.

9.3 Termination by MS. MS shall have the right, in its sole discretion, to terminate this Agreement as follows:

9.3.1 with respect to the entire Agreement, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against MN, and MS provides not less than thirty (30) days prior written notice of such termination to MN, provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if MN consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof;

9.3.2 with respect to the entire Agreement, upon or after the breach of any material provision of this Agreement by MN, including without limitation, MN's failure to purchase, obtain, keep in force and maintain the insurance as set forth in Section 11.4, if MN has not cured such breach within ninety (90) days after written notice thereof from MS; provided, however, that if the breach is not capable of being cured within ninety (90) days of such written notice, this Agreement may not be terminated so long as MN commences and is taking commercially reasonable actions to cure such breach as promptly as practicable;

9.3.3 with respect to the entire Agreement or any particular country or jurisdiction, at the option and sole discretion of MS, in accordance with Section 2.1.4, by providing written notice of such termination to MN; or

9.3.4 with respect to the entire Agreement, in the event that any delay by MN in fulfilling or performing any term of this Agreement for any of the reasons set forth in Section 12.1 extends longer than twelve (12) months, by providing written notice of such termination to MN.

9.4 <u>Rights Not Affected</u>. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of 11 U.S.C. §101 et seq. (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that MN and MS shall retain and may fully exercise all of their respective rights, remedies and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy or reorganization case by or against a Party under the Bankruptcy Code, the other Party shall be entitled to all applicable rights under Section 365 (including 365(n)) of the Bankruptcy Code. Upon rejection of this Agreement by a Party or a trustee in bankruptcy for such Party, pursuant to Section 365(n) of the Bankruptcy Code, the other Party may elect (i) to treat this Agreement as terminated by such rejection or (ii) to retain its rights (including any right to enforce any exclusivity provision of this Agreement) to intellectual property (including any embodiment of such intellectual property) under this Agreement and under any agreement supplementary to this Agreement of all amounts owing under this Agreement, all of which this Agreement could have been extended by such ore Party, subject, however, to the continued payment of all amounts owing under this Agreement, all of which this Agreement could have been extended by such other Party any intellectual property (including any embodiment of such intellectual property) held by the trustee or Party, as applicable, shall (i) provide to the other Party ary intellectual property (including any embodiment of such intellectual property and all embodiments of such intellectual property and (ii) not interfere with the rights of the other Party to such intellectual property as provided in this Agreement or any agreement supplementary to this Agreement, including any right to obtain such intellectual property (or such embodiment or

9.5 Effect of Expiration and Termination.

9.5.1 Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing on or prior to such expiration or termination.

9.5.2 Subject to the provisions of this Section 9.5, all rights, licenses and obligations of MS and of MN with respect to and under this Agreement, in its entirety or with respect to the terminated country, jurisdiction or the MN Sub-Territory in the MN Territory, as applicable, shall terminate in the event of a termination pursuant to Section 9.2 or 9.3, provided, however, that in the event of a partial termination by MN under Section 9.2, this Agreement shall continue in full force and effect with respect to the countries, jurisdictions or MN Sub-Territory in the MN Territory unaffected by such partial termination, and such terminated country, jurisdiction or MN Sub-Territory shall be excluded from the countries or jurisdictions in the MN Territory and thereafter shall be deemed a country or jurisdiction in the MS Territory and treated accordingly hereunder.

9.5.3 In the event of any termination of this Agreement by MN under Section 9.2 or by MS under Section 9.3., MS shall, if requested by any then MN Sublicensee, accept assignment of the sublicense agreement as of the effective date of termination of this Agreement, provided that (a) the MN Sublicensee is not in breach of its sublicense agreement at the effective date of termination of this Agreement; and (b) the MN

Sublicensee acquires no rights from or obligations on the part of MS, other than those that are specifically granted in this Agreement, and the MN Sublicensee assumes all obligations to MS required of MN by this Agreement, including past due obligations existing at the time of assumption of the sublicense with such MN Sublicensee.

9.5.4 In case of any termination of this Agreement, MN, MN Affiliates and MN Sublicensees shall, for a period of six (6) months from the effective date of such termination, have the right to sell or otherwise dispose of the stock of any Product then on hand or in process of manufacture or supply, subject to MN's obligation under this Agreement to pay to MS pursuant to Section 4.3 or Section 4.7, as applicable.

9.5.5 In the event that this Agreement is terminated in its entirety by MN under Section 9.2.1, 9.2.2 or 9.2.5, (i) all rights and licenses granted by one Party to the other Party under this Agreement shall revert to the first Party; and (ii) if MS so requests of MN in writing, MN shall grant to MS in any country or jurisdiction in the MS Territory and/or MN Territory an exclusive (even to MN) license, including the right to grant sublicenses, to and under the MN Intellectual Property, including all right, title and interest in and to MN Regulatory Filings pertaining to Compound and Product, solely to research, develop, make, have made, use, offer for sale, market, sell, import, export, and distribute Compound, API and Product in the Field; provided, however, that such license [***]; and (iii) with the exception of the termination of this Agreement in its entirety under Section 9.2.1, if MS so requests of MN in writing, MN shall, at MS's expense, render MS assistance for implementation of MS's rights granted under this Section 9.5.5, including, if MN or its designee (including an MN Affiliate and an MN Sublicensee) is then manufacturing API or Product for development and/or commercial use prior to the effective date of such termination, providing MS with assistance in transfer of Manufacturing Technology.

9.5.6 In the event that this Agreement is terminated in its entirety by MN under Section 9.2.4, MN shall have an irrevocable, perpetual and exclusive (even to MS) license under MS Intellectual Property to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound and Product in the MN Territory. In consideration for such license, MN shall pay MS an amount [***]; provided, however, that ARTICLES 4 and 5 and any other provision required to interpret and enforce the Parties' rights and obligations under this Section 9.5.6 shall survive such termination, but only to the extent required for the full observation and performance of this Section 9.5.6.

9.5.7 In the event that this Agreement is terminated by MS under Section 9.3.2 and 9.3.3, (i) all rights and licenses granted by one Party to the other Party hereunder shall revert to the first Party; (ii) if MS so requests of MN in writing, MN shall grant to MS in any country or jurisdiction in the MS Territory and in the MN Territory an irrevocable, perpetual, fully paid-up, exclusive (even to MN) license, including the right to grant sublicenses, to and under the MN Intellectual Property including all right, title and interest in and to MN Regulatory Filings pertaining to Compound, API and Product, solely to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field; and (iii) if MS so requests of MN in writing, MN shall, at MN's expense, render MS assistance for implementation of MS's rights granted under this Section 9.5.7, including, if MN or its designee (including an MN

Affiliate and an MN Sublicensee) is then manufacturing API or Product for development and/or commercial use prior to the effective date of such termination, providing MS with assistance in transfer of Manufacturing Technology.

9.5.8 In the event that this Agreement is terminated by MS under Section 9.3. 4, (i) all rights and licenses granted by one Party to the other Party hereunder shall revert to the first Party; (ii) if MS so requests of MN in writing, MN shall grant to MS in any country or jurisdiction in the MS Territory and/or MN Territory an exclusive (even to MN) license, including the right to grant sublicenses, to and under the MN Intellectual Property including all right, title and interest in and to MN Regulatory Filings pertaining to Compound, API and Product, solely to research, develop, make, have made, use, offer for sale, market, sell, import, export and distribute Compound, API and Product in the Field; provided, however, that such license shall be **[***]**; and (iii) if MS so requests of MN in writing, MN shall, at MS's expense, render MS assistance for implementation of MS's rights granted under this Section 9.5.8, including, if MN or its designee (including an MN Affiliate and an MN Sublicensee) is then manufacturing API or Product for development and/or commercial use prior to the effective date of such termination, providing MS with assistance in transfer of Manufacturing Technology.

9.5.9 In addition to any other provision of this Agreement which by their terms continue after the expiration or termination of this Agreement, the following provisions shall survive the expiration or termination of this Agreement and shall continue in full force and effect: ARTICLE 1, ARTICLES 4, 5 and 6 (solely with respect to any amounts that have accrued or are owing and not paid), ARTICLE 7, ARTICLE 8, ARTICLE 9, ARTICLE 10, and ARTICLE 11. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.

9.5.10 Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

ARTICLE 10 REPRESENTATIONS AND WARRANTIES

10.1 Each Party hereby represents and warrants to the other Party as follows:

10.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

10.1.2 Such Party has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and the execution, delivery and performance by such Party of this Agreement have been duly authorized by all necessary corporate action. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except as enforceability may be limited by (A) any

applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor's rights generally, or (B) general principles of equity, whether considered in a proceeding in equity or at law;

10.1.3 All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained; and

10.1.4 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations or any judgment, injunction, decree, determination or award presently in effect having applicability to it, and (b) do not conflict with, or constitute a default under, any agreement of such Party.

10.2 Additional MS Representations and Warranties. MS hereby represents and warrants that: (a) the MS Intellectual Property in the MN Territory are owned or Controlled solely and exclusively by MS free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental or university entity or subdivision thereof, has any valid claim of ownership with respect to the MS Intellectual Property in the MN Territory, whatsoever; (b) MS has not previously granted, and will not grant during the term of this Agreement, any right, license or interest in and to the MS Intellectual Property, or any portion thereof, inconsistent with the license granted to MN herein; (c) as of the Effective Date, MS is aware of no reason why MS Patent Assets listed on Schedule 1.44 could be held invalid or unenforceable; (d) as of the Effective Date, there are no pending or, to the best knowledge of MS, threatened actions, suits, investigations, claims or proceedings in any way relating to the MS Intellectual Property in the MN Territory; (e) as of the Effective Date, there are no pending or, to the best knowledge of MS, threatened actions, suits, or claims by any Third Party alleging that use of the MS Intellectual Property in the MN Territory and the contemplated research, development, importation or exportation, manufacture, use, offer for sale and sale of any Compound or Product in the Field in the MN Territory would infringe any patent rights owned or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification, or any official proceeding involving a MS Patent Asset in the MN Territory) and will continue such disclosure with respect to new events during the term of the Agreement; and (g) **Schedule 1.44** contains a complete and accurate list of all MS Patent Assets in the MN Territory which are owned or Controlled by MS as of the Effective Date.

10.3 <u>Additional MN Covenant</u>. MN agrees that it will not grant during the term of this Agreement and thereafter, any right, license or interest in and to the MN Intellectual Property, or any portion thereof, that would prohibit or materially adversely affect the ability of MN to grant MS the license granted to MS herein in the MS Territory and, when applicable, in the MN Territory.

10.4 Effect of Representations and Warranties. It is understood that if the representations and warranties made by a Party under this ARTICLE 10 are not true and

accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, the Party making such representations and warranties shall indemnify and hold the other Party harmless from and against any such damages, liabilities, costs or other expenses incurred as a result. Notwithstanding the foregoing, if the representations and warranties made by MS under Section 10.2 (e) are not true and accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, Section 8.11 shall operate to indemnify MN and MS shall have no further obligation to compensate MN for such damages, liabilities, costs or other expenses incurred as a result.

10.5 <u>MS Warranty Disclaimer</u>. Except for the warranties expressly provided under Sections 10.1 and 10.2, the rights granted to MN by MS under this Agreement and the associated MS Intellectual Property are provided WITHOUT ANY OTHER WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED OR STATUTORY, AND MS HEREBY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, TITLE, AND ANY WARRANTY THAT MAY ARISE FROM COURSE OF DEALING, COURSE OF PERFORMANCE OR USAGE OF TRADE. MS DOES NOT MAKE, AND HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY THAT COMPOUND, API, PRODUCT OR THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, OFFER FOR SALE, SALE, MARKETING, DISTRIBUTION, IMPORT OR EXPORT THEREOF DO NOT INFRINGE OR VIOLATE ANY PATENT OR ANY OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY OR THAT ANY PATENTS WITHIN THE MS PATENT ASSETS ARE VALID OR ENCORCEABLE OR THAT ANY PATENTS WILL ISSUE UPON ANY PATENT APPLICATIONS WITHIN THE MS PATENT ASSETS.

10.6 <u>MN Warranty Disclaimer</u>. Except for the warranties expressly provided under Section 10.1 and 10.3, the rights granted to MS by MN under this Agreement and the associated MN Intellectual Property are provided WITHOUT ANY OTHER WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED OR STATUTORY, AND MN HEREBY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, TITLE, AND ANY WARRANTY THAT MAY ARISE FROM COURSE OF DEALING, COURSE OF PERFORMANCE OR USAGE OF TRADE. MN DOES NOT MAKE, AND HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY THAT COMPOUND, API, PRODUCT OR THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, OFFER FOR SALE, SALE, MARKETING, DISTRIBUTION, IMPORT OR EXPORT THEREOF DO NOT INFRINGE OR VIOLATE ANY PATENT OR ANY OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY OR THAT ANY PATENTS WITHIN THE MN PATENT ASSETS ARE VALID OR ENCORCEABLE OR THAT ANY PATENTS WILL ISSUE UPON ANY PATENT APPLICATIONS WITHIN THE MN PATENT ASSETS.

10.7 Without limiting the generality of the foregoing, this Agreement does not:

10.7.1 obligate MS or MN to bring or prosecute actions or suits against Third Parties for patent infringement except as provided in ARTICLE 8;

10.7.2 confer by implication, estoppel or otherwise any license or rights under any patents or know-how of MS or MN other than MS Intellectual Property or MN Intellectual Property, as defined in this Agreement, regardless of whether those patents are dominant or subordinate to MS Patent Assets or MN Patent Assets, respectively; or

10.7.3 obligate MS or MN to furnish any know-how or other information except as expressly set forth herein.

ARTICLE 11 INDEMNIFICATION

11.1 <u>MN's Obligation</u>. MN shall defend, indemnify, and hold harmless MS, MS Affiliates and their respective directors, officers, shareholders, employees and agents (hereinafter referred to as "MS Indemnitees"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expense, including, but not limited to the amount of any judgment or settlement and reasonable attorney's fees (hereinafter referred to as "Damages") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against the MS Indemnitee that is due to, arising from or based upon:

- (a) any breach of a representation, warranty, covenant or obligation of MN under this Agreement,
- (b) any negligent or more culpable act or omission of MN under this Agreement, or
- (c) the research, development, manufacture, use, offer for sale, sale, importation, exportation, distribution, or other commercialization or exploitation of Compound, API and/or Products by MN, MN Affiliates or MN Sublicensees in the MN Territory.

However, MN shall not be required to indemnify or hold harmless the MS Indemnitees from Damages to the extent that such Damages are determined to have resulted from the negligent or more culpable acts or omissions of an MS Indemnitee.

11.2 MS's Obligation. MS shall defend, indemnify, and hold harmless MN, MN Affiliates and their respective directors, officers, shareholders, employees and agents (hereinafter referred to as "MN Indemnitees"), from and against any and all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against the MN Indemnitee that is due to, arising from or based upon:

- (a) any breach of a representation, warranty, covenant or obligation of MS under this Agreement,
- (b) any negligent or more culpable act or omission of MS under this Agreement, or
- (c) the research, development, manufacture, use, offer for sale, sale, importation, exportation, distribution, or other commercialization or

exploitation of Compound, API and/or Products by MS, MS Affiliates or MS Licensees in the MS Territory.

However, MS shall not be required to indemnify or hold harmless the MN Indemnitees from Damages to the extent that such Damages are determined to have resulted from the negligent or more culpable acts or omissions of an MN Indemnitee.

11.3 <u>Indemnification Procedure</u>. Each Party shall promptly notify the other Party in writing of any claim for which such Party intends to seek indemnification hereunder. Concurrent with the provision of notice pursuant to this Section 11.3, such Party shall provide to the other Party copies of any complaint, summons, praecipe, subpoena or other court filings or correspondence related to such claim and will give such other information with respect thereto as the other Party shall reasonably request. A Party seeking indemnification hereunder will cooperate with the indemnitor at the indemnitor's expense in the defense of any suit.

11.4 Insurance. MN shall maintain and keep in force during the term of this Agreement and for a period of at least five (5) years after it has ceased commercial distribution, Sale or use of any Compound and/or Product comprehensive general liability insurance, including Products/Completed Operations, Contractual and Broad Form Property Damage, in such amount as MN customarily maintains with respect to its other products and which is reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities at the respective place of business of MN but in any event with the coverage of [***] per occurrence or series of occurrences, combined single limit for Bodily Injury and Property Damage. It is understood that such insurance shall not be construed to limit MN's liability with respect to such indemnification obligations. Such insurance shall be placed with a first class insurance carrier with at least BBB rating by Standard & Poor's. Upon MS's request, MN shall furnish a certificate of such insurance to MS (or provide MS with a written affirmation of the adequacy of an existing certificate) evidencing the foregoing endorsements, coverage and limits, and MN shall provide MS with notice prior to any cancellation, non-renewal or material change in such insurance, to the extent MN receives advance notice of such matters from its insurer.

ARTICLE 12 MISCELLANEOUS

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, earthquakes, embargoes, power shortage or failure, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; provided, however, that, in the event any such delay extends longer than twelve (12) months, the other Party may terminate this Agreement in accordance with ARTICLE 9. As soon as practicable after the occurrence of any such event the affected Party shall (a) notify the other Party thereof, (b) provide to such other Party as much detail as possible with respect to such event and shall keep the other Party informed of any further development and results of such event, and (c) use its Commercially Reasonable Efforts

to limit the resulting delay in its performance. Immediately after such event ceases or is removed, the affected Party shall perform its obligation suspended by such events.

12.2 <u>Assignment</u>. Except as expressly provided hereunder, this Agreement shall not be assigned or otherwise transferred, nor shall any right or obligations hereunder be assigned or transferred by MN without the prior written consent of MS, which consent shall not be unreasonably withheld by MS; provided, however, that MN may, without such consent, assign this Agreement and its rights and obligations hereunder to an MN Affiliate or in connection with (i) a merger in which MN is not the surviving entity, (ii) a consolidation or division of MN, (iii) a sale of all or substantially all of the assets or the business(es) of MN, (iv) a change of control resulting from a sale or repurchase of shares or similar transaction (whether in one or more related transactions) involving MN, or (v) any similar transaction. Any purported assignment or other disposition by MN or MS, except as permitted herein, shall be null and void. For the avoidance of doubt, MS may assign this Agreement and its rights and obligations hereunder to any Person at MS's sole discretion. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Subject to the foregoing, this Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assignees.

12.3 <u>Severability</u>. In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the original purposes of this Agreement.

12.4 <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered by hand or by facsimile or email (and promptly confirmed by personal delivery, U.S. or international first class mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated in the first paragraph of this Agreement, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

12.5 <u>Applicable Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to the conflicts of law principles thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Assets in question.

12.6 Dispute Resolution.

(a) The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (hereinafter referred to as "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within thirty (30) days, shall be referred, by written notice

from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within thirty (30) days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers are unable to settle the Dispute between themselves within thirty (30) days, they shall so report to the Parties in writing. The Dispute shall then be referred to arbitration as set forth in the following subsection (b).

(b) Any dispute which could not be settled by the Chief Executive Officers pursuant to subsection (a) above shall be finally settled by arbitration, which shall be conducted in New York, U.S.A in accordance with the rules of the American Arbitration Association (hereinafter referred to as "AAA") then in force, if initiated by MS, or in Tokyo, Japan in accordance with the rules of the Japan Commercial Arbitration Association (hereinafter referred to as "JCAA") then in force, if initiated by MN, and the language of the arbitration shall be English. The arbitration shall be conducted by a panel of three arbitrators with experience in the pharmaceutical industry: one arbitrator shall be appointed by each of MN and MS and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two-Party appointed arbitrators.

The tribunal shall issue its award within forty-five (45) days after the date on which the arbitration proceedings have closed. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the arbitration levied by the AAA or JCAA, as the case may be.

12.7 <u>Injunctive Relief</u>. Each party acknowledges and agrees that, due to the unique and valuable nature of Proprietary Information and materials of the other Party, there may be no adequate remedy at law for any breach by such Party of Section 3.1, 3.3 and/or ARTICLE 7 of this Agreement, that any such breach may result in irreparable harm to the non-breaching Party for which monetary damages would be inadequate to compensate the non-breaching Party, and that the non-breaching Party shall have the right, in addition to any other rights available under applicable law, to obtain from any court of competent jurisdiction injunctive relief to restrain any breach or threatened breach of, or otherwise to specifically enforce, any covenant or obligation of such Party under such Section 3.1, 3.3 and/or ARTICLE 7.

12.8 <u>LIMITATION OF LIABILITY</u>. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

12.9 <u>Further Assurances</u>. At any time or from time to time on and after the Effective Date, each Party shall at the request of the other (i) deliver to the other such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or

cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as such Party or the other Party may reasonably deem necessary or desirable in order for the other Party to obtain the full benefits of this Agreement and the transactions contemplated herein.

12.10 <u>Entire Agreement</u>. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made including Confidential Disclosure Agreement executed on September 29, 2003 and Letter of Intent executed on September 22, 2004, are expressly superseded by this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

12.11 <u>Headings</u>. The captions to the several ARTICLES and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several ARTICLES and Sections hereof.

12.12 <u>Independent Contractors</u>. It is expressly agreed that MS and MN shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MS nor MN shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

12.13 <u>Waiver</u>. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

12.14 <u>Counterparts</u>. This Agreement may be executed in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank.]

³⁸

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

MediciNova, Inc.

By:/s/ Yuichi IwakiName:Yuichi Iwaki, MD., Ph. D.Title:Chairman of the Board, Chief Executive Officer

Meiji Seika Kaisha, Ltd.

By: /s/ Akinobu Otsubo

Name: Akinobu Otsubo Title: Executive Vice President, President of Pharmaceutical Company

SCHEDULE 1.12

COMPOUND DIAGRAM

[***]

[***]

SCHEDULE 1.44 MS PATENT ASSETS

[***]

SCHEDULE 4.3

EXAMPLES OF ROYALTY CALCULATION

For the purpose of calculation of Section 4.3 Royalty Payments payable by MN to MS hereunder:

"Patent/Exclusivity Net Sales" shall mean Net Sales during the Royalty Term set forth in Sections 4.3.1 and 4.3.2;

"<u>Non-Patent/Exclusivity Net Sales</u>" shall mean Net Sales during the Royalty Term set forth in Section 4.3.4 (a);

"Generic Competition Net Sales" shall mean Net Sales during the Royalty Term set forth in Section 4.3.4 (b);

"Tier 1", "Tier 2" and "Tier 3" shall mean as follows; and

Annual Net Sales in U.S.:	Royalty Rate:
Tier 1; Up to [***]	[***]
Tier 2; From [***]	[***]
Tier 3; From and over [***]	[***]
Aggregate Annual Net Sales outside U.S.:	Royalty Rate:
Tier 1; Up to [***]	[***]
Tier 2; From [***]	[***]
Tier 3: From and over [***]	[***]

"
 $\underline{\$}$ " shall mean United States dollar.

Case 1) When Product is Sold solely by MN in U.S.

In the event that in a particular Royalty Year there are Net Sales of [***] (Patent/Exclusivity Net Sales);

of such Net Sales, in accordance with Section 4.3.1, [***]

Tier 1 Royalty: [***]	= [***]
Tier 2 Royalty: [***]	= [***]
Tier 3 Royalty: [***]	= [***]
Total Section 4.3 Milestone Payments	[***]

Case 2) When Product is Sold solely by MN in all countries and jurisdictions other than U.S. in MN Territory

In the event that in a particular Royalty Year there are Net Sales of [***] in the MN Territory, broken down as follows;

Patent/Exclusivity Net Sales:	[***]
Non-Patent Exclusivity Net Sales:	[***]
Generic Competition Net Sales:	[***]
Net Sales:	[***]

A) In order to calculate Section 4.3 Royalty Payments on such Net Sales [***], one must first calculate what percentage of such Net Sales will be subject to Tier 1, Tier 2 and Tier 3:

Tier 1; [***]	= [***]
Tier 2; [***]	= [***]
Tier 3; [***]	= [***]

B) Then MN shall pay MS royalties based on Patent/Exclusivity Net Sales

STEP1: calculate portion of Patent/Exclusivity Net Sales [***] applicable to each Tier

Tier 1 Patent/Exclusivity Net Sales:	[***] = [***]
Tier 2 Patent/Exclusivity Net Sales:	[***] = [***]
Tier 3 Patent/Exclusivity Net Sales:	[***] = [***]

STEP2: apply appropriate royalty rate to portion of Patent/Exclusivity Net Sales calculated in STEP1 above

Tier 1 Royalty: [***]	= [***]
Tier 2 Royalty: [***]	= [***]
Tier 3 Royalty: [***]	= [***]
Total:	[***]

C) Then MN shall pay MS royalties based on Non-Patent/Exclusivity Net Sales

STEP1: calculate portion of Non-Patent/Exclusivity Net Sales [***] applicable to each Tier

Tier 1 Non-Patent/Exclusivity Net Sales:	[***] = [***]
Tier 2 Non-Patent/Exclusivity Net Sales:	[***] = [***]
Tier 3 Non-Patent/Exclusivity Net Sales:	[***] = [***]

STEP2: apply appropriate royalty rate to portion of Non-Patent/Exclusivity Net Sales calculated in STEP1 above (Note: royalty rates are [***] of those set forth in Section 4.3.2)

Tier 1 Royalty: [***]	=[***]
Tier 2 Royalty: [***]	=[***]
Tier 3 Royalty: [***]	=[***]
Total:	[***]

D) Then MN shall pay MS royalties based on Generic Competition Net Sales

STEP1: calculate portion of Generic Competition Net Sales [***] applicable to each Tier

Tier 1 Generic Competition Net Sales:	[***] =[***]
Tier 2 Generic Competition Net Sales:	[***]=[***]
Tier 3 Generic Competition Net Sales:	[***]=[***]

STEP2: apply appropriate royalty rate to portion of Generic Competition Net Sales calculated in STEP1 above (Note: royalty rates are [***] of those set forth in Section 4.3.2)

Tier 1 Royalty:	[***]=[***]
Tier 2 Royalty:	[***] =[***]
Tier 3 Royalty:	[***] =[***]
Total:	[***]

E) Then total Section 4.3 Royalty Payments shall be summed:

Royalties based on Patent/Exclusivity Net Sales:	[***]
Royalties based on Non-Patent/Exclusivity Net Sales:	[***]
Royalties based on Generic Competition Net Sales:	[***]
Total Section 4.3 Royalty Payments:	[***]



FOR IMMEDIATE RELEASE

CONTACT: Kenneth W. Locke, Ph.D. Chief Business Officer MediciNova, Inc. Phone: 858-373-1200 E-mail: locke@medicinova.com

MediciNova Announces the Acquisition of Two Novel Antithrombotic Agents from Meiji Seika Kaisha, Ltd.

New Mechanisms of Action Against Blood Clot Formation Demonstrated in Preclinical Studies

SAN DIEGO, Calif. – October 31, 2006 – MediciNova, Inc., a biopharmaceutical company that is publicly traded on the Hercules Market of the Osaka Securities Exchange (Code Number: 4875), today announced the acquisition of two novel small molecule cardiovascular agents from Meiji Seika Kaisha, Ltd. (Tokyo, Japan). MN-447 and MN-462 are antithrombic (anti-clotting) agents that represent novel approaches to blood clot formation and lysis, respectively, and are expected to treat a variety of thrombotic disorders.

"MN-447 and MN-462 represent potentially important new interventions to treat thrombosis-related cardiovascular diseases, and commercially valuable additions to MediciNova's advancing portfolio of product candidates," said Yuichi Iwaki, M.D., Ph.D., Executive Chairman and CEO of MediciNova, Inc. "MediciNova's portfolio of product candidates today includes eight drugs under clinical evaluation in ten therapeutic indications at stages ranging from preclinical development to Phase III clinical testing. MediciNova continues to execute its business strategy to in-license and develop differentiated, high quality assets with broad intellectual property rights and large commercial potential through alliances with Japanese pharmaceutical partners."

MN-447 is a novel cardioprotective, anti-platelet agent that acts as a potent dual antagonist of glycoprotein (GP) IIbIIIa and integrin alpha-v-beta-3 (a_vb_3) receptors that play key roles in blood clot formation and various cell behaviors and functions such as leukocyte adhesion. MN-447 acts downstream by inhibiting the final common pathway of platelet aggregation - the cross-linking of platelets via fibrinogen bridges to GP IIbIIIa receptors. Inhibition of integrin (a_vb_3) receptors has been linked to an inhibition of leukocyte adhesion to endothelium (the layer of cells lining blood vessels), reduction of hyperplasia (abnormal cellular proliferation) and lumen stenosis (blood vessel constriction) in response to vascular injury. In animal models of myocardial infarction and unstable angina, the dual inhibitory activity of MN-447 produced superior cardioprotective efficacy, such as reduction in infarct size after reperfusion (restoration of blood flow), compared to inhibition of the GP IIbIIIa receptor alone and showed a low risk of bleeding.

MN-462 is a selective inhibitor of a key enzyme in the intrinsic antifibrinolytic mechanism, plasma carboxypeptidase B (CPB; also called activated thrombinactivatable fibrinolysis inhibitor (TAFIa)), which inhibits physiological fibrinolysis (the lysis or dissolving of blood clots). By enhancing intrinsic fibrinolysis through plasma CPB inhibition, MN-462 has the potential to both reduce and prevent thrombus or blood clot formation as well as to dissolve formed thrombus, and consequently, represents a novel approach to treating various thrombotic disorders. In preclinical studies, MN-462 has demonstrated significant fibrinolyticenhancing and anti-thrombotic activities as monotherapy in several thrombosis models, as well as activities when used as an adjunct to fibrinolytics such as tissue plasminogen activator (t-PA). The effect of MN-462 in enhancing the intrinsic fibrinolytic process has also been observed to result in a low risk of bleeding.

Despite advances in the treatment of cardiovascular disease (CVD), we believe there remains an unmet medical need for safe and effective treatments for conditions that

include acute coronary syndrome, myocardial infarction, peripheral arterial disease and percutaneous coronary interventions. Given the high mortality and morbidity rates associated with CVD, we believe there is an urgent need for more targeted therapies that can intervene in known molecular pathways and minimize damage to the heart and related tissues. CVD remains the leading cause of death in the U.S. for both men and women among all racial and ethnic groups. Approximately one million Americans die of CVD each year, constituting 42% of all deaths. Heart disease is the leading cause of death for all Americans age 35 and older. One out of every four Americans has CVD; heart disease and stroke account for almost six million hospitalizations each year and cause disability for almost 10 million Americans age 65 years and older.

MediciNova acquired a license to MN-447 and MN-462 from Meiji Seika Kaisha, Ltd. for global markets, with the exception of Japan and other selected Asian countries (Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam). The data acquired from Meiji Seika Kaisha, Ltd. includes extensive preclinical efficacy and safety data. Terms of the licensing agreements are not disclosed.

About MediciNova

MediciNova, Inc. is a publicly traded biopharmaceutical company focused on accelerating the global development and commercialization of innovative pharmaceutical products. MediciNova's pipeline, which includes six compounds in clinical testing, targets a variety of prevalent medical conditions, including asthma, Generalized Anxiety Disorder, multiple sclerosis, interstitial cystitis, status asthmaticus, preterm labor, cancer, urinary incontinence and thrombotic disorders. For more information on MediciNova, Inc., please visit <u>www.medicinova.com</u>.

This press release may contain "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include statements regarding clinical trials supporting efficacy of one of our product candidates as well as

the potential novelty of that candidate as a treatment for disease. These statements are based on certain assumptions made by the Company's management that are believed to be reasonable at the time. Such statements are subject to a number of risks and uncertainties, many of which are beyond the control of the Company, including the results of clinical studies and other risks and uncertainties, including those described in the Company's filings with the Securities and Exchange Commission. These assumptions, risks and uncertainties could cause the Company's actual results to differ materially from those implied or expressed by the forward-looking statements.