

**AMENDED AND RESTATED**  
**MANUFACTURING AND SUPPLY AGREEMENT**  
**BETWEEN**  
**DENDREON CORPORATION**  
**AND**  
**KIRIN BREWERY CO., LTD.**

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## **AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT**

THIS AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement" or "Manufacturing and Supply Agreement") is made and entered into effective as of August 6, 2002 (the "Restated Effective Date") by and between **DENDREON CORPORATION**, a Delaware corporation having its principal place of business at 3005 1<sup>st</sup> Avenue, Seattle, Washington, U.S.A. ("Dendreon"), and **KIRIN BREWERY CO., LTD.**, a corporation organized and existing under the laws of Japan having its principal place of business at 10-1, Shinkawa 2-chome, Chuo-ku, Tokyo, Japan ("Kirin"). Dendreon and Kirin may be referred to herein collectively as the "Parties" or individually as a "Party."

### **RECITALS**

A. Dendreon has developed and owns certain proprietary technology relating to the manufacture of devices, reagents and proprietary antigens necessary for Dendreon Products and Kirin Products.

B. Kirin has developed and owns certain proprietary technology relating to the manufacture of certain proprietary antigens and other proprietary components necessary for Kirin Products and Dendreon Products.

C. Kirin desires to purchase from Dendreon certain of its devices, reagents and certain of its proprietary antigens from Dendreon for use in clinical trials and commercialization of Kirin Products and Licensed Dendreon Products, and Dendreon is willing to supply Kirin with such devices, reagents and antigens for such uses.

D. Dendreon desires to purchase from Kirin certain components necessary for making Licensed Kirin Products for use in clinical trials and commercialization of Licensed Kirin Products and Dendreon Products, and Kirin is willing to provide Dendreon with Kirin proprietary antigens and other Kirin proprietary components and certain Dendreon Components, if applicable, necessary for Licensed Kirin Products and Dendreon Products for such use.

E. The Parties contemplate that Dendreon may supply Kirin with commercial quantities of devices, reagents and Dendreon proprietary antigens, and Kirin may supply Dendreon with commercial quantities of Kirin proprietary antigens and other Kirin proprietary components, in the event marketing approval is obtained for any Products, in which case the Parties shall negotiate appropriate amendments to this Agreement.

F. The Parties contemplate that Dendreon may license Kirin to manufacture devices, reagents and Dendreon proprietary antigens, and Kirin may license Dendreon to manufacture Kirin components, necessary for making Products.

G. Kirin and Dendreon entered into a Manufacturing and Supply Agreement on July 27, 1999 to formalize their plans set forth in Recitals A through F. (The Manufacturing and Supply Agreement executed on July 27, 1999 is hereinafter defined as the "Original Supply Agreement"; and the date of its execution is hereinafter defined as the "Effective Date".)

H. Kirin and Dendreon entered into a Memorandum of Modifications to Kirin and Dendreon Collaboration on August 3, 2001 (hereinafter defined as the "Memorandum"). The Memorandum, among other things, directs that the Original Supply Agreement be amended to conform to the Parties' agreements in the Memorandum.

I. Kirin has an option for a fully paid non-exclusive license (with right to sublicense) to manufacture Dendreon Antigen PA2024 using Dendreon Technology as set forth in this Agreement and in the Collaborative License Agreement.

J. This Agreement and the Amended and Restated Collaborative License Agreement of even date supercede and terminate the Memorandum.

NOW, THEREFORE, the Parties agree to amend and restate the Original Supply Agreement in its entirety as follows:

## **ARTICLE 1: DEFINITIONS**

The following capitalized terms shall have the following meanings when used in this Agreement.

1.1 “**Affiliate**” means, with respect to a particular Party, a person, corporation or other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For the purposes of this definition, “control” means the direct or indirect ownership by a Party of at least fifty percent (50%) of the outstanding voting securities of the controlled entity; provided, that in any country where the law does not permit foreign equity ownership of at least fifty percent (50%), then with respect to corporations organized under such country’s laws, “control” shall mean the direct or indirect ownership by a Party of outstanding voting securities of such corporation at the maximum amount permitted by the law of such country.

1.2 “**Back-Up License**” shall have the meaning set forth in Section 3.7(c).

1.3 “**Business Day**” means any day that is not a Saturday, Sunday or other day on which (a) banks in the State of Washington are authorized or required to close for the purposes of any action to be taken by or any notice to be provided to Dendreon, or (b) the banks in Japan are authorized or required to close for the purposes of any action to be taken by or any notice to be provided to Kirin.

1.4     **“Collaborative License Agreement”** shall mean the Amended and Restated Collaborative License Agreement by and between the Parties of even date.

1.5     **“Component” or “Components”** shall mean either a Kirin Component or a Dendreon Component, depending upon the context of the applicable Section and the Party to which such section then applies.

1.6     **“Controlled” or “Control”** means, with respect to a particular item, material, or intellectual property right, that a Party owns or has a license under such item, material or intellectual property right and has the ability to grant to the other Party access to and/or a license or sublicense under such item, material or intellectual property right without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party.

1.7     **“Dendreon Antigen”** means an antigen that is claimed by a patent or is otherwise covered by intellectual property rights that are Controlled by Dendreon.

1.8     **“Dendreon Component” or “Dendreon Components”** shall mean a Separation Device, Reagent or Dendreon Antigen, or any combination thereof, other than a combination which comprises a Dendreon Product.

1.9     **“Dendreon Product”** means: (a) any therapeutic product comprising Dendritic Cells that have been activated or loaded with a specific antigen, engineered antigen or antigen gene, (including without limitation Dendreon Antigen), for use in human therapy, which product has been developed by Dendreon based on the Dendreon Technology; or (b) any service provided by or on behalf of Dendreon to a patient that utilizes the Dendreon Technology and involves isolation or preparation of Dendritic Cells, activation or loading with specific antigen, engineered antigen or antigen gene, (including without limitation Dendreon Antigen), and administration of such activated or antigen loaded Dendritic Cells into a patient. Further, the Parties may agree in writing to amend and extend the definition of Dendreon Product as provided in Section 5.8 of the Collaborative License Agreement.

1.10 “**Dendreon Technology**” means the Dendreon Know-How, the Dendreon Improvements and the Dendreon Patents, (as such terms are defined in the Collaborative License Agreement) either collectively or any part thereof.

1.11 “**Dendritic Cell**” means a human dendritic cell or other antigen-presenting cell or other cells from which dendritic cells can be derived.

1.12 “**Effective Date**” means the date of the Original Supply Agreement, July 27, 1999. Any amendment to the Original License Agreement contained in this Agreement shall be effective as of the Restated Effective Date.

1.13 “**Fully-Burdened Manufacturing Costs**” means the actual fully burdened costs and expenses of manufacturing a particular Component, including without limitation the costs of all raw materials and labor (including all allocable benefits) used or consumed in such manufacture, Third Party contract manufacturing costs, packaging costs and expenses, all quality assurance and quality control related expenses, all overhead amounts allocable to such manufacturing (including without limitation appropriately amortized capital equipment costs), all royalty amounts payable by Supplier to any Third Party based upon the manufacture of such Component, and all amounts related to failed production units or yield losses, all the foregoing as calculated in accordance with (i) U.S. generally accepted accounting principles consistently applied for manufacture of Components by Dendreon and (ii) Japan’s generally accepted accounting principles consistently applied for manufacture of Components by Kirin.

1.14 “**Information**” means any and all information and data of any kind, including without limitation techniques, inventions, practices, methods, knowledge, know-how, skill, experience, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, marketing, cost, sales and manufacturing data and descriptions, compositions, and assays.

1.15 “**Kirin Antigen**” means an antigen that is claimed by a patent or is otherwise covered by intellectual property rights that are Controlled by Kirin.

1.16 “**Kirin Component**” or “**Kirin Components**” shall mean any Kirin Antigen or any other Kirin proprietary component of a Kirin Product, and any combination thereof, that Dendreon is either unable to prepare or generally does not prepare for Kirin or for itself.

1.17 “**Kirin PA2024 Option**” shall have the meaning set forth in Section 2.5 of the Collaborative License Agreement.

1.18 “**Kirin Product**” means: (a) any therapeutic product developed by or on behalf of Kirin based on, derived from or incorporating the Dendreon Technology that comprises Dendritic Cells that have been activated or loaded with a specific antigen, engineered antigen or antigen gene, (including without limitation a Kirin Antigen), for use in human therapy; or (b) any service provided by or on behalf of Kirin to a patient that involves isolation or preparation of Dendritic Cells, activation or loading of a specific antigen, engineered antigen or antigen gene, (including without limitation a Kirin Antigen), and administration of such activated or antigen loaded Dendritic Cells into a patient, wherein such service is based on, utilizes, comprises or is derived from the Dendreon Technology. The Parties may agree in writing to amend and extend the definition of Kirin Product as provided in Section 5.8 of the Collaborative License Agreement.

1.19 “**Kirin Hiring Period**” shall have the meaning set forth in Section 3.9(b)(iii)(3).

1.20 “**Licensed Dendreon Product**” shall have the meaning set forth in Section 2.3(b) of the Collaborative License Agreement.

1.21 “**Licensed Kirin Product**” shall have the meaning set forth in Section 2.4(b) of the Collaborative License Agreement.

1.22 “**Manufacturing and Supply Agreement**” means this Agreement

1.23 “**Manufacturing Know-How**” means all Information other than Patents necessary for the manufacture of a Kirin Antigen or Dendreon Antigen which is subject to the Back-Up License.

1.24 “**Manufacturing Plan**” shall mean the plan prepared by the Supplier and delivered to the Purchaser for its review and approval, in good faith, which plan details the Supplier’s manufacturing plan for achieving manufacture of the Components at levels at least equal to the Purchaser’s forecasted orders for the first year after commercial launch of the first Kirin Product or Dendreon Product, as applicable.

1.25 “**Memorandum**” shall have the meaning set forth in Recital H.

1.26 “**Net Revenue**” means the total revenue received by a Party for sale or other disposition of a Product by such Party or an Affiliate or Sublicensee of such Party to a Third Party less the following to the extent actually incurred or allowed with respect to such sale or disposition: (i) reasonable costs paid, if any, by the Party to a Third Party on account of apheresis performed as part of or in association with the Product; (ii) discounts, including cash discounts, or rebates, retroactive price reductions or allowances actually allowed or granted from the billed amount; (iii) credits or allowances actually granted upon claims, rejections or returns of Products, including recalls, regardless of the Party requesting such; (iv) freight, postage, shipping and insurance charges paid for delivery of Product, to the extent billed; and (v) taxes, duties or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for rebates and refunds; *provided, however,* that with respect to sales of a particular Kirin Product or Licensed Dendreon Product by Kirin or its Affiliate or Sublicensee in Japan, the “total revenue received”, as set forth above in the first line of this definition, shall not in any event be less than the NHI Price established for insurance reimbursement of Single Treatment (as defined in the Collaborative License Agreement), less the average amount charged by the particular hospital purchaser of such Product for the same number of apheresis services and administration services needed for and performed for Single Treatment (as defined in the Collaborative License Agreement) where such averages are calculated including all apheresis services or infusion services, as applicable, that were performed for any purpose during the applicable period.

1.27 “**Non-listed Facilities**” shall have the meaning set forth in Section 3.9(b)(iii)(3).

1.28 “**Original Supply Agreement**” means the Manufacturing and Supply Agreement by and between the Parties dated July 27, 1999.

1.29 “**PA2024 Price Election**” shall have the meaning set forth in Section 5.1(a)(ii).

1.30 “**Parties’ Agreements**” mean this Manufacturing and Supply Agreement, the Parties’ Amended and Restated Collaborative License Agreement, of even date, the Parties’ Research and License Agreement, dated February 1, 1999, and the Parties’ Joint Commercialization Agreement, dated February 1, 2001 and all amendments thereto, but not the Memorandum.

1.31 “**Patent**” means (i) a valid and enforceable patent, including any extension, registration, confirmation, reissue, re-examination or renewal thereof; and (ii) to the extent valid and enforceable rights are granted by a governmental authority thereunder, a patent application.

1.32 “**Product**” means a Kirin Product or a Dendreon Product.

1.33 “**Purchaser**” shall mean the Party purchasing Components from the other Party to the Agreement, as applicable, in the applicable section.

1.34 “**Reagent**” means, with respect to a particular Licensed Dendreon Product, any proprietary reagent of Dendreon (excluding any reagents contained in a Separation Device) that is required for commercial manufacture and/or use of such Licensed Dendreon Product.

1.35 “**Reasonable Efforts**” shall mean efforts and resources commonly used in the research-based pharmaceutical industry for the research, development and commercialization of a product at a similar stage in its product life taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory structure involved, the profitability of the product and other relevant factors.

1.36 “**Research and License Agreement**” shall mean the Research and License Agreement by and between the Parties dated as of February 1, 1999.

1.37 “**Regulatory Approval**” means any approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other

government entity, necessary for the manufacture, use, storage, import, transport or sale of Products in a regulatory jurisdiction.

1.38 The “**Restated Effective Date**” means the date of this Agreement, set forth in the preamble above.

1.39 “**Scale**” means that the designated drug, antigen (e.g., PA2024), reagent or biologic is manufactured at a specified per batch volume (e.g., 2000L) all in accordance with cGMP such that each batch reliably and reproducibly conforms to the specifications for the designated drug, antigen, reagent or biologic.

1.40 “**Separation Devices**” means any Dendreon device, including all containers and proprietary reagents comprising such device, that is intended for use by Dendreon and its licensees for the isolation and purification of Dendritic Cells for use in human therapy by activation or loading with specific antigen, engineered antigen or antigen gene, and administration into a patient.

1.41 “**Steering Committee**” shall have the meaning set forth in Section 3.1 of the Collaborative License Agreement.

1.42 “**Sublicensee**” shall mean any Third Party expressly licensed by a Party to make and sell one or more Products. A Sublicensee shall not include distributors or sales agents that do no more than purchase and resell finished Products on behalf of a Party.

1.43 “**Supplier**” shall mean the Party supplying Components to the other Party to the Agreement, its Affiliates or Sublicensees, as applicable, in the applicable section.

1.44 “**Supplier Patent**” shall mean any Patent Controlled by the Supplier during the term of the Agreement.

1.45 “**Third Party**” means any entity other than Dendreon or Kirin or an Affiliate of Dendreon or Kirin.

**ARTICLE 2:**  
**SUPPLY FOR CLINICAL DEVELOPMENT**

**2.1 Supply for Clinical Development.**

(a) Subject to the terms of this Agreement and the Collaborative License Agreement, Kirin agrees to purchase from Dendreon, and Dendreon agrees to sell to Kirin, such Separation Devices and Reagents as Kirin requires to conduct clinical development of Kirin Products and/or Licensed Dendreon Products in the Kirin Territory.

(b) Subject to the terms of this Agreement and the Collaborative License Agreement, Kirin agrees to purchase from Dendreon, and Dendreon agrees to sell to Kirin, such quantities of Dendreon Antigen as Kirin requires to conduct clinical development of Licensed Dendreon Products in the Kirin Territory, to the extent such Dendreon Antigen is reasonably available to Dendreon. However, Dendreon's duty to sell to Kirin quantities of Dendreon Antigen PA2024 shall terminate three (3) years after the date Kirin exercises the Kirin PA2024 Option and receives Dendreon PA2024 Manufacturing Technology for the manufacture of PA2024 under Section 2.5 of the Collaborative License Agreement. In the absence of Kirin's exercise of the Kirin PA2024 Option, Dendreon's obligation to furnish Kirin with Dendreon Antigen PA2024 shall continue to be as set forth in this Agreement.

(c) Subject to the terms of this Agreement and the Collaborative License Agreement, Dendreon agrees to purchase from Kirin, and Kirin agrees to sell to Dendreon, such quantities of Kirin Components as Dendreon requires to conduct clinical development of Licensed Kirin products and Dendreon Products in the Dendreon Territory, to the extent such Kirin Components are reasonably available to Kirin.

**2.2 Forecasts.** A reasonable period prior to the first expected order hereunder by the Purchaser of Components (at least six (6) months if possible), Purchaser shall provide the Supplier with a good faith written estimate of its expected requirements, on a per quarter basis, for all such Components for the first two (2) years after such first order. Commencing three (3) months before the first expected order, Purchaser shall provide Supplier with quarterly rolling twelve (12) month forecasts for its expected orders for Components to be ordered during each

quarter during such period, with detail on each specific Component and quantities to be ordered. An updated forecast will be provided to Supplier within the first three (3) Business Days of each subsequent calendar quarter. In each such forecast provided to Supplier as required herein (after the first such rolling forecast), the forecast for the calendar quarter in which such forecast is delivered shall constitute a binding commitment of Purchaser and/or its Affiliates to submit purchase orders for not less than one hundred percent (100%) of the amounts listed in such forecast during such quarter. Further, such binding forecast for such quarter may not deviate by more than twenty-five percent (25%) from the amount forecasted to be ordered during such quarter in the most recent previous forecast provided to Supplier.

**2.3 Order Placement Procedure.** The Purchaser shall place orders for Components to be supplied under the Agreement on Purchaser's standard English-language purchase order form, specifying the quantity of each type of Component ordered and the requested delivery date, which shall not in any event be longer than one hundred and twenty (120) days from the date of such purchase order; provided, however, that if due to complications and lead time for a particular Component (such as antigen) the Supplier of such Component requires a delivery lead time for manufacture of such Component greater than one hundred twenty days (120) from the date of such purchase order, the Parties shall negotiate in good faith a reasonable delivery date for such Component, not to be greater than one hundred and eighty (180) days from the date of the purchase order. Supplier shall not be obligated to deliver Components ordered prior to sixty (60) days after the applicable order is placed; however, Supplier agrees that it will use Reasonable Efforts to meet any earlier delivery date reasonably requested by Purchaser. To the extent any purchase order, invoice or acknowledgment form used by Supplier or Purchaser contains any provisions additional or contrary to the provisions of this Agreement, such additional or contrary provision shall have no force or effect and the terms of this Agreement shall control. In addition, all such orders shall comply with the other requirements of this Article 2. The total amount of Components ordered by Purchaser during a particular calendar quarter shall not in any event be less than one hundred percent (100%) of the amount of each such Component that was forecasted to be ordered for such quarter in the most recent forecast provided to Supplier, as set forth in Section 2.2 above, unless Supplier otherwise agrees in writing. In addition, Supplier shall not be obligated to supply any amounts in such order that are

in excess of one hundred ten percent (110%) of the amount of the particular Component that was forecasted in the most recent binding forecast to be ordered for such quarter; however, Supplier agrees that it will use Reasonable Efforts to supply such additional amounts. The Supplier shall use Reasonable Efforts to deliver the Components ordered in compliance with this Article 2. The Supplier shall immediately notify Purchaser in writing if Supplier determines that Supplier will not be able to supply a material amount of the most recent orders and/or forecasts of orders for any Component. Shipment and delivery of Components ordered hereunder shall be in accordance with Section 2.4.

#### **2.4 Delivery and Risk of Loss.**

(a) Delivery of Dendreon Components ordered hereunder by Kirin shall be by FCA Dendreon's actual manufacturing facility for such Components. "FCA" shall be construed in accordance with INCOTERMS 1990 of the International Chamber of Commerce. At Kirin's request and cost, Dendreon shall arrange shipping to specified Kirin locations. Delivered Dendreon Components shall be appropriately packaged by Dendreon, at Dendreon's expense, for export shipment.

(b) Delivery of Kirin Components (and any Dendreon Components, if applicable) ordered hereunder by Dendreon shall be by FCA Kirin's actual manufacturing facility for such Components. "FCA" shall be construed in accordance with INCOTERMS 1990 of the International Chamber of Commerce. At Dendreon's request and cost, Kirin shall arrange shipping to specified Dendreon locations. Delivered Kirin Components shall be appropriately packaged by Kirin, at Kirin's expense, for export shipment.

**2.5 Acceptance and Rejection.** Purchaser shall have the right to test at its expense, using testing procedures agreed upon by the Parties and set forth in the specifications for the applicable Component, a portion of each shipment of Components to confirm that such shipment meets the applicable specifications. Where it is required by local regulations, further testing on importation in accordance with the applicable specifications shall be carried out by Purchaser. If Purchaser rejects in whole or in part any nonconforming shipment of Components, Purchaser shall provide Supplier written notice of such rejection no later than thirty (30) days after receipt of such shipment of Components. If Purchaser fails to provide Supplier with such notice of

rejection within such thirty (30) day inspection period, Purchaser shall be deemed to have accepted the applicable shipment of Components. If Supplier agrees with Purchaser's determination that a shipment of Components does not comply with applicable specifications, Supplier shall use Reasonable Efforts to replace the nonconforming Components, at no additional cost to Purchaser. If Supplier reasonably disputes Purchaser's conclusion that such Components do not meet the applicable specifications, Supplier shall use Reasonable Efforts to replace such shipment of Components to Purchaser, at Purchaser's expense. If Supplier disagrees with Purchaser's determination that the rejected shipment did not meet the applicable specifications, a sample of the rejected shipment shall be submitted to an independent, qualified Third Party laboratory that is mutually acceptable and selected by the Parties promptly in good faith. Such laboratory shall determine whether the rejected Components meet the applicable specifications, and such laboratory's determination shall be final and determinative for purposes of this Agreement. The Party against whom the laboratory rules shall bear all costs of the laboratory testing. If the laboratory rules that the shipment of Components failed to meet the applicable specifications, then at Purchaser's choice, the price paid by Purchaser for such nonconforming shipment shall be reimbursed to Purchaser (provided Purchaser paid for such shipment) or Components meeting the applicable specifications shall be shipped. If the laboratory rules that the Components do not meet the applicable specifications, and if Supplier is unable to produce conforming Components, any sums actually paid therefore shall be refunded to Purchaser with interest. At such time, the Parties will discuss in good faith potential solutions to the supply problem. If the laboratory rules the rejected shipment of Components met the applicable specifications, then Purchaser shall accept such shipment (including all costs of shipping and insurance). Shipments of Components not meeting the applicable specifications may, at Supplier's option and expense, be returned to Supplier or destroyed by Purchaser. If Supplier has acknowledged in writing that it is unable to produce conforming Components, any sums actually paid therefor will be refunded. The remedy of replacement or refund is available only if such nonconformance was not caused by Purchaser's misuse, unauthorized modifications, neglect, improper testing or improper storage, including without limitation storage at inappropriate temperatures, of such shipment of Components.

**2.6 Manufacturing Modifications.** If the laws of a country require Supplier's established specifications for a particular Component or Components to be modified in order for Purchaser to obtain Regulatory Approval of a Product in such country, Purchaser will submit the matter to the Steering Committee for discussion and proposed resolution. The Parties agree to negotiate in good faith any proposed modifications to the specifications for such Component or Components for such Products proposed by the Steering Committee. Any such resolution of the Steering Committee must be agreed in writing by the Parties.

**2.7 Restrictions on Sale.** Kirin and its Affiliates shall not resell the Separation Devices purchased pursuant to this Article 2 except as part of a Kirin Product or a Licensed Dendreon Product, and shall not use Separation Devices, Reagents or Dendreon Antigen for any purpose other than those purposes permitted in this Agreement, the Collaborative License Agreement or the Research and License Agreement. Dendreon shall retain all rights to manufacture or have manufactured the Separation Devices, Reagents and Dendreon Antigens. Dendreon and its Affiliates shall not use Kirin Antigen for any purpose other than those purposes permitted in this Agreement, the Collaborative License Agreement or the Research and License Agreement.

**2.8 Use of Separation Devices by Kirin Collaborators.** With Dendreon's prior written approval, which may be withheld for any reason, Kirin may provide certain academic or medical doctor collaborators with a limited number of Separation Devices solely for use by such individuals in research and development purposes in the Field; *provided, however,* that before any such delivery Kirin shall require such collaborator: (i) to be appropriately trained in the use of the Separation Devices, (ii) to share the results of any and all research and development performed using the Separation Devices with Kirin and Dendreon; (iii) not to sell, distribute or otherwise provide such Separation Devices to Third Parties; and (iv) unless such antigen is within the public domain, to grant Dendreon an option to license any specific antigen, engineered antigen or antigen gene used or developed in conjunction with the use of the Separation Devices. Except as explicitly provided in this Agreement, Kirin obtains no license or rights to make or to practice any of the Dendreon Technology to make Separation Devices, Reagents or any other devices or products for use in the isolation or purification of Dendritic Cells or any other cells. Notwithstanding anything else in this Agreement, Kirin may use Separation Devices to isolate

Dendritic Cells only as part of preparing a Kirin Product or Licensed Dendreon Product or performing a service comprising a Kirin Product or Licensed Dendreon Product, or with Dendreon's prior written consent, as provided in this Section 2.8.

## ARTICLE 3: COMMERCIAL SUPPLY

**3.1 Commercial Supply.** Subject to the other terms of this Agreement, Dendreon agrees to provide Kirin, its Affiliates and Sublicensees with their commercial requirements of Separation Devices, Reagents and Dendreon Antigens necessary for use in manufacturing or using Kirin Products or Licensed Dendreon Products for which Regulatory Approval has been obtained in the Kirin Territory. In the event Dendreon implements improvements, upgrades or changes to Separation Devices, Reagents and Dendreon Antigens, Kirin, its Affiliates and Sublicensees shall have the right to continue to purchase the unimproved, un-upgraded or unchanged Separation Devices, Reagents and Dendreon Antigens (*i.e.*, the model that Dendreon has been providing as provided in Section 5.1) necessary for use in manufacturing or using Kirin Products or Licensed Dendreon Products for which Regulatory Approval has been obtained in the Kirin Territory. However, Dendreon's duty to sell to Kirin quantities of Dendreon Antigen PA2024 shall terminate three (3) years after the date Kirin exercises the Kirin PA2024 Option and receives Dendreon PA2024 Manufacturing Technology for the manufacture of PA2024 under Section 2.5 of the Collaborative License Agreement. In the absence of Kirin's exercise of the Kirin PA2024 Option, Dendreon's obligation to furnish Kirin with Dendreon Antigen PA2024 shall continue to be as set forth in this Agreement.

**3.2 Preparation.** At such time after the Effective Date that Supplier has prepared the Manufacturing Plan, but no later than one hundred and twenty (120) days before the commercial launch of the first Kirin Product or Dendreon Product, as applicable, Supplier shall provide to Purchaser such Information in Supplier's control relating to lead times Supplier requires to achieve manufacture of Components on a commercial scale hereunder, necessary to determine appropriate procedures and mechanisms for providing to Supplier forecasts of Purchaser's, its Affiliates' and Sublicensees' requirements for Components to be ordered and purchased hereunder, and for ordering such requirements. The Purchaser shall review such Information

promptly after receipt, and appropriate representatives from Purchaser and Supplier shall then meet to determine the appropriate forecasting, ordering and inventory mechanisms that will be used by the Parties for ordering and supplying the commercial requirements of Components hereunder. Such forecasting, ordering and inventory mechanisms shall be consistent with the terms of this Article 3 and shall be set forth in a writing, and upon mutual execution of such writing by the Parties, such mechanisms (the "Supply Procedures") shall become part of this Agreement.

**3.3 Forecasts.** With respect to the forecasting mechanism, such Supply Procedures shall provide: (a) that within an agreed period of time prior to the first expected Regulatory Approval of a Product, Purchaser shall provide a good faith estimate of its expected requirements, on a per quarter basis, for each particular Component which is part of such Product to be ordered, for an agreed period before and an agreed period after the launch of such Product; (b) as of an agreed time before the first expected Regulatory Approval of a particular Product, Purchaser shall provide Supplier a rolling twelve (12) month forecast for Purchaser's expected orders for each particular Component during each month during such twelve (12) month period; (c) Purchaser shall provide Supplier updated forecasts for expected orders of Components at agreed intervals of time; (d) that in each forecast provided, the forecasted orders for an agreed time period for each forecasted Component shall constitute binding orders by Purchaser for such Components, to be placed during such agreed time period; and (e) that forecasted orders for each Component in a particular forecast delivered to Supplier may not deviate by more than twenty-five percent (25%) from the forecast for orders for such Components in the most recent previous forecast submitted to Supplier. The Parties further agree that if a Party determines that the foregoing forecasting mechanisms are inappropriate given the then-existing manufacturing and supply circumstances for any Component, the Parties will discuss and agree in good faith on appropriate written amendments to the forecasting mechanisms for such Component.

**3.4 Order Placement Procedure.** With respect to the ordering mechanism, such Supply Procedures shall provide: (a) that Purchaser shall place orders for Components to be supplied under the Agreement on Purchaser's standard purchase order form, specifying the quantity of each specific Component ordered and the requested delivery date, which shall not in any event be sooner or later than agreed time period(s) from the date of such purchase order; (b)

that to the extent any purchase order, invoice or acknowledgment form used by Purchaser contains any provisions additional or contrary to the provisions of this Agreement, such additional or contrary provision shall have no force or effect and the terms of this Agreement shall control; (c) that Supplier shall not be obligated to supply any amounts of a particular Component in such order more than an agreed percentage of the unit quantity of such Component specified in the binding forecast for the applicable time period; (d) that Purchaser's orders for a Component may not be less than an agreed percentage of the binding forecast for such Component for the applicable time period; and (e) that Supplier will use Reasonable Efforts to provide additional amounts of a particular Component beyond the foregoing limitation on Supplier's obligation to supply, upon Purchaser's reasonable request, but consistent with Supplier's other business obligations.

**3.5 Inventory.** The Supply Procedures shall also establish an inventory mechanism for Components, which shall provide that: (a) within an agreed period of time after the commercial launch of a particular Product, Supplier shall use Reasonable Efforts to maintain an inventory of the Components in such Product at least equal to the written forecast for purchases of such Product to be made during an agreed number of months in the most recent forecast provided to Supplier by Purchaser under the forecasting mechanism of the Supply Procedures; (b) Purchaser shall maintain an inventory of all Components in accordance with Purchaser's normal practices, and shall give Supplier quarterly updates of the extent of such inventory; (c) Supplier's inventory of Components maintained under such inventory mechanism shall only be permitted to fall below the levels established in subsection (a) above in the event that Purchaser submits orders in excess of the forecasted amounts or Supplier experiences manufacturing or supply problems with respect to the Components; and (d) Supplier shall use Reasonable Efforts in accordance with Supplier's normal practices to promptly replenish any inventory of Components that is depleted in satisfying purchases of such Component by Purchaser hereunder.

**3.6 Amendments.** The Parties further agree that if the foregoing forecasting, ordering or inventory mechanisms established in the Supply Procedures are determined by the Parties, in good faith cooperation and giving reasonable consideration to each Party's economic and business needs, to be inappropriate given the experience of the Parties and the then-existing manufacturing and supply circumstances regarding Components hereunder, the Parties will

discuss in good faith appropriate amendments to the applicable mechanisms in the Supply Procedures.

### **3.7 Resolution of Supply Problems.**

(a) If Supplier determines that Supplier will not be able to supply to Purchaser a material amount of the most recent orders and/or binding forecasts of orders for a particular Component submitted by Purchaser in accordance with the applicable Supply Procedures, Supplier shall immediately notify Purchaser in writing of such determination, which notice shall provide Purchaser with the details on the extent of the expected shortfall of supply, the causes of such inability to supply, and Supplier's proposed solution to the problem. Upon such notice of a supply problem, or in any event upon Supplier's failure to satisfy, within the delivery time frame specified by Purchaser consistent with the Supply Procedures, a portion of the Components ordered by Purchaser in compliance with this Agreement, (provided that such supply problem or failure cannot be satisfied or addressed by Purchaser's and Supplier's existing inventories for such Components and will cause an interruption in the supply of such Components by Purchaser or its Affiliates to the commercial market for more than thirty (30) days), Purchaser and Supplier will immediately meet and work together, in good faith, to identify an appropriate resolution to the supply problem. The Parties will discuss all appropriate means of resolving the problem, including without limitation establishing an alternative source of supply for the affected Components, creating a back-up manufacturing facility, or permitting Purchaser to manufacture an agreed amount of Components to cover the shortfall in supply, with Supplier continuing to supply an agreed amount of such Components. Any agreed resolution to the supply problem will be set forth in a writing executed by both Parties.

(b) If the Parties cannot reach agreement on an appropriate resolution to the supply problem within ten (10) days of commencing such discussions under subsection (a) above, senior management representatives of the Parties will immediately meet to discuss in good faith the problem in an effort to reach agreement on such resolution. As part of such discussions, Supplier shall make a firm commitment of the amount of the affected Components that Supplier will be able to supply, on a monthly basis, during the period when such supply problem with respect to such Components is expected to continue. Any agreed resolution by the

Parties to the supply problem will be set forth in a writing executed by both Parties. If, despite good faith efforts, the senior management officials are unable to reach agreement on the resolution of such supply problem within twenty (20) days of their commencing such discussions, then at either Party's immediate written request, the problem will be governed by the terms of Section 11.7 if it affects Components other than Kirin Antigen or Dendreon Antigen, and by the terms of Section 3.7(c) if it affects Kirin Antigen or Dendreon Antigen.

(c) If there is a material supply problem with respect to Kirin Antigen or Dendreon Antigen subject to the provisions of subsections 3.7(a) and (b) above, and (i) the Parties have failed to reach agreement on the resolution of such problem within the time frames set forth above by the end of the twenty (20) day period as provided under subsection (b), or (ii) Supplier has failed to meet to discuss the problems as required above, then at Purchaser's written request provided to Supplier no more than sixty (60) days after the foregoing conditions have been met, Supplier shall grant to Purchaser a co-exclusive license as to Kirin Antigen or Dendreon Antigen, as applicable, (the "Back-Up License"), under the relevant Supplier Patents and Manufacturing Know-how, as necessary to permit Purchaser to make or have made such Kirin Antigen or Dendreon Antigen that is the subject of such supply problem that was not resolved by the Parties, solely for sale in accordance with the terms of this Agreement, the Collaborative License Agreement and the Research and License Agreement, and solely in quantities to meet the amounts of Purchaser's and its Affiliates' and sublicensees' (if any), and Supplier's and its Affiliates' and sublicensees' (if any), if applicable, requirements for such Kirin Antigen or Dendreon Antigen above the amounts of such Kirin Antigen or Dendreon Antigen that Supplier remains able and willing to supply on a timely basis under this Article 3. Purchaser covenants, represents and warrants that Purchaser shall not exercise the Back-Up License unless and until the conditions specified in the first sentence of this Section 3.7(c) have been completely satisfied and shall not use or practice the licensed Supplier Patents and Manufacturing Know-how for any purpose except as expressly permitted in the foregoing. Immediately upon Purchaser's written request hereunder to obtain the Back-Up License, Supplier shall transfer to Purchaser copies of all information, including technical information, that is Controlled by Supplier, relates to the manufacture of the Kirin Antigen or Dendreon Antigen that is the subject of the Back-Up License and is reasonably necessary to enable Purchaser to manufacture such

Kirin Antigen or Dendreon Antigen. Thereafter, but only during the period when Purchaser is permitted hereunder to exercise the Back-Up License, Purchaser shall be permitted access to and a right of reference to any Regulatory Approvals held in Supplier's name for the Kirin Antigen or Dendreon Antigen that is the subject of such Back-Up License. Supplier shall provide Purchaser reasonable assistance, at Purchaser's request and Purchaser's expense, with respect to understanding such manufacturing information and practicing the Back-Up License.

(i) At such time as Supplier is reasonably able to meet all of Purchaser's forecasted orders for Kirin Antigen or Dendreon Antigen, as applicable, the Back-Up License granted under this Section 3.7(c) shall terminate with respect to such Kirin Antigen or Dendreon Antigen, and Purchaser shall immediately cease to exercise and practice the Back-Up License, provided that Purchaser shall retain all rights under this Section 3.7 with respect to any subsequent supply problem as to any Kirin Antigen or Dendreon Antigen, as applicable.

(ii) Purchaser will pay Supplier a royalty of two percent (2%) of the Net Revenue of Kirin Products or Dendreon Products (as applicable) manufactured by or on behalf of Purchaser pursuant to exercise of the Back-Up License and sold by Purchaser or its Affiliate or sublicensee. Nothing in the foregoing shall limit or affect in any way Purchaser's obligations to make the payments set forth in this Agreement to the full extent required on all Components supplied to Purchaser by Supplier.

**3.8 Acceptance and Rejection.** Purchaser shall have the right to test at its expense, using testing procedures agreed upon by the Parties and set forth in the specifications for the applicable Component, a portion of each shipment of Components to confirm that such shipment meets the applicable specifications. Where it is required by local regulations, further testing on importation in accordance with the applicable specifications shall be carried out by Purchaser. If Purchaser rejects in whole or in part any nonconforming shipment of Components, Purchaser shall immediately provide Supplier written notice of such rejection. If Supplier agrees with Purchaser's determination that a shipment of Components does not comply with applicable specifications, Supplier shall use Reasonable Efforts to replace the nonconforming Components, at no additional cost to Purchaser. If Supplier reasonably disputes Purchaser's conclusion that such Components do not meet the applicable specifications, Supplier shall use Reasonable

Efforts to replace such shipment of Components to Purchaser, at Purchaser's expense. If Supplier disagrees with Purchaser's determination that the rejected shipment did not meet the applicable specifications, a sample of the rejected shipment shall be submitted to an independent, qualified Third Party laboratory that is mutually acceptable and selected by the Parties promptly in good faith. Such laboratory shall determine whether the rejected Components (as applicable) meet the applicable specifications, and such laboratory's determination shall be final and determinative for purposes of this Agreement. The Party against whom the laboratory rules shall bear all costs of the laboratory testing. If the laboratory rules that the shipment of Components failed to meet the applicable specifications, at Purchaser's choice, the price paid by Purchaser for such nonconforming shipment shall be reimbursed to Purchaser (provided Purchaser paid for such shipment) or Components meeting the applicable specifications shall be shipped to Purchaser by Supplier. If the laboratory rules the rejected shipment of Components met the applicable specifications, then Purchaser shall accept such shipment (including all costs of shipping and insurance). Shipments of Components not meeting the applicable specifications may, at Supplier's option and expense, be returned to Supplier or destroyed by Purchaser. If Supplier has acknowledged in writing that it is unable to produce conforming Components, any sums actually paid therefor will be refunded with interest, and the supply problem will be resolved in accordance with Section 3.7. The remedy of replacement or refund is available only if such nonconformance was not caused by Purchaser's misuse, unauthorized modifications, neglect, improper testing or improper storage, including without limitation storage at inappropriate temperatures, of such shipment of Components.

### **3.9 Kirin Manufacture of Dendreon Components.**

(a) Kirin agrees to provide Dendreon, its Affiliates and Sublicensees with their commercial requirements of Kirin Components necessary for Licensed Kirin Products for which Regulatory Approval has been obtained, pursuant to the terms of this Article 3. In addition, if so requested by Dendreon, Kirin may negotiate with Dendreon for the manufacture and supply by Kirin to Dendreon of certain Separation Devices, Reagents and/or Dendreon Antigens at a transfer price in an amount in U.S. dollars equal to Kirin's Fully-Burdened Manufacturing Costs for such Separation Devices, Reagents and/or Dendreon Antigens plus a handling fee of twenty percent (20%), with any manufacture and supply to be governed by the

terms of this Agreement and any additional terms negotiated by the Parties. The Parties also agree to amend the terms of the Agreement to reflect such agreed terms for the manufacture and supply by Kirin of Separation Devices, Reagents and/or Dendreon Antigens, if any.

(b) Subject to the terms of its license to manufacture PA2024 (under the Kirin PA2024 Option set forth in Section 2.5 of the Collaborative License Agreement), Kirin shall manufacture PA2024 on the following terms and conditions:

(i) Neither Kirin's manufacture nor use of PA2024 shall interfere with Kirin's use of Reasonable Efforts to develop, obtain Regulatory Approval in the Kirin Territory for, and market and sell in the Kirin Territory, APC 8015.

(ii) The manufacturing shall be conducted in accordance with all applicable laws, regulations and Regulatory Approvals.

(iii) Kirin may manufacture Dendreon Antigen PA2024 at manufacturing facilities anywhere in the world on the following terms and conditions:

(1) Kirin shall have no right to execute an agreement to engage or hire any Third-Party manufacturing facility until after it exercises the Kirin PA2024 Option. Kirin shall promptly notify Dendreon (within thirty (30) days) after it engages or hires any Third-Party manufacturing facility. Kirin may submit a request for a Third Party manufacturing facility under this Section 3.9(b)(iii) without exercising the Kirin PA2024 Option. Kirin's request for Third-Party manufacturing facilities under this Section 3.9(b)(iii) shall not be treated as an exercise of the Kirin PA2024 Option (which exercise shall require a separate notice).

(2) Prior to commencing manufacturing of PA2024 (from time to time) at any Third-Party manufacturing facility outside the Kirin Territory, Kirin shall notify and request Dendreon's approval of Kirin's good faith plan to commence manufacturing operations at a specific manufacturing facility (which notice from Kirin shall specify the address of the Third-Party manufacturing facility, the status of the tentative facility's Regulatory Approval, the tentative facility's estimated, available manufacturing capacity, the owner of the tentative facility and the owner's Affiliates to the extent information on the owner's Affiliates is reasonably

available). Dendreon shall have the right to disapprove Kirin's plan to use the Third-Party manufacturing facility only if Dendreon has actual manufacturing plans for the facility at the time of Kirin's request. Dendreon shall give notice of its approval or disapproval within fifteen (15) days after Kirin gives its notice of intended use. If Dendreon approves Kirin's plan or fails to give timely disapproval, then Kirin shall have the right to commence manufacturing operations of PA2024 at the facility within the next five hundred forty (540) days. If the five hundred forty (540) days expire without Kirin commencing manufacturing operations at the facility, then Dendreon's approval shall be deemed to lapse and Kirin shall be required to again request Dendreon's approval (under the first sentence of this Section 3.9(b)(iii)(2)) before commencing manufacturing operations. If Dendreon gives notice of disapproval of the manufacturing facility, then Kirin shall have no right to commence manufacturing at (or otherwise engage or hire) the facility for the manufacture of PA2024. Kirin shall have no right to engage or hire more than one (1) Third-Party manufacturing facility at a time under this Section 3.9(b)(iii)(2) without requesting Dendreon's approval for each such facility (under the first sentence of this Section 3.9(b)(iii)(2)). As used in this Agreement, "actual manufacturing plans" mean that a written proposal, letter of intent or purchase order has been delivered to the Third-Party manufacturing facility about engaging or hiring the facility, but not necessarily the achievement of a manufacturing agreement or option with the Third-Party manufacturing facility.

(3) If Dendreon gives notice of disapproval of Kirin's intended use of a specific Third-Party manufacturing facility under Section 3.9(b)(iii)(2), then the notice of disapproval shall be accompanied by Dendreon's list of Third-Party manufacturing facilities for which Dendreon has actual manufacturing plans; and the list shall be deemed to include the Third-Party manufacturing facilities for which Dendreon had disapproved Kirin's manufacturing plans under Section 3.9(b)(iii)(2). Kirin shall have no right to commence manufacturing of PA2024 at (or otherwise engage or hire) the listed facilities. If Dendreon lists no Third-Party manufacturing facilities or fails to deliver its list with the notice of disapproval, then all Third-Party manufacturing facilities (except the Third-Party manufacturing facilities for which Dendreon had disapproved Kirin's manufacturing plans under Section 3.9(b)(iii)(2)) shall be deemed to be non-listed (the "Non-listed Facilities"). After Dendreon delivers its list or fails to

deliver its list in a timely manner, Kirin shall then have the right to commence manufacturing of PA2024 at up to two (2) Non-listed Facilities within a period starting on the date of Dendreon's notice of its list or, if no list is delivered, the due date for Dendreon's list and ending on the earlier of (a) five hundred forty (540) days after the start date or (b) upon Kirin's engagement or hire of two (2) Non-listed Facilities (the "Kirin Hiring Period"). After the Kirin Hiring Period expires, if Kirin then wishes to engage or hire any additional Third-Party manufacturing facilities, Kirin shall be required to request Dendreon's approval of a specific Third-Party manufacturing facility (under the first sentence of Section 3.9(b)(iii)(2)).

(4) Prior to commencing manufacturing of PA2024 (from time to time) at any Non-listed facility during the Kirin Hiring Period, Dendreon shall notify and request Kirin's approval of Dendreon's good faith plan to commence manufacturing operations at a specific manufacturing facility (which notice from Dendreon shall specify the address of the Third-Party manufacturing facility, the status of the tentative facility's Regulatory Approval, the tentative facility's estimated, available manufacturing capacity, the owner of the tentative facility and the owner's Affiliates to the extent information on the owner's Affiliates is reasonably available). During the Kirin Hiring Period, Dendreon shall have the right to commence manufacturing of PA2024 at up to two (2) Non-listed Facilities. Dendreon shall not engage or hire any Non-listed Facility during the Kirin Hiring Period without Kirin's approval, which approval may be withheld for up to two (2) Non-listed Facilities and which approval may be withheld based solely upon Kirin's actual manufacturing plans for the facility at the time of Dendreon's request. Kirin shall give notice of its approval or disapproval within fifteen (15) days after Dendreon gives its notice of intended use. If Kirin approves Dendreon's plan or fails to give timely disapproval, then Dendreon shall have the right to commence manufacturing operations of PA2024 at the facility at any time thereafter. If Dendreon commences manufacturing operations at the facility, the facility shall then be treated as appearing on Dendreon's list (as defined in Section 3.9(b)(iii)(3)). If Kirin disapproves Dendreon's request to engage or hire a Non-listed Facility, then Dendreon shall have no right to commence manufacturing (or otherwise engage or hire) the Non-listed Facility for the manufacture of PA2024 during the Kirin Hiring Period.

(5) Dendreon may not restrict Kirin's right to select Third-Party manufacturing facilities within the Kirin Territory and may not restrict Kirin's right to manufacture PA2024 at any manufacturing facility anywhere in the world that is wholly owned by Kirin or by one of its Affiliates. Outside the Kirin Hiring Period, Dendreon shall have the right to hire or engage any Third-Party manufacturing facility for PA2024 without Kirin's approval. Upon the request of any Party after the Kirin PA2024 Option is exercised, the Parties shall confer and exchange information about their manufacturing plans for PA2024.

## **ARTICLE 4:** **REGULATORY REQUIREMENTS**

**4.1 Manufacturing Facilities, Equipment and Licenses.** Supplier shall, at Supplier's expense, acquire or cause to be acquired all equipment and licenses, including, without limitation, all necessary plant equipment and facilities licenses, necessary to enable the manufacture and testing of the Components as required hereunder. Supplier shall obtain and maintain all necessary Regulatory Approvals. Purchaser, its Affiliates and Sublicensees shall obtain any required importation licenses or approvals for importation of Dendreon Products and Kirin Products, and the Components necessary for such Kirin Products and Dendreon Products, as applicable for sale in any given country. Supplier shall cooperate reasonably with Purchaser, at Purchaser's reasonable request and expense, to obtain such licenses or approvals.

**4.2 Manufacturing Regulatory Matters.**

(a) Supplier will be responsible for any reporting of matters regarding the manufacture of Components, as applicable, to the FDA and other relevant regulatory authorities, in accordance with pertinent laws and regulations. Supplier shall notify Purchaser of any such matter if significant or serious and promptly furnish complete copies of such reports to Purchaser in the English language. Supplier also shall advise Purchaser of any occurrence or information which arises out of Supplier's manufacturing activities which has adverse regulatory compliance and/or reporting consequences concerning a Component.

(b) Supplier shall be responsible for handling and responding to any appropriate governmental agency inspections with respect to manufacturing of Components

during the term of this Agreement. Supplier shall provide to Purchaser any information requested by any governmental agency in connection with any governmental inspection related to Components. Supplier shall use reasonable efforts to promptly advise Purchaser of any requests by any governmental agency for such inspections with respect to manufacturing of Components.

(c) Any changes by Supplier to the manufacturing process for Components that may require approval by the FDA or other authorities or amendment of existing Regulatory Approvals shall require the prior written approval of Purchaser, not to be unreasonably withheld or delayed.

(d) Supplier certifies it did not and will not use in any capacity the services of any person, including any firm or individual, debarred or subject to debarment under the Generic Drug Enforcement Act of 1992, amending the Food Drug and Cosmetic Act at 21 USC 335a. Supplier agrees to notify Purchaser immediately in the event any person providing services to Supplier under the scope of the work of this Agreement is debarred or becomes subject to debarment.

(e) For the limited purpose of permitting a quality and compliance audit, Supplier shall grant to authorized representatives of Purchaser upon reasonable notice and not more than once per year, unless a substantial and reasonable need for an additional audit can be shown, access to areas of Supplier's plants and each of Supplier's Third Party supply contractor's plants, and to those technical records made by Supplier that only relate solely to Quality Assurance testing and regulatory compliance monitoring for manufacturing of Components, at such times as Components are being manufactured, solely for the purpose of Purchaser determining that such manufacture is in compliance with regulatory requirements. Purchaser shall provide Supplier at least thirty (30) Business Days notice in writing of its desire to have such access. Supplier shall promptly respond to Purchaser's request and the Parties shall agree on the time of and procedures for the audit. All such inspections shall be subject to confidentiality obligations.

**4.3 Product Recall Procedures.** The Parties shall immediately inform each other in writing of all Information relating to: (a) any incident relating to a Product and/or any Product or

Component that is the subject of recall, market withdrawal or correction; or (b) any Components that may require, whether based on manufacturing defect, tampering, or otherwise, a recall, field alert, product withdrawal or field correction arising from any defect in any such Component provided under this Agreement. The Parties then shall meet and discuss the situation in good faith to determine if a recall, field alert, product withdrawal, or field correction is necessary. In the event that either Purchaser or Supplier decides that a recall, field alert, product withdrawal, or field correction is necessary due to any defect or other problem in any Component, the Parties shall cooperate and use Reasonable Efforts in effecting any such required recall, market withdrawal or correction. Payment of costs and expenses associated with recalls, market withdrawals, market corrections and the costs associated with replacement of the recalled or withdrawn Products or Components shall be borne by the Party whose negligent or defective manufacturing, processing, testing, packing or storage necessitated such recall, market withdrawal or market correction.

**4.4 Documentation.** Supplier shall keep complete, accurate and authentic accounts, notes, data and records of the work performed under this Agreement. Each Party shall maintain complete and adequate records pertaining to the methods and facilities used by it for the manufacture, processing, testing, packing, labeling, holding and distribution of Components in accordance with the applicable regulations in the United States and other countries so that the Components may be used in Dendreon Products and Kirin Products to be used in human therapies.

## **ARTICLE 5:** **FINANCIAL OBLIGATIONS**

### **5.1 Purchase Prices.**

#### **(a) Kirin's Purchase of Particular Dendreon Components.**

**(i)** Per Kirin's purchase of particular Dendreon Components hereunder (except for the purchase of Dendreon Antigen PA2024, the purchase of which is addressed in Section 5.1(a)(ii)), Kirin shall pay Dendreon for the purchase of such Dendreon Components a transfer price in an amount in U.S. Dollars equal to Dendreon's Fully-Burdened

Manufacturing Costs of such Dendreon Components plus a handling fee of twenty percent (20%); provided, however, that for Dendreon Components that are purchased by Kirin for use in a Dendreon Product for which the costs of manufacturing development (including process development) was supported by Kirin pursuant to Section 5.3, Kirin shall pay Dendreon a transfer price in an amount in U.S. Dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of such Dendreon Components for such Dendreon Product plus a handling fee of ten percent (10%). For its purchase of Dendreon Separation Devices, Kirin shall pay Dendreon a transfer price in an amount in U.S. dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of the Separation Devices, plus a handling fee of ten percent (10%). (The Parties acknowledge and agree that Kirin supported the costs of manufacturing development of the Separation Devices so that Kirin is entitled to the purchase price set forth in the preceding sentence.) Kirin shall pay Dendreon fifty percent (50%) of the transfer price for a particular order of Dendreon Components within thirty (30) days of placing its order for such Dendreon Components, and fifty percent (50%) of such transfer price within thirty (30) days of delivery of such Dendreon Components, pursuant to Section 2.4.

(ii) Per Kirin's purchase of Dendreon Antigen PA2024 (which is a Dendreon Component), Kirin shall pay Dendreon the purchase price calculated as follows: for PA2024 manufactured up to and at the 2000L Scale, Kirin shall pay Dendreon a transfer price in U.S. dollars in the amount of Dendreon's Fully-Burdened Manufacturing Costs of PA2024 at the time of its manufacture, plus a handling fee of ten percent (10%). Kirin's transfer price for PA2024 shall equal (in U.S. dollars) the Fully-Burdened Manufacturing Costs of PA2024 last manufactured at the 2000L Scale plus a handling fee of ten percent (10%), even if Dendreon scales up the manufacture of PA2024 to greater than 2000L Scale from time to time. In calculating the transfer price of PA2024 above, all costs shall be excluded for scaling up the manufacture of PA2024 to the 2000L Scale. However, in the event from time to time Dendreon scales up the manufacture of PA2024 to greater than 2000L Scale, Kirin may elect in writing (the "PA2024 Price Election") to purchase PA2024 at a transfer price in U.S. Dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of PA2024 at the time of manufacture at such greater Scale, plus a handling fee of ten percent (10%). Kirin's PA2024 Price Election shall apply to all of Kirin's purchase orders for PA2024 placed from the date the election is made until

Kirin gives notice to Dendreon of a new PA2024 Price Election, whereupon, Kirin shall become obligated to pay a transfer price in U.S. Dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of PA2024 at the time of manufacture at such greater Scale, plus a handling fee of ten percent (10%). Prior to each PA2024 Price Election, Kirin may notify Dendreon in writing of Kirin's good faith tentative intention to make the election, and request a statement from Dendreon of the actual scale-up costs to Dendreon of the scale-up to that manufacturing level. Dendreon shall furnish Kirin with a statement of such scale-up costs no later than thirty (30) days after Kirin requests such statement. Dendreon shall furnish Kirin, at Kirin's request, periodic progress reports on such scale-up costs and efforts. At the time Kirin makes a PA2024 Price Election, Kirin shall become obligated to reimburse to Dendreon as part of the transfer price: (a) ten percent (10%) of the documented cost (in U.S. dollars) to Dendreon of the scale-up to which the PA2024 Price Election and purchase relates and (b) ten percent (10%) of the documented cost (in U.S. dollars) to Dendreon of any lesser scale-up costs not previously reimbursed by Kirin to Dendreon. The full reimbursable amount under the preceding sentence shall be paid as part of the transfer price of the first order placed by Kirin under the PA2024 Price Election. Kirin shall pay Dendreon fifty percent (50%) of the transfer price for a particular order of PA2024 within thirty (30) days of placing its order for PA2024, and fifty percent (50%) of such transfer price within thirty (30) days of delivery of the ordered PA2024, pursuant to Section 2.4.

**(b) Dendreon's Purchase of Particular Kirin Components.** Per Dendreon's purchase of particular Kirin Components, Dendreon shall pay Kirin for the purchase of such Kirin Components a transfer price in an amount in U.S. Dollars equal to Kirin's Fully-Burdened Manufacturing Costs of such Kirin Components plus a handling fee of twenty percent (20%). Dendreon shall pay Kirin fifty percent (50%) of the transfer price for a particular order of Kirin Components within thirty (30) days of placing its order for such Kirin Components, and fifty percent (50%) of such transfer price within thirty (30) days of delivery of such Kirin Components, pursuant to Section 2.4.

## 5.2 Audit.

(a) Upon the written request of a Party (the "Auditing Party"), and not more than once in each calendar year, the other Party (the "Audited Party") shall permit an independent certified public accounting firm of nationally recognized standing selected by the Auditing Party, and reasonably acceptable to the Audited Party, at the Auditing Party's expense, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of the Audited Party as may be reasonably necessary to verify the accuracy of (1) the reports of the Audited Party's Fully-Burdened Manufacturing Costs for Components hereunder or (2) Dendreon's claim for reimbursement of scale-up costs under Section 5.1(a)(ii). However, the Audited Party shall only be obligated to maintain and produce records for any calendar year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm shall disclose to the Auditing Party and the Audited Party only whether such reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Auditing Party.

(b) If such accounting firm concludes that the Audited Party overstated its Fully-Burdened Manufacturing Costs for a particular Component or Components during such period, the Audited Party shall reimburse the Auditing Party the difference between what the Auditing Party paid and what was actually owed, with interest from the date originally due at the prime rate, as published in The Wall Street Journal (Eastern U.S. Edition) on the last business day preceding such date, within thirty (30) days after the date the Auditing Party delivers to the Audited Party such accounting firm's written report. If the amount of the difference is greater than five percent (5%) of the total amount owed, then the Audited Party shall in addition reimburse the Auditing Party for all costs related to such audit.

(c) The Auditing Party shall treat all information subject to review under this Section 5.2 in accordance with the confidentiality provisions of Article 6 of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the Audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

(d) If the Audited Party in good faith disputes the conclusion of the accounting firm under subsection (b) above that the Audited Party overstated its Fully-Burdened Manufacturing Costs for a particular Component or Components, or any specific aspect of the conclusion, then the Audited Party shall inform the Auditing Party by written notice within thirty (30) days of receiving a copy of the audit containing such conclusion, specifying in detail the reasons for the Audited Party's disputing such conclusion. The Parties shall promptly thereafter meet and negotiate in good faith a resolution to such dispute. In the event that the Parties are unable to resolve such dispute within sixty (60) days after such Audited Party notice, the matter shall be resolved in a manner consistent with the procedures set forth in Section 11.7.

### **5.3      Financing the Development of Dendreon Products.**

(a) As set forth below, Kirin shall have the option, but not the obligation, to provide financial support for the development of Dendreon Products which Dendreon desires Kirin to financially support and which are to be supplied to Kirin hereunder. To exercise its option to support those certain Dendreon Products, Kirin shall notify Dendreon in writing, within thirty (30) days of Kirin's receipt of written notice from Dendreon that Dendreon is developing such a Dendreon Product, that Kirin agrees to pay Dendreon for all of its scale-up and other development costs related to the development of the Dendreon Components for such Dendreon Product up to a total of one million U.S. dollars (\$1,000,000) for such Dendreon Product. All payments due to Dendreon pursuant to this Section 5.3 shall be made by Kirin within thirty (30) days of receipt of Dendreon's invoice therefor. The foregoing option shall be exercised, if at all, on a product-by-product basis as to each Dendreon Product for which Dendreon provides Kirin the applicable notice.

(b) The Parties acknowledge that Kirin has properly exercised its option to provide financial support for Licensed Dendreon Products APC 8015 and APC 8020 within the meaning of Section 5.3(a) of the Agreement and that Kirin has provided its full share of such financial support for purposes of fixing the transfer price of the Separation Devices and PA2024.

## ARTICLE 6: CONFIDENTIALITY

**6.1 Confidentiality; Exceptions.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for ten (10) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose to a Third Party or use for any purpose other than as provided for in this Agreement any Information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "Confidential Information"), except to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

- (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or
- (d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

**6.2 Authorized Disclosure.** Each Party may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement

and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed.

**6.3 Survival.** This Article 6 shall survive the termination or expiration of this Agreement for a period of ten (10) years.

## **ARTICLE 7: INTELLECTUAL PROPERTY**

Unless specifically and expressly granted herein, no licenses or rights under either Party's intellectual property rights are implied or granted in this Agreement. Each Party shall retain full ownership of all its inventions and intellectual property. The prosecution of any patents, patent applications and any and all other intellectual property rights associated with the manufacture and supply of Components shall be governed by the terms of the Collaborative License Agreement.

## **ARTICLE 8: REPRESENTATIONS AND WARRANTIES**

**8.1 General.** Each of the Parties hereby represents and warrants: (a) the Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms; (b) the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound; and (c) the Agreement does not violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

### **8.2 Component Warranty.**

(a) Dendreon warrants to Kirin, for a period of twelve (12) months from delivery for Separation Devices and Reagent, a period of nine (9) months from delivery for recombinant antigen PA 2024 and a period of six (6) months from delivery for Dendreon Antigen other than recombinant antigen PA 2024, that the Separation Devices, Reagent and Dendreon Antigen, as applicable, supplied by Dendreon to Kirin shall: (i) be manufactured in accordance with current Good Manufacturing Practices (for medical devices and drugs as

promulgated and amended by the FDA); and (ii) conform with applicable Dendreon specifications at the time of delivery by Dendreon. The preceding warranty specifically excludes, and Dendreon shall not be liable for, any action or omission by Kirin or any other entity, specifically including any failure to store or transport Dendreon Components in accordance with applicable specifications, which results in the damage or destruction of Dendreon Components after Dendreon has delivered the Dendreon Components to Kirin pursuant to Section 2.4. Kirin's sole remedy for breach of the foregoing warranty as to a particular Dendreon Component shall be repair, replacement or refund of the purchase price paid by Kirin, at Dendreon's sole option.

(b) Kirin warrants to Dendreon, for a period of twelve (12) months from delivery, pursuant to Section 2.4, for any Kirin Components other than Kirin Antigen, and a period of six (6) months from delivery for Kirin Antigen, that the Kirin Components supplied by Kirin to Dendreon shall: (i) be manufactured in accordance with current Good Manufacturing Practices (for medical devices and drugs as promulgated and amended by the FDA); and (ii) conform with applicable Kirin specifications at the time of delivery by Kirin. The preceding warranty specifically excludes, and Kirin shall not be liable for, any action or omission by Dendreon or any other entity, specifically including any failure to store or transport Kirin Components in accordance with applicable specifications, which results in the damage or destruction of Kirin Components after Kirin has delivered the Kirin Components to Dendreon pursuant to Section 2.4. Dendreon's sole remedy for breach of the foregoing warranty as to a particular Kirin Component shall be repair, replacement or refund of the purchase price paid by Dendreon, at Kirin's sole option.

**8.3 Warranty Disclaimer.** THE EXPRESS WARRANTIES IN THIS ARTICLE 8 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

## **ARTICLE 9:** **TERM AND TERMINATION**

**9.1 Term.** This Agreement shall commence on the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the expiration or termination of the Collaborative License Agreement, unless extended upon the mutual, written agreement of the Parties.

**9.2 Termination.**

(a) If either Party materially breaches this Agreement at any time, which breach is not cured within thirty (30) days of written notice thereof if such breach is caused by the failure of a Party to meet its financial obligations under this Agreement, or within ninety (90) days of written notice thereof for any other material breach of this Agreement, from the non-breaching Party specifying in detail the nature of the breach, the non-breaching Party shall have the right to terminate the Agreement.

(b) Either Party may terminate this Agreement, effective immediately upon the giving of written notice, if the other Party shall file a petition for bankruptcy, or shall be adjudicated a bankrupt or insolvent, or shall take advantage of the insolvency laws of any state of the United States or of any country, or shall make an assignment for the benefit of creditors, or shall have a receiver appointed, whether by private instrument or by court officer, for its property which is not dismissed within sixty (60) days, or become subject to an involuntary petition for bankruptcy which is not dismissed within sixty (60) days.

**9.3 Surviving Obligations.** Termination or expiration of this Agreement shall not (a) affect any other rights of either Party which may have accrued up to the date of such termination or expiration, or (b) relieve Purchaser of its obligation to pay to Supplier sums due in respect of Components delivered and accepted prior to termination or expiration of this Agreement. The provisions of Articles 6, 7 and 10, and Sections 3.9(b), 4.4, 5.2 and 11.6 of this Agreement shall survive termination or expiration of this Agreement.

**9.4 Termination Without Cause.** This Agreement may be terminated at any time upon mutual, written agreement of the Parties.

## **ARTICLE 10:** **INDEMNIFICATION**

### **10.1 Indemnification by Dendreon.**

**(a)** Subject to compliance with Section 10.3, Dendreon agrees to indemnify, defend and hold harmless Kirin, its Affiliates, and their respective officers, directors, shareholders, representatives, agents and employees (the "Kirin Indemnitees"), from and against any and all losses, liabilities, damages, costs, fees and expenses, including reasonable legal costs and attorneys' fees ("Losses") resulting from a Third Party claim, suit or action based upon: (i) death or injury to any person or damage to any property to the extent caused by the defective or negligent manufacture of a Component or Product manufactured by or on behalf of Dendreon and sold to Kirin and its Affiliates hereunder (the "Defective Manufacturing Claim"); (ii) death or injury to any person or damage to any property to the extent caused by the defective or negligent marketing or promotion of a Product by Dendreon or its Affiliates hereunder (a "Defective Marketing Claim"); (iii) harm or damage attributable to or caused by the acts or omissions of Dendreon or its Affiliates or their respective officers, directors, representatives, agents or employees; or (iv) breach of any representation or warranty of Dendreon set forth in Article 8.

**(b)** Dendreon shall have no obligation under this Section 10.1 with respect to any Losses resulting from: (i) the negligent or intentionally wrongful act or omission of Kirin, its Affiliates or their respective officers, directors, representatives, agents or employees; (ii) the improper storage, transportation, marketing, training, or handling of a Component or Product by any person or entity other than Dendreon, its Affiliates or their respective officers, directors, representatives, agents or employees; (iii) the improper use of a Component or Product by any person or entity other than Dendreon, its Affiliates or their respective officers, directors, agents or employees; or (iv) any claims based upon death or injury to any person or damage to any property caused by a Component or Product that is attributable to or caused by acts or omissions of Kirin or its sublicensees or their respective Affiliates or their respective officers, directors,

representatives, agents or employees. With respect to any Third Party claim, suit or action based upon death or injury to any person or damage to any property based on use of a Product, Dendreon agrees to provide Kirin, at Kirin's expense, with reasonable assistance in Kirin's defense of such claim, suit or action.

## **10.2 Indemnification by Kirin.**

(a) Subject to compliance with Section 10.3, Kirin agrees to indemnify and defend Dendreon, its Affiliates, and their respective officers, directors, shareholders, representatives, agents and employees (the "Dendreon Indemnitees"), from and against any and all Losses (as defined in Section 10.1) resulting from a Third Party claim, suit or action based upon: (i) a Defective Manufacturing Claim (as defined in Section 10.1); (ii) a Defective Marketing Claim (as defined in Section 10.1); (iii) harm or damage attributable to or caused by the acts or omissions of Kirin or its Affiliates or their respective officers, directors, representatives, agents or employees; or (iv) breach of any representation or warranty of Kirin in Article 8.

(b) Kirin shall have no obligation under this Section 10.2 with respect to any Losses resulting from: (i) the negligent or intentionally wrongful act or omission of Dendreon, its Affiliates or their respective officers, directors, representatives, agents or employees; (ii) the improper storage, transportation, marketing, training, or handling of a Component or Product by entities or persons other than Kirin or its sublicensees or their respective Affiliates, or their respective officers, directors, representatives, agents or employees; (iii) the improper use of a Product or Component, unless caused by Kirin or its sublicensees or their respective Affiliates, or their respective officers, directors, representatives, agents or employees; or (iv) any claims based upon death or injury to any person or damage to any property caused by a Component or Product that is attributable to or caused by acts or omissions of Dendreon or its sublicensees or their respective Affiliates or their respective officers, directors, representatives, agents or employees. With respect to any Third Party claim, suit or action based upon death or injury to any person or damage to any property based on use of a Product, Kirin agrees to provide Dendreon, at Dendreon's expense, with reasonable assistance in Dendreon's defense of such claim, suit or action.

**10.3 Indemnity Procedure.** In the event that a Party is seeking indemnification under Section 10.1 or 10.2, it shall inform the other Party (the “Indemnifying Party”) of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and, at the Indemnifying Party’s expense, shall cooperate as reasonably requested in the defense of the claim. The Indemnified Party shall have the right to retain its own counsel, subject to the approval of any such outside counsel by the Indemnifying Party, with the fees and expenses to be paid by the Indemnifying Party if representation of such Party by the counsel retained by Indemnifying Party would be inappropriate due to actual or potential differing interests between such indemnitee and any other Party represented by such counsel in such proceedings. The Indemnifying Party may not settle such action or claim, or otherwise consent to an adverse judgment in such action or claim, without the express written consent of the Indemnified Party if such settlement or adverse judgment diminishes the rights or interests of the Indemnified Party.

## **ARTICLE 11:** **MISCELLANEOUS**

**11.1 Assignment.** Neither Party shall assign any of its rights and obligations hereunder except (i) as incident to the merger, consolidation, reorganization or acquisition of stock affecting actual voting control or of substantially all of the assets of the assigning Party; or (ii) to an Affiliate; provided, however, that in no event shall either Party’s rights and obligations hereunder be assigned without prior written notice to the other Party. In any case, neither Party may make an assignment of its assets which renders it unable to perform its material obligations hereunder. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns.

**11.2 Retained Rights.** Nothing in this Agreement shall limit in any respect the right of either Party to conduct research and development with respect to, and market products outside of, the Field using such Party’s Technology, but no license to use the other Party’s technology to do so is granted herein expressly or by implication.

**11.3 Force Majeure.** Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, in no event shall a Party be required to settle any labor dispute or disturbance.

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

**11.5 No Trademark Rights.** Except as otherwise provided in the Collaborative License Agreement, no right, express or implied, is granted by the Agreement to use in any manner the name "Dendreon" or "Kirin" or any other trade name or trademark of the other Party in connection with the performance of the Agreement.

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

If to Dendreon, addressed to:

Dendreon Corporation  
3005 1<sup>st</sup> Avenue  
Seattle, WA 98121-1010

Attention: General Counsel  
Telephone: (206) 256-4545  
Facsimile: (206) 256-0571

With copy to:

McNaul Ebel Nawrot Helgren & Vance P.L.L.C.  
One Union Square  
600 University Street, Suite 2700  
Seattle, WA 98101-3143

Attention: Peter M. Vial, Esq.  
Telephone: (206) 467-1816  
Facsimile: (206) 624-5128

If to Kirin, addressed to:

Kirin Brewery Co., Ltd.  
26-1, Jingumae 6-chome  
Shibuya-ku  
Tokyo 150-8011, Japan

Attention: General Manager  
Planning Department  
Pharmaceutical Division  
Telephone: (03) 5485-6292  
Facsimile: (03) 5485-6316

With a copy to:

Pennie & Edmonds LLP  
1155 Avenue of the Americas  
New York, NY 10036

Attention: Rory J. Radding, Esq.  
Telephone: (212) 790-9090  
Facsimile: (212) 869-9741

**11.7 Dispute Resolution.** If any dispute, controversy or claim arises out of or in connection with this Agreement, the Parties shall use reasonable efforts to settle it by friendly negotiation within sixty (60) days of notice from one Party to the other of such dispute, controversy or claim, before pursuing any other remedies available to them. If either Party fails or refuses to participate in such negotiations, or if, in any event, the dispute, controversy or claim is not resolved to the satisfaction of both Parties within the sixty (60) day period, any such dispute, controversy or claim shall be settled by arbitration. Any such arbitration shall be conducted in accordance with the Japan-American Trade Arbitration Agreement of September 16, 1952. The Parties agree that any such arbitration shall be conducted in the English language in a location within the United States selected by the Party that did not initiate such arbitration,

and the Agreement shall be governed by and construed in accordance with the laws of the State of California and the United States of America. The arbitrators shall include one independent, unaffiliated nominee selected by each Party and a third neutral arbitrator selected by such nominees. The Parties agree that any arbitration panel shall include members knowledgeable as to the evaluation of biopharmaceutical technology. Judgment upon the award rendered may be entered in the highest state or federal court or forum, state or federal, having jurisdiction; *provided, however,* that the provisions of this Section 11.7 shall not apply to any dispute or controversy as to which any treaty or law prohibits such arbitration. The prevailing Party shall be entitled to reasonable attorney's fees and costs to be fixed by the arbitrators.

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

**11.9 Severability.** If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law.

**11.10 Ambiguities.** Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**11.11 Entire Agreement.** This Agreement and any agreements referenced herein set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with regard to the subject matter discussed herein and supersedes and terminates all prior agreements and understanding between the Parties with regard to the subject matter discussed herein. Specifically, this Agreement supercedes and terminates the Original Supply Agreement and the Memorandum. There are no covenants, promises, agreements, warranties, representations conditions or understandings, either oral or

written, between the Parties with regard to the subject matter discussed herein other than as set forth in this Manufacturing and Supply Agreement or any agreements referenced herein. For clarity, a redlined version of this Agreement, showing the changes made to the Original Supply Agreement, is attached hereto as Exhibit A. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

**11.12 Headings.** The Section and Paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the Section or Paragraphs to which they apply.

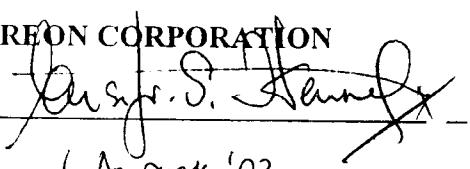
**11.13 Undefined Terms.** Terms that are capitalized but undefined in this Manufacturing and Supply Agreement shall be defined as set forth in any other of the Parties' Agreements (and in amendments to the foregoing agreements). Terms that are capitalized but undefined in any amendment to this Manufacturing and Supply Agreement shall be defined as set forth in this Manufacturing and Supply Agreement and in any other of the Parties' Agreements (and in amendments to the foregoing agreements). However, if there is a conflict or inconsistency between the definition of a capitalized term appearing in this Manufacturing and Supply Agreement or in any amendments hereto, on the one hand, and a definition of the same capitalized term appearing in any other of the Parties' Agreements and amendments thereto, on the other, then the definition of the capitalized term set forth in the Collaborative License Agreement and in the amendment hereto shall control.

**IN WITNESS WHEREOF,** the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

**DENDREON CORPORATION**

By: \_\_\_\_\_

Title: \_\_\_\_\_

  
6 August '02

**KIRIN BREWERY CO., LTD.**

By: \_\_\_\_\_

Title: \_\_\_\_\_

**11.12 Headings.** The Section and Paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the Section or Paragraphs to which they apply.

**11.13 Undefined Terms.** Terms that are capitalized but undefined in this Manufacturing and Supply Agreement shall be defined as set forth in any other of the Parties' Agreements (and in amendments to the foregoing agreements). Terms that are capitalized but undefined in any amendment to this Manufacturing and Supply Agreement shall be defined as set forth in this Manufacturing and Supply Agreement and in any other of the Parties' Agreements (and in amendments to the foregoing agreements). However, if there is a conflict or inconsistency between the definition of a capitalized term appearing in this Manufacturing and Supply Agreement or in any amendments hereto, on the one hand, and a definition of the same capitalized term appearing in any other of the Parties' Agreements and amendments thereto, on the other, then the definition of the capitalized term set forth in the Collaborative License Agreement and in the amendment hereto shall control.

**IN WITNESS WHEREOF,** the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

**DENDREON CORPORATION**

By: \_\_\_\_\_

Title: \_\_\_\_\_

**KIRIN BREWERY CO., LTD**

By:   
Title: President, Pharmaceutical Division

## **EXHIBIT A**

### **REDLINED AGREEMENT**

### **AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT**

THIS AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement" or "Manufacturing and Supply Agreement") is made and entered into effective as of August 6, 2002 (the "Restated Effective Date") by and between DENDREON CORPORATION, a Delaware corporation having its principal place of business at 3005 1<sup>st</sup> Avenue, Seattle, Washington, U.S.A. ("Dendreon"), and KIRIN BREWERY CO., LTD., a corporation organized and existing under the laws of Japan having its principal place of business at 10-1, Shinkawa 2-chome, Chuo-ku, Tokyo, Japan ("Kirin"). Dendreon and Kirin may be referred to herein collectively as the "Parties" or individually as a "Party."

#### **RECITALS**

A. Dendreon has developed and owns certain proprietary technology relating to the manufacture of devices, reagents and proprietary antigens necessary for Dendreon Products and Kirin Products.

B. Kirin has developed and owns certain proprietary technology relating to the manufacture of certain proprietary antigens and other proprietary components necessary for Kirin Products and Dendreon Products.

C. Kirin desires to purchase from Dendreon certain of its devices, reagents and certain of its proprietary antigens from Dendreon for use in clinical trials and commercialization of Kirin Products and Licensed Dendreon Products, and Dendreon is willing to supply Kirin with such devices, reagents and antigens for such uses.

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D. Dendreon desires to purchase from Kirin certain components necessary for making Licensed Kirin Products for use in clinical trials and commercialization of Licensed Kirin Products and Dendreon Products, and Kirin is willing to provide Dendreon with Kirin proprietary antigens and other Kirin proprietary components and certain Dendreon Components, if applicable, necessary for Licensed Kirin Products and Dendreon Products for such use.

E. The Parties contemplate that Dendreon may supply Kirin with commercial quantities of devices, reagents and Dendreon proprietary antigens, and Kirin may supply Dendreon with commercial quantities of Kirin proprietary antigens and other Kirin proprietary components, in the event marketing approval is obtained for any Products, in which case the Parties shall negotiate appropriate amendments to this Agreement.

F. The Parties contemplate that Dendreon may license Kirin to manufacture devices, reagents and Dendreon proprietary antigens, and Kirin may license Dendreon to manufacture Kirin components, necessary for making Products.

G. Kirin and Dendreon entered into a Manufacturing and Supply Agreement on July 27, 1999 to formalize their plans set forth in Recitals A through F. (The Manufacturing and Supply Agreement executed on July 27, 1999 is hereinafter defined as the "Original Supply Agreement"; and the date of its execution is hereinafter defined as the "Effective Date".)

H. Kirin and Dendreon entered into a Memorandum of Modifications to Kirin and Dendreon Collaboration on August 3, 2001 (hereinafter defined as the "Memorandum"). The Memorandum, among other things, directs that the Original Supply Agreement be amended to conform to the Parties' agreements in the Memorandum.

I. Kirin has an option for a fully paid non-exclusive license (with right to sublicense) to manufacture Dendreon Antigen PA2024 using Dendreon Technology as set forth in this Agreement and in the Collaborative License Agreement.

J. This Agreement and the Amended and Restated Collaborative License Agreement of even date supercede and terminate the Memorandum.

Now, ~~THEREFORE~~THEREFORE, the Parties agree to amend and restate the Original Supply Agreement in its entirety as follows:

## **ARTICLE 1**

### **ARTICLE 1:** **DEFINITIONS**

The following capitalized terms shall have the following meanings when used in this Agreement

**1.1 Affiliate** means, with respect to a particular Party, a person, corporation or other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For the purposes of this definition, "control" means the direct or indirect ownership by a Party of at least fifty percent (50%) of the outstanding voting securities of the controlled entity; provided, that in any country where the law does not permit foreign equity ownership of at least fifty percent (50%), then with respect to corporations organized under such country's laws, "control" shall mean the direct or indirect ownership by a Party of outstanding voting securities of such corporation at the maximum amount permitted by the law of such country.

**1.2 Back-Up License** shall have the meaning set forth in Section 3.7(c).

**1.3 Business Day** means any day that is not a Saturday, Sunday or other day on which (a) banks in the State of Washington are authorized or required to close for the purposes of any action to be taken by or any notice to be provided to Dendreon, or (b) the banks in Japan are authorized or required to close for the purposes of any action to be taken by or any notice to be provided to Kirin.

**1.4 Collaborative License Agreement** shall mean the Amended and Restated Collaborative License Agreement by and between the Parties ~~dated December 10, 1998, of even date.~~

**1.5 Component or Components** shall mean either a Kirin Component or a Dendreon Component, depending upon the context of the applicable Section and the Party to which such section then applies.

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**1.6 Controlled or Control** means, with respect to a particular item, material, or intellectual property right, that a Party owns or has a license under such item, material or intellectual property right and has the ability to grant to the other Party access to and/or a license or sublicense under such item, material or intellectual property right without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party.

**1.7 1.7 Dendreon Antigen** means an antigen that is claimed by a patent or is otherwise covered by intellectual property rights that are Controlled by Dendreon.

**1.8 1.8 Dendreon Component or Dendreon Components** shall mean a Separation Device, Reagent or Dendreon Antigen, or any combination thereof, other than a combination which comprises a Dendreon Product.

**1.9 1.9 Dendreon Product** means: (a) any therapeutic product comprising Dendritic Cells that have been activated or loaded with a specific antigen, engineered antigen or antigen gene, (including without limitation Dendreon Antigen), for use in human therapy ~~by infusion into a patient~~, which product has been developed by Dendreon based on the Dendreon Technology; or (b) any service provided by or on behalf of Dendreon to a patient that utilizes the Dendreon Technology and involves isolation or preparation of Dendritic Cells, activation or loading with specific antigen, engineered antigen or antigen gene, (including without limitation Dendreon Antigen), and ~~infusion administration~~ of such activated or antigen loaded Dendritic Cells into a patient. Further, the Parties may agree in writing to amend and extend the definition of Dendreon Product as provided in Section 5.8 of the Collaborative License Agreement.

**1.10 1.10 Dendreon Technology** means the Dendreon Know-How, the Dendreon Improvements and the Dendreon Patents, (as such terms are defined in the Collaborative License Agreement) either collectively or any part thereof.

**1.11 1.11 Dendritic Cell** means a human dendritic cell or other antigen-presenting cell or other cells from which dendritic cells can be derived.

1.12 "Effective Date" means the date of the Original Supply Agreement, July 27, 1999. Any amendment to the Original License Agreement contained in this Agreement shall be effective as of the Restated Effective Date.

1.12-1.13     **"Fully-Burdened Manufacturing Costs"** means the actual fully burdened costs and expenses of manufacturing a particular Component, including without limitation the costs of all raw materials and labor (including all allocable benefits) used or consumed in such manufacture, Third Party contract manufacturing costs, packaging costs and expenses, all quality assurance and quality control related expenses, all overhead amounts allocable to such manufacturing (including without limitation appropriately amortized capital equipment costs), all royalty amounts payable by Supplier to any Third Party based upon the manufacture of such Component, and all amounts related to failed production units or yield losses, all the foregoing as calculated in accordance with (i) U.S. generally accepted accounting principles consistently applied for manufacture of Components by Dendreon and (ii) Japan's generally accepted accounting principles consistently applied for manufacture of Components by Kirin.

1.13-1.14     **"Information"** means any and all information and data of any kind, including without limitation techniques, inventions, practices, methods, knowledge, know-how, skill, experience, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, marketing, cost, sales and manufacturing data and descriptions, compositions, and assays.

1.14-1.15     **"Kirin Antigen"** means an antigen that is claimed by a patent or is otherwise covered by intellectual property rights that are Controlled by Kirin.

1.15-1.16     **"Kirin Component"** or **"Kirin Components"** shall mean any Kirin Antigen or any other Kirin proprietary component of a Kirin Product, and any combination thereof, that Dendreon is either unable to prepare or generally does not prepare for Kirin or for itself.

1.17 "Kirin PA2024 Option" shall have the meaning set forth in Section 2.5 of the Collaborative License Agreement.

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**1.16-1.18**     “**Kirin Product**” means: (a) any therapeutic product developed by or on behalf of Kirin based on, derived from or incorporating the Dendreon Technology that comprises Dendritic Cells that have been activated or loaded with a specific antigen, engineered antigen or antigen gene, (including without limitation a Kirin Antigen), for use in human therapy—~~by infusion into a patient~~; or (b) any service provided by or on behalf of Kirin to a patient that involves isolation or preparation of Dendritic Cells, activation or loading of a specific antigen, engineered antigen or antigen gene, (including without limitation a Kirin Antigen), and ~~infusion administration~~ of such activated or antigen loaded Dendritic Cells into a patient, wherein such service is based on, utilizes, comprises or is derived from the Dendreon Technology. The Parties may agree in writing to amend and extend the definition of Kirin Product as provided in Section 5.8 of the Collaborative License Agreement.

**1.19** “**Kirin Hiring Period**” shall have the meaning set forth in Section 3.9(b)(iii)(3).

**1.17-1.20**     “**Licensed Dendreon Product**” shall have the meaning set forth in Section 2.3(b) of the Collaborative License Agreement.

**1.18-1.21**     “**Licensed Kirin Product**” shall have the meaning set forth in Section 2.4(b) of the Collaborative License Agreement.

**1.22** “**Manufacturing and Supply Agreement**” means this Agreement

**1.19-1.23**     “**Manufacturing Know-How**” means all Information other than Patents necessary for the manufacture of a Kirin Antigen or Dendreon Antigen which is subject to the Back-Up License.

**1.20-1.24**     “**Manufacturing Plan**” shall mean the plan prepared by the Supplier and delivered to the Purchaser for its review and approval, in good faith, which plan details the Supplier’s manufacturing plan for achieving manufacture of the Components at levels at least equal to the Purchaser’s forecasted orders for the first year after commercial launch of the first Kirin Product or Dendreon Product, as applicable.

**1.25** “**Memorandum**” shall have the meaning set forth in Recital H.

**1.21-1.26** “**Net Revenue**” means the total revenue received by a Party for sale or other disposition of a Product by such Party or an Affiliate or Sublicensee of such Party to a Third Party less the following to the extent actually incurred or allowed with respect to such sale or disposition: (i) reasonable costs paid, if any, by the Party to a Third Party on account of apheresis performed as part of or in association with the Product; (ii) discounts, including cash discounts, or rebates, retroactive price reductions or allowances actually allowed or granted from the billed amount; (iii) credits or allowances actually granted upon claims, rejections or returns of Products, including recalls, regardless of the Party requesting such; (iv) freight, postage, shipping and insurance charges paid for delivery of Product, to the extent billed; and (v) taxes, duties or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for rebates and refunds; *provided, however,* that with respect to sales of a particular Kirin Product or Licensed Dendreon Product by Kirin or its Affiliate or Sublicensee in Japan, the “total revenue received”, as set forth above in the first line of this definition, shall not in any event be less than the NHI Price established for insurance reimbursement of Single Treatment (as defined in the Collaborative License Agreement), less the average amount charged by the particular hospital purchaser of such Product for the same number of apheresis services and infusion administration services needed for and performed for Single Treatment (as defined in the Collaborative License Agreement) where such averages are calculated including all apheresis services or infusion services, as applicable, that were performed for any purpose during the applicable period.

**1.27 “Non-listed Facilities”** shall have the meaning set forth in Section 3.9(b)(iii)(3).

**1.28 “Original Supply Agreement”** means the Manufacturing and Supply Agreement by and between the Parties dated July 27, 1999.

**1.29 “PA2024 Price Election”** shall have the meaning set forth in Section 5.1(a)(ii).

**1.30 “Parties’ Agreements”** mean this Manufacturing and Supply Agreement, the Parties’ Amended and Restated Collaborative License Agreement, of even date, the Parties’ Research and License Agreement, dated February 1, 1999, and the Parties’ Joint Commercialization Agreement, dated February 1, 2001 and all amendments thereto, but not the Memorandum.

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**1.22-1.31**     “**Patent**” means (i) a valid and enforceable patent, including any extension, registration, confirmation, reissue, re-examination or renewal thereof; and (ii) to the extent valid and enforceable rights are granted by a governmental authority thereunder, a patent application.

**1.23-1.32**     “**Product**” means a Kirin Product or a Dendreon Product.

**1.24-1.33**     “**Purchaser**” shall mean the Party purchasing Components from the other Party to the Agreement, as applicable, in the applicable section.

**1.25-1.34**     “**Reagent**” means, with respect to a particular Licensed Dendreon Product, any proprietary reagent of Dendreon (excluding any reagents contained in a Separation Device) that is required for commercial manufacture and/or use of such Licensed Dendreon Product.

**1.26-1.35**     “**Reasonable Efforts**” shall mean efforts and resources commonly used in the research-based pharmaceutical industry for the research, development and commercialization of a product at a similar stage in its product life taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory structure involved, the profitability of the product and other relevant factors.

**1.27-1.36**     “**Research and License Agreement**” shall mean the Research and License Agreement by and between the Parties dated as of February 1, 1999.

**1.28-1.37**     “**Regulatory Approval**” means any approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other government entity, necessary for the manufacture, use, storage, import, transport or sale of Products in a regulatory jurisdiction.

**1.38** The “**Restated Effective Date**” means the date of this Agreement, set forth in the preamble above.

1.39 "Scale" means that the designated drug, antigen (e.g., PA2024), reagent or biologic is manufactured at a specified per batch volume (e.g., 2000L) all in accordance with cGMP such that each batch reliably and reproducibly conforms to the specifications for the designated drug, antigen, reagent or biologic.

1.29-1.40 "Separation Devices" means any Dendreon device, including all containers and proprietary reagents comprising such device, that is intended for use by Dendreon and its licensees for the isolation and purification of Dendritic Cells for use in human therapy by activation or loading with specific antigen, engineered antigen or antigen gene, and infusion/administration into a patient.

1.30-1.41 "Steering Committee" shall have the meaning set forth in Section 3.1 of the Collaborative License Agreement.

1.31-1.42 "Sublicensee" shall mean any Third Party expressly licensed by a Party to make and sell one or more Products. A Sublicensee shall not include distributors or sales agents that do no more than purchase and resell finished Products on behalf of a Party.

1.32-1.43 "Supplier" shall mean the Party supplying Components to the other Party to the Agreement, its Affiliates or Sublicensees, as applicable, in the applicable section.

1.33-1.44 "Supplier Patent" shall mean any Patent Controlled by the Supplier during the term of the Agreement.

1.34-1.45 "Third Party" means any entity other than Dendreon or Kirin or an Affiliate of Dendreon or Kirin.

## **ARTICLE 2**

### **ARTICLE 2:**

#### **SUPPLY FOR CLINICAL DEVELOPMENT**

##### **2.1-2.1 Supply for Clinical Development.**

(a)—(a) Subject to the terms of this Agreement and the Collaborative License Agreement, Kirin agrees to purchase from Dendreon, and Dendreon agrees to sell to Kirin, such

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Separation Devices and Reagents as Kirin requires to conduct clinical development of Kirin Products and/or Licensed Dendreon Products in the Kirin Territory.

(b) — (b) Subject to the terms of this Agreement and the Collaborative License Agreement, Kirin agrees to purchase from Dendreon, and Dendreon agrees to sell to Kirin, such quantities of Dendreon Antigen as Kirin requires to conduct clinical development of Licensed Dendreon Products in the Kirin Territory, to the extent such Dendreon Antigen is reasonably available to Dendreon. However, Dendreon's duty to sell to Kirin quantities of Dendreon Antigen PA2024 shall terminate three (3) years after the date Kirin exercises the Kirin PA2024 Option and receives Dendreon PA2024 Manufacturing Technology for the manufacture of PA2024 under Section 2.5 of the Collaborative License Agreement. In the absence of Kirin's exercise of the Kirin PA2024 Option, Dendreon's obligation to furnish Kirin with Dendreon Antigen PA2024 shall continue to be as set forth in this Agreement.

(e) — (c) Subject to the terms of this Agreement and the Collaborative License Agreement, Dendreon agrees to purchase from Kirin, and Kirin agrees to sell to Dendreon, such quantities of Kirin Components as Dendreon requires to conduct clinical development of Licensed Kirin ~~Products~~products and Dendreon Products in the Dendreon Territory, to the extent such Kirin Components are reasonably available to Kirin.

**2.2-2.2 Forecasts.** A reasonable period prior to the first expected order hereunder by the Purchaser of Components (at least six (6) months if possible), Purchaser shall provide the Supplier with a good faith written estimate of its expected requirements, on a per quarter basis, for all such Components for the first two (2) years after such first order. Commencing three (3) months before the first expected order, Purchaser shall provide Supplier with quarterly rolling twelve (12) month forecasts for its expected orders for Components to be ordered during each quarter during such period, with detail on each specific Component and quantities to be ordered. An updated forecast will be provided to Supplier within the first three (3) Business Days of each subsequent calendar quarter. In each such forecast provided to Supplier as required herein (after the first such rolling forecast), the forecast for the calendar quarter in which such forecast is delivered shall constitute a binding commitment of Purchaser and/or its Affiliates to submit purchase orders for not less than one hundred percent (100%) of the amounts listed in such

forecast during such quarter. Further, such binding forecast for such quarter may not deviate by more than twenty-five percent (25%) from the amount forecasted to be ordered during such quarter in the most recent previous forecast provided to Supplier.

**2.3** **2.3 Order Placement Procedure.** The Purchaser shall place orders for Components to be supplied under the Agreement on Purchaser's standard English-language purchase order form, specifying the quantity of each type of Component ordered and the requested delivery date, which shall not in any event be longer than one hundred and twenty (120) days from the date of such purchase order; provided, however, that if due to complications and lead time for a particular Component (such as antigen) the Supplier of such Component requires a delivery lead time for manufacture of such Component greater than one hundred twenty days (120) from the date of such purchase order, the Parties shall negotiate in good faith a reasonable delivery date for such Component, not to be greater than one hundred and eighty (180) days from the date of the purchase order. Supplier shall not be obligated to deliver Components ordered prior to sixty (60) days after the applicable order is placed; however, Supplier agrees that it will use Reasonable Efforts to meet any earlier delivery date reasonably requested by Purchaser. To the extent any purchase order, invoice or acknowledgment form used by Supplier or Purchaser contains any provisions additional or contrary to the provisions of this Agreement, such additional or contrary provision shall have no force or effect and the terms of this Agreement shall control. In addition, all such orders shall comply with the other requirements of this Article 2. The total amount of Components ordered by Purchaser during a particular calendar quarter shall not in any event be less than one hundred percent (100%) of the amount of each such Component that was forecasted to be ordered for such quarter in the most recent forecast provided to Supplier, as set forth in Section 2.2 above, unless Supplier otherwise agrees in writing. In addition, Supplier shall not be obligated to supply any amounts in such order that are in excess of one hundred ten percent (110%) of the amount of the particular Component that was forecasted in the most recent binding forecast to be ordered for such quarter; however, Supplier agrees that it will use Reasonable Efforts to supply such additional amounts. The Supplier shall use Reasonable Efforts to deliver the Components ordered in compliance with this Article 2. The Supplier shall immediately notify Purchaser in writing if Supplier determines that Supplier will not be able to supply a material amount of the most recent orders and/or forecasts of orders

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for any Component. Shipment and delivery of Components ordered hereunder shall be in accordance with Section 2.4.

**2.4 2.4 Delivery and Risk of Loss.**

(a) — (a) Delivery of Dendreon Components ordered hereunder by Kirin shall be by FCA Dendreon's actual manufacturing facility for such Components. "FCA" shall be construed in accordance with INCOTERMS 1990 of the International Chamber of Commerce. At Kirin's request and cost, Dendreon shall arrange shipping to specified Kirin locations. Delivered Dendreon Components shall be appropriately packaged by Dendreon, at Dendreon's expense, for export shipment.

(b) — (b) Delivery of Kirin Components (and any Dendreon Components, if applicable) ordered hereunder by Dendreon shall be by FCA Kirin's actual manufacturing facility for such Components. "FCA" shall be construed in accordance with INCOTERMS 1990 of the International Chamber of Commerce. At Dendreon's request and cost, Kirin shall arrange shipping to specified Dendreon locations. Delivered Kirin Components shall be appropriately packaged by Kirin, at Kirin's expense, for export shipment.

**2.5 2.5 Acceptance and Rejection.** Purchaser shall have the right to test at its expense, using testing procedures agreed upon by the Parties and set forth in the specifications for the applicable Component, a portion of each shipment of Components to confirm that such shipment meets the applicable specifications. Where it is required by local regulations, further testing on importation in accordance with the applicable specifications shall be carried out by Purchaser. If Purchaser rejects in whole or in part any nonconforming shipment of Components, Purchaser shall provide Supplier written notice of such rejection no later than thirty (30) days after receipt of such shipment of Components. If Purchaser fails to provide Supplier with such notice of rejection within such thirty (30) day inspection period, Purchaser shall be deemed to have accepted the applicable shipment of Components. If Supplier agrees with Purchaser's determination that a shipment of Components does not comply with applicable specifications, Supplier shall use Reasonable Efforts to replace the nonconforming Components, at no additional cost to Purchaser. If Supplier reasonably disputes Purchaser's conclusion that such Components do not meet the applicable specifications, Supplier shall use Reasonable Efforts to

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replace such shipment of Components to Purchaser, at Purchaser's expense. If Supplier disagrees with Purchaser's determination that the rejected shipment did not meet the applicable specifications, a sample of the rejected shipment shall be submitted to an independent, qualified Third Party laboratory that is mutually acceptable and selected by the Parties promptly in good faith. Such laboratory shall determine whether the rejected Components meet the applicable specifications, and such laboratory's determination shall be final and determinative for purposes of this Agreement. The Party against whom the laboratory rules shall bear all costs of the laboratory testing. If the laboratory rules that the shipment of Components failed to meet the applicable specifications, then at Purchaser's choice, the price paid by Purchaser for such nonconforming shipment shall be reimbursed to Purchaser (provided Purchaser paid for such shipment) or Components meeting the applicable specifications shall be shipped. If the laboratory rules that the Components do not meet the applicable specifications, and if Supplier is unable to produce conforming Components, any sums actually paid therefore shall be refunded to Purchaser with interest. At such time, the Parties will discuss in good faith potential solutions to the supply problem. If the laboratory rules the rejected shipment of Components met the applicable specifications, then Purchaser shall accept such shipment (including all costs of shipping and insurance). Shipments of Components not meeting the applicable specifications may, at Supplier's option and expense, be returned to Supplier or destroyed by Purchaser. If Supplier has acknowledged in writing that it is unable to produce conforming Components, any sums actually paid therefor will be refunded. The remedy of replacement or refund is available only if such nonconformance was not caused by Purchaser's misuse, unauthorized modifications, neglect, improper testing or improper storage, including without limitation storage at inappropriate temperatures, of such shipment of Components.

**2.6-2.6 Manufacturing Modifications.** If the laws of a country require Supplier's established specifications for a particular Component or Components to be modified in order for Purchaser to obtain Regulatory Approval of a Product in such country, Purchaser will submit the matter to the Steering Committee for discussion and proposed resolution. The Parties agree to negotiate in good faith any proposed modifications to the specifications for such Component or Components for such Products proposed by the Steering Committee. Any such resolution of the Steering Committee must be agreed in writing by the Parties.

**2.7** **2.7 Restrictions on Sale.** Kirin and its Affiliates shall not resell the Separation Devices purchased pursuant to this Article 2 except as part of a Kirin Product or a Licensed Dendreon Product, and shall not use Separation Devices, Reagents or Dendreon Antigen for any purpose other than those purposes permitted in this Agreement, the Collaborative License Agreement or the Research and License Agreement. Dendreon shall retain all rights to manufacture or have manufactured the Separation Devices, Reagents and Dendreon Antigens. Dendreon and its Affiliates shall not use Kirin Antigen for any purpose other than those purposes permitted in this Agreement, the Collaborative License Agreement or the Research and License Agreement.

**2.8** **2.8 Use of Separation Devices by Kirin Collaborators.** With Dendreon's prior written approval, which may be withheld for any reason, Kirin may provide certain academic or medical doctor collaborators with a limited number of Separation Devices solely for use by such individuals in research and development purposes in the Field; *provided, however,* that before any such delivery Kirin shall require such collaborator: (i) to be appropriately trained in the use of the Separation Devices, (ii) to share the results of any and all research and development performed using the Separation Devices with Kirin and Dendreon; (iii) not to sell, distribute or otherwise provide such Separation Devices to Third Parties; and (iv) unless such antigen is within the public domain, to grant Dendreon an option to license any specific antigen, engineered antigen or antigen gene used or developed in conjunction with the use of the Separation Devices. Except as explicitly provided in this Agreement, Kirin obtains no license or rights to make or to practice any of the Dendreon Technology to make Separation Devices, Reagents or any other devices or products for use in the isolation or purification of Dendritic Cells or any other cells. Notwithstanding anything else in this Agreement, Kirin may use Separation Devices to isolate Dendritic Cells only as part of preparing a Kirin Product or Licensed Dendreon Product or performing a service comprising a Kirin Product or Licensed Dendreon Product, or with Dendreon's prior written consent, as provided in this Section 2.8.

## **ARTICLE 3**

### **ARTICLE 3:**

#### **COMMERCIAL SUPPLY**

**3.1 3.1 Commercial Supply.** Subject to the other terms of this Agreement, Dendreon agrees to provide Kirin, its Affiliates and Sublicensees with their commercial requirements of Separation Devices, Reagents and Dendreon Antigens necessary for use in manufacturing or using Kirin Products or Licensed Dendreon Products for which Regulatory Approval has been obtained in the Kirin Territory. In the event Dendreon implements improvements, upgrades or changes to Separation Devices, Reagents and Dendreon Antigens, Kirin, its Affiliates and Sublicensees shall have the right to continue to purchase the unimproved, un-upgraded or unchanged Separation Devices, Reagents and Dendreon Antigens (i.e., the model that Dendreon has been providing as provided in Section 5.1) necessary for use in manufacturing or using Kirin Products or Licensed Dendreon Products for which Regulatory Approval has been obtained in the Kirin Territory. However, Dendreon's duty to sell to Kirin quantities of Dendreon Antigen PA2024 shall terminate three (3) years after the date Kirin exercises the Kirin PA2024 Option and receives Dendreon PA2024 Manufacturing Technology for the manufacture of PA2024 under Section 2.5 of the Collaborative License Agreement. In the absence of Kirin's exercise of the Kirin PA2024 Option, Dendreon's obligation to furnish Kirin with Dendreon Antigen PA2024 shall continue to be as set forth in this Agreement.

**3.2 3.2 Preparation.** At such time after the Effective Date that Supplier has prepared the Manufacturing Plan, but no later than one hundred and twenty (120) days before the commercial launch of the first Kirin Product or Dendreon Product, as applicable, Supplier shall provide to Purchaser such Information in Supplier's control relating to lead times Supplier requires to achieve manufacture of Components on a commercial scale hereunder, necessary to determine appropriate procedures and mechanisms for providing to Supplier forecasts of Purchaser's, its Affiliates' and Sublicensees' requirements for Components to be ordered and purchased hereunder, and for ordering such requirements. The Purchaser shall review such Information promptly after receipt, and appropriate representatives from Purchaser and Supplier shall then meet to determine the appropriate forecasting, ordering and inventory mechanisms that will be used by the Parties for ordering and supplying the commercial requirements of Components

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hereunder. Such forecasting, ordering and inventory mechanisms shall be consistent with the terms of this Article 3 and shall be set forth in a writing, and upon mutual execution of such writing by the Parties, such mechanisms (the "Supply Procedures") shall become part of this Agreement.

**3.3 3.3 Forecasts.** With respect to the forecasting mechanism, such Supply Procedures shall provide: (a) that within an agreed period of time prior to the first expected Regulatory Approval of a Product, Purchaser shall provide a good faith estimate of its expected requirements, on a per quarter basis, for each particular Component which is part of such Product to be ordered, for an agreed period before and an agreed period after the launch of such Product; (b) as of an agreed time before the first expected Regulatory Approval of a particular Product, Purchaser shall provide Supplier a rolling twelve (12) month forecast for Purchaser's expected orders for each particular Component during each month during such twelve (12) month period; (c) Purchaser shall provide Supplier updated forecasts for expected orders of Components at agreed intervals of time; (d) that in each forecast provided, the forecasted orders for an agreed time period for each forecasted Component shall constitute binding orders by Purchaser for such Components, to be placed during such agreed time period; and (e) that forecasted orders for each Component in a particular forecast delivered to Supplier may not deviate by more than twenty-five percent (25%) from the forecast for orders for such Components in the most recent previous forecast submitted to Supplier. The Parties further agree that if a Party determines that the foregoing forecasting mechanisms are inappropriate given the then-existing manufacturing and supply circumstances for any Component, the Parties will discuss and agree in good faith on appropriate written amendments to the forecasting mechanisms for such Component.

**3.4 3.4 Order Placement Procedure.** With respect to the ordering mechanism, such Supply Procedures shall provide: (a) that Purchaser shall place orders for Components to be supplied under the Agreement on Purchaser's standard purchase order form, specifying the quantity of each specific Component ordered and the requested delivery date, which shall not in any event be sooner or later than agreed time period(s) from the date of such purchase order; (b) that to the extent any purchase order, invoice or acknowledgment form used by Purchaser contains any provisions additional or contrary to the provisions of this Agreement, such additional or contrary provision shall have no force or effect and the terms of this Agreement

shall control; (c) that Supplier shall not be obligated to supply any amounts of a particular Component in such order more than an agreed percentage of the unit quantity of such Component specified in the binding forecast for the applicable time period; (d) that Purchaser's orders for a Component may not be less than an agreed percentage of the binding forecast for such Component for the applicable time period; and (e) that Supplier will use Reasonable Efforts to provide additional amounts of a particular Component beyond the foregoing limitation on Supplier's obligation to supply, upon Purchaser's reasonable request, but consistent with Supplier's other business obligations.

**3.5-3.5 Inventory.** The Supply Procedures shall also establish an inventory mechanism for Components, which shall provide that: (a) within an agreed period of time after the commercial launch of a particular Product, Supplier shall use Reasonable Efforts to maintain an inventory of the Components in such Product at least equal to the written forecast for purchases of such Product to be made during an agreed number of months in the most recent forecast provided to Supplier by Purchaser under the forecasting mechanism of the Supply Procedures; (b) Purchaser shall maintain an inventory of all Components in accordance with Purchaser's normal practices, and shall give Supplier quarterly updates of the extent of such inventory; (c) Supplier's inventory of Components maintained under such inventory mechanism shall only be permitted to fall below the levels established in subsection (a) above in the event that Purchaser submits orders in excess of the forecasted amounts or Supplier experiences manufacturing or supply problems with respect to the Components; and (d) Supplier shall use Reasonable Efforts in accordance with Supplier's normal practices to promptly replenish any inventory of Components that is depleted in satisfying purchases of such Component by Purchaser hereunder.

**3.6-3.6 Amendments.** The Parties further agree that if the foregoing forecasting, ordering or inventory mechanisms established in the Supply Procedures are determined by the Parties, in good faith cooperation and giving reasonable consideration to each Party's economic and business needs, to be inappropriate given the experience of the Parties and the then-existing manufacturing and supply circumstances regarding Components hereunder, the Parties will discuss in good faith appropriate amendments to the applicable mechanisms in the Supply Procedures.

### **3.7 Resolution of Supply Problems.**

(a) ——(a) If Supplier determines that Supplier will not be able to supply to Purchaser a material amount of the most recent orders and/or binding forecasts of orders for a particular Component submitted by Purchaser in accordance with the applicable Supply Procedures, Supplier shall immediately notify Purchaser in writing of such determination, which notice shall provide Purchaser with the details on the extent of the expected shortfall of supply, the causes of such inability to supply, and Supplier's proposed solution to the problem. Upon such notice of a supply problem, or in any event upon Supplier's failure to satisfy, within the delivery time frame specified by Purchaser consistent with the Supply Procedures, a portion of the Components ordered by Purchaser in compliance with this Agreement, (provided that such supply problem or failure cannot be satisfied or addressed by Purchaser's and Supplier's existing inventories for such Components and will cause an interruption in the supply of such Components by Purchaser or its Affiliates to the commercial market for more than thirty (30) days), Purchaser and Supplier will immediately meet and work together, in good faith, to identify an appropriate resolution to the supply problem. The Parties will discuss all appropriate means of resolving the problem, including without limitation establishing an alternative source of supply for the affected Components, creating a back-up manufacturing facility, or permitting Purchaser to manufacture an agreed amount of Components to cover the shortfall in supply, with Supplier continuing to supply an agreed amount of such Components. Any agreed resolution to the supply problem will be set forth in a writing executed by both Parties.

(b) ——(b) If the Parties cannot reach agreement on an appropriate resolution to the supply problem within ten (10) days of commencing such discussions under subsection (a) above, senior management representatives of the Parties will immediately meet to discuss in good faith the problem in an effort to reach agreement on such resolution. As part of such discussions, Supplier shall make a firm commitment of the amount of the affected Components that Supplier will be able to supply, on a monthly basis, during the period when such supply problem with respect to such Components is expected to continue. Any agreed resolution by the Parties to the supply problem will be set forth in a writing executed by both Parties. If, despite good faith efforts, the senior management officials are unable to reach agreement on the resolution of such supply problem within twenty (20) days of their commencing such

discussions, then at either Party's immediate written request, the problem will be governed by the terms of Section 11.7 if it affects Components other than Kirin Antigen or Dendreon Antigen, and by the terms of Section 3.7(c) if it affects Kirin Antigen or Dendreon Antigen.

(e) —— (c) If there is a material supply problem with respect to Kirin Antigen or Dendreon Antigen subject to the provisions of subsections 3.7(a) and (b) above, and (i) the Parties have failed to reach agreement on the resolution of such problem within the time frames set forth above by the end of the twenty (20) day period as provided under subsection (b), or (ii) Supplier has failed to meet to discuss the problems as required above, then at Purchaser's written request provided to Supplier no more than sixty (60) days after the foregoing conditions have been met, Supplier shall grant to Purchaser a co-exclusive license as to Kirin Antigen or Dendreon Antigen, as applicable, (the "Back-Up License"), under the relevant Supplier Patents and Manufacturing Know-~~How~~How, as necessary to permit Purchaser to make or have made such Kirin Antigen or Dendreon Antigen that is the subject of such supply problem that was not resolved by the Parties, solely for sale in accordance with the terms of this Agreement, the Collaborative License Agreement and the Research and License Agreement, and solely in quantities to meet the amounts of Purchaser's and its Affiliates' and sublicensees' (if any), and Supplier's and its Affiliates' and sublicensees' (if any), if applicable, requirements for such Kirin Antigen or Dendreon Antigen above the amounts of such Kirin Antigen or Dendreon Antigen that Supplier remains able and willing to supply on a timely basis under this Article 3. Purchaser covenants, represents and warrants that Purchaser shall not exercise the Back-Up License unless and until the conditions specified in the first sentence of this Section 3.7(c) have been completely satisfied and shall not use or practice the licensed Supplier Patents and Manufacturing Know-~~How~~How for any purpose except as expressly permitted in the foregoing. Immediately upon Purchaser's written request hereunder to obtain the Back-Up License, Supplier shall transfer to Purchaser copies of all information, including technical information, that is Controlled by Supplier, relates to the manufacture of the Kirin Antigen or Dendreon Antigen that is the subject of the Back-Up License and is reasonably necessary to enable Purchaser to manufacture such Kirin Antigen or Dendreon Antigen. Thereafter, but only during the period when Purchaser is permitted hereunder to exercise the Back-Up License, Purchaser shall be permitted access to and a right of reference to any Regulatory Approvals held in Supplier's name for the Kirin Antigen

or Dendreon Antigen that is the subject of such Back-Up License. Supplier shall provide Purchaser reasonable assistance, at Purchaser's request and Purchaser's expense, with respect to understanding such manufacturing information and practicing the Back-Up License.

(i) — (ii) At such time as Supplier is reasonably able to meet all of Purchaser's forecasted orders for Kirin Antigen or Dendreon Antigen, as applicable, the Back-Up License granted under this Section 3.7(c) shall terminate with respect to such Kirin Antigen or Dendreon Antigen, and Purchaser shall immediately cease to exercise and practice the Back-Up License, provided that Purchaser shall retain all rights under this Section 3.7 with respect to any subsequent supply problem as to any Kirin Antigen or Dendreon Antigen, as applicable.

(iii) — (iv) Purchaser will pay Supplier a royalty of two percent (2%) of the Net Revenue of Kirin Products or Dendreon Products (as applicable) manufactured by or on behalf of Purchaser pursuant to exercise of the Back-Up License and sold by Purchaser or its Affiliate or sublicensee. Nothing in the foregoing shall limit or affect in any way Purchaser's obligations to make the payments set forth in this Agreement to the full extent required on all Components supplied to Purchaser by Supplier.

**3.8 Acceptance and Rejection**. Purchaser shall have the right to test at its expense, using testing procedures agreed upon by the Parties and set forth in the specifications for the applicable Component, a portion of each shipment of Components to confirm that such shipment meets the applicable specifications. Where it is required by local regulations, further testing on importation in accordance with the applicable specifications shall be carried out by Purchaser. If Purchaser rejects in whole or in part any nonconforming shipment of Components, Purchaser shall immediately provide Supplier written notice of such rejection. If Supplier agrees with Purchaser's determination that a shipment of Components does not comply with applicable specifications, Supplier shall use Reasonable Efforts to replace the nonconforming Components, at no additional cost to Purchaser. If Supplier reasonably disputes Purchaser's conclusion that such Components do not meet the applicable specifications, Supplier shall use Reasonable Efforts to replace such shipment of Components to Purchaser, at Purchaser's expense. If Supplier disagrees with Purchaser's determination that the rejected shipment did not meet the applicable specifications, a sample of the rejected shipment shall be submitted to an independent,

qualified Third Party laboratory that is mutually acceptable and selected by the Parties promptly in good faith. Such laboratory shall determine whether the rejected Components (as applicable) meet the applicable specifications, and such laboratory's determination shall be final and determinative for purposes of this Agreement. The Party against whom the laboratory rules shall bear all costs of the laboratory testing. If the laboratory rules that the shipment of Components failed to meet the applicable specifications, at Purchaser's choice, the price paid by Purchaser for such nonconforming shipment shall be reimbursed to Purchaser (provided Purchaser paid for such shipment) or Components meeting the applicable specifications shall be shipped to Purchaser by Supplier. If the laboratory rules the rejected shipment of Components met the applicable specifications, then Purchaser shall accept such shipment (including all costs of shipping and insurance). Shipments of Components not meeting the applicable specifications may, at Supplier's option and expense, be returned to Supplier or destroyed by Purchaser. If Supplier has acknowledged in writing that it is unable to produce conforming Components, any sums actually paid therefor will be refunded with interest, and the supply problem will be resolved in accordance with Section 3.7. The remedy of replacement or refund is available only if such nonconformance was not caused by Purchaser's misuse, unauthorized modifications, neglect, improper testing or improper storage, including without limitation storage at inappropriate temperatures, of such shipment of Components.

### **3.9 Kirin Manufacture of Dendreon Components.**

**(a)** Kirin agrees to provide Dendreon, its Affiliates and Sublicensees with their commercial requirements of Kirin Components necessary for Licensed Kirin Products for which Regulatory Approval has been obtained, pursuant to the terms of this Article 3. In addition, if so requested by Dendreon, Kirin may negotiate with Dendreon for the manufacture and supply by Kirin to Dendreon of certain Separation Devices, Reagents and/or Dendreon Antigens at a transfer price in an amount in U.S. dollars equal to Kirin's Fully-Burdened Manufacturing Costs for such Separation Devices, Reagents and/or Dendreon Antigens plus a handling fee of twenty percent (20%), with any manufacture and supply to be governed by the terms of this Agreement and any additional terms negotiated by the Parties. The Parties also agree to amend the terms of the Agreement to reflect such agreed terms for the manufacture and supply by Kirin of Separation Devices, Reagents and/or Dendreon Antigens, if any.

(b) Subject to the terms of its license to manufacture PA2024 (under the Kirin PA2024 Option set forth in Section 2.5 of the Collaborative License Agreement), Kirin shall manufacture PA2024 on the following terms and conditions:

(i) Neither Kirin's manufacture nor use of PA2024 shall interfere with Kirin's use of Reasonable Efforts to develop, obtain Regulatory Approval in the Kirin Territory for, and market and sell in the Kirin Territory, APC 8015.

(ii) The manufacturing shall be conducted in accordance with all applicable laws, regulations and Regulatory Approvals.

(iii) Kirin may manufacture Dendreon Antigen PA2024 at manufacturing facilities anywhere in the world on the following terms and conditions:

(1) Kirin shall have no right to execute an agreement to engage or hire any Third-Party manufacturing facility until after it exercises the Kirin PA2024 Option. Kirin shall promptly notify Dendreon (within thirty (30) days) after it engages or hires any Third-Party manufacturing facility. Kirin may submit a request for a Third Party manufacturing facility under this Section 3.9(b)(iii) without exercising the Kirin PA2024 Option. Kirin's request for Third-Party manufacturing facilities under this Section 3.9(b)(iii) shall not be treated as an exercise of the Kirin PA2024 Option (which exercise shall require a separate notice).

(2) Prior to commencing manufacturing of PA2024 (from time to time) at any Third-Party manufacturing facility outside the Kirin Territory, Kirin shall notify and request Dendreon's approval of Kirin's good faith plan to commence manufacturing operations at a specific manufacturing facility (which notice from Kirin shall specify the address of the Third-Party manufacturing facility, the status of the tentative facility's Regulatory Approval, the tentative facility's estimated, available manufacturing capacity, the owner of the tentative facility and the owner's Affiliates to the extent information on the owner's Affiliates is reasonably available). Dendreon shall have the right to disapprove Kirin's plan to use the Third-Party manufacturing facility only if Dendreon has actual manufacturing plans for the facility at the time of Kirin's request. Dendreon shall give notice of its approval or disapproval within fifteen (15) days after Kirin gives its notice of intended use. If Dendreon approves Kirin's plan or fails

to give timely disapproval, then Kirin shall have the right to commence manufacturing operations of PA2024 at the facility within the next five hundred forty (540) days. If the five hundred forty (540) days expire without Kirin commencing manufacturing operations at the facility, then Dendreon's approval shall be deemed to lapse and Kirin shall be required to again request Dendreon's approval (under the first sentence of this Section 3.9(b)(iii)(2)) before commencing manufacturing operations. If Dendreon gives notice of disapproval of the manufacturing facility, then Kirin shall have no right to commence manufacturing at (or otherwise engage or hire) the facility for the manufacture of PA2024. Kirin shall have no right to engage or hire more than one (1) Third-Party manufacturing facility at a time under this Section 3.9(b)(iii)(2) without requesting Dendreon's approval for each such facility (under the first sentence of this Section 3.9(b)(iii)(2)). As used in this Agreement, "actual manufacturing plans" mean that a written proposal, letter of intent or purchase order has been delivered to the Third-Party manufacturing facility about engaging or hiring the facility, but not necessarily the achievement of a manufacturing agreement or option with the Third-Party manufacturing facility.

(3) If Dendreon gives notice of disapproval of Kirin's intended use of a specific Third-Party manufacturing facility under Section 3.9(b)(iii)(2), then the notice of disapproval shall be accompanied by Dendreon's list of Third-Party manufacturing facilities for which Dendreon has actual manufacturing plans; and the list shall be deemed to include the Third-Party manufacturing facilities for which Dendreon had disapproved Kirin's manufacturing plans under Section 3.9(b)(iii)(2). Kirin shall have no right to commence manufacturing of PA2024 at (or otherwise engage or hire) the listed facilities. If Dendreon lists no Third-Party manufacturing facilities or fails to deliver its list with the notice of disapproval, then all Third-Party manufacturing facilities (except the Third-Party manufacturing facilities for which Dendreon had disapproved Kirin's manufacturing plans under Section 3.9(b)(iii)(2)) shall be deemed to be non-listed (the "Non-listed Facilities"). After Dendreon delivers its list or fails to deliver its list in a timely manner, Kirin shall then have the right to commence manufacturing of PA2024 at up to two (2) Non-listed Facilities within a period starting on the date of Dendreon's notice of its list or, if no list is delivered, the due date for Dendreon's list and ending on the earlier of (a) five hundred forty (540) days after the start date or (b) upon Kirin's engagement or

hire of two (2) Non-listed Facilities (the “Kirin Hiring Period”). After the Kirin Hiring Period expires, if Kirin then wishes to engage or hire any additional Third-Party manufacturing facilities, Kirin shall be required to request Dendreon’s approval of a specific Third-Party manufacturing facility (under the first sentence of Section 3.9(b)(iii)(2)).

(4) Prior to commencing manufacturing of PA2024 (from time to time) at any Non-listed facility during the Kirin Hiring Period, Dendreon shall notify and request Kirin’s approval of Dendreon’s good faith plan to commence manufacturing operations at a specific manufacturing facility (which notice from Dendreon shall specify the address of the Third-Party manufacturing facility, the status of the tentative facility’s Regulatory Approval, the tentative facility’s estimated, available manufacturing capacity, the owner of the tentative facility and the owner’s Affiliates to the extent information on the owner’s Affiliates is reasonably available). During the Kirin Hiring Period, Dendreon shall have the right to commence manufacturing of PA2024 at up to two (2) Non-listed Facilities. Dendreon shall not engage or hire any Non-listed Facility during the Kirin Hiring Period without Kirin’s approval, which approval may be withheld for up to two (2) Non-listed Facilities and which approval may be withheld based solely upon Kirin’s actual manufacturing plans for the facility at the time of Dendreon’s request. Kirin shall give notice of its approval or disapproval within fifteen (15) days after Dendreon gives its notice of intended use. If Kirin approves Dendreon’s plan or fails to give timely disapproval, then Dendreon shall have the right to commence manufacturing operations of PA2024 at the facility at any time thereafter. If Dendreon commences manufacturing operations at the facility, the facility shall then be treated as appearing on Dendreon’s list (as defined in Section 3.9(b)(iii)(3)). If Kirin disapproves Dendreon’s request to engage or hire a Non-listed Facility, then Dendreon shall have no right to commence manufacturing (or otherwise engage or hire) the Non-listed Facility for the manufacture of PA2024 during the Kirin Hiring Period.

(5) Dendreon may not restrict Kirin’s right to select Third-Party manufacturing facilities within the Kirin Territory and may not restrict Kirin’s right to manufacture PA2024 at any manufacturing facility anywhere in the world that is wholly owned by Kirin or by one of its Affiliates. Outside the Kirin Hiring Period, Dendreon shall have the right to hire or engage any Third-Party manufacturing facility for PA2024 without Kirin’s

approval. Upon the request of any Party after the Kirin PA2024 Option is exercised, the Parties shall confer and exchange information about their manufacturing plans for PA2024.

## **ARTICLE 4**

### **ARTICLE 4:**

#### **REGULATORY REQUIREMENTS**

**4.1-4.1 Manufacturing Facilities, Equipment and Licenses.** Supplier shall, at Supplier's expense, acquire or cause to be acquired all equipment and licenses, including, without limitation, all necessary plant equipment and facilities licenses, necessary to enable the manufacture and testing of the Components as required hereunder. Supplier shall obtain and maintain all necessary Regulatory Approvals. Purchaser, its Affiliates and Sublicensees shall obtain any required importation licenses or approvals for importation of Dendreon Products and Kirin Products, and the Components necessary for such Kirin Products and Dendreon Products, as applicable for sale in any given country. Supplier shall cooperate reasonably with Purchaser, at Purchaser's reasonable request and expense, to obtain such licenses or approvals.

#### **4.2-4.2 Manufacturing Regulatory Matters.**

**(a) — (a)** Supplier will be responsible for any reporting of matters regarding the manufacture of Components, as applicable, to the FDA and other relevant regulatory authorities, in accordance with pertinent laws and regulations. Supplier shall notify Purchaser of any such matter if significant or serious and promptly furnish complete copies of such reports to Purchaser in the English language. Supplier also shall advise Purchaser of any occurrence or information which arises out of Supplier's manufacturing activities which has adverse regulatory compliance and/or reporting consequences concerning a Component.

**(b) — (b)** Supplier shall be responsible for handling and responding to any appropriate governmental agency inspections with respect to manufacturing of Components during the term of this Agreement. Supplier shall provide to Purchaser any information requested by any governmental agency in connection with any governmental inspection related to Components. Supplier shall use reasonable efforts to promptly advise Purchaser of any

requests by any governmental agency for such inspections with respect to manufacturing of Components.

(e) — (c) Any changes by Supplier to the manufacturing process for Components that may require approval by the FDA or other authorities or amendment of existing Regulatory Approvals shall require the prior written approval of Purchaser, not to be unreasonably withheld or delayed.

(d) — (d) Supplier certifies it did not and will not use in any capacity the services of any person, including any firm or individual, debarred or subject to debarment under the Generic Drug Enforcement Act of 1992, amending the Food Drug and Cosmetic Act at 21 USC 335a. Supplier agrees to notify Purchaser immediately in the event any person providing services to Supplier under the scope of the work of this Agreement is debarred or becomes subject to debarment.

(e) — (e) For the limited purpose of permitting a quality and compliance audit, Supplier shall grant to authorized representatives of Purchaser upon reasonable notice and not more than once per year, unless a substantial and reasonable need for an additional audit can be shown, access to areas of Supplier's plants and each of Supplier's Third Party supply contractor's plants, and to those technical records made by Supplier that only relate solely to Quality Assurance testing and regulatory compliance monitoring for manufacturing of Components, at such times as Components are being manufactured, solely for the purpose of Purchaser determining that such manufacture is in compliance with regulatory requirements. Purchaser shall provide Supplier at least thirty (30) Business Days notice in writing of its desire to have such access. Supplier shall promptly respond to Purchaser's request and the Parties shall agree on the time of and procedures for the audit. All such inspections shall be subject to confidentiality obligations.

**4.3-4.3 Product Recall Procedures.** The Parties shall immediately inform each other in writing of all Information relating to: (a) any incident relating to a Product and/or any Product or Component that is the subject of recall, market withdrawal or correction; or (b) any Components that may require, whether based on manufacturing defect, tampering, or otherwise, a recall, field alert, product withdrawal or field correction arising from any defect in any such Component

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provided under this Agreement. The Parties then shall meet and discuss the situation in good faith to determine if a recall, field alert, product withdrawal, or field correction is necessary. In the event that either Purchaser or Supplier decides that a recall, field alert, product withdrawal, or field correction is necessary due to any defect or other problem in any Component, the Parties shall cooperate and use Reasonable Efforts in effecting any such required recall, market withdrawal or correction. Payment of costs and expenses associated with recalls, market withdrawals, market corrections and the costs associated with replacement of the recalled or withdrawn Products or Components shall be borne by the Party whose negligent or defective manufacturing, processing, testing, packing or storage necessitated such recall, market withdrawal or market correction.

**4.4.4 Documentation.** Supplier shall keep complete, accurate and authentic accounts, notes, data and records of the work performed under this Agreement. Each Party shall maintain complete and adequate records pertaining to the methods and facilities used by it for the manufacture, processing, testing, packing, labeling, holding and distribution of Components in accordance with the applicable regulations in the United States and other countries so that the Components may be used in Dendreon Products and Kirin Products to be used in human therapies.

## **ARTICLE 5**

### **ARTICLE 5:**

#### **FINANCIAL OBLIGATIONS**

##### **5.1 Purchase Prices.**

###### **(a) Kirin's Purchase of Particular Dendreon Components.**

(a) (i) Per Kirin's purchase of particular Dendreon Components hereunder (except for the purchase of Dendreon Antigen PA2024, the purchase of which is addressed in Section 5.1(a)(ii)), Kirin shall pay Dendreon for the purchase of such Dendreon Components a transfer price in an amount in U.S. Dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of such Dendreon Components plus a handling fee of twenty percent (20%); provided, however, that for Dendreon Components that are purchased by Kirin for use in a Dendreon

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Product for which the costs of manufacturing development (including process development) was supported by Kirin pursuant to Section 5.3, Kirin shall pay Dendreon a transfer price in an amount in U.S. Dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of such Dendreon Components for such Dendreon Product plus a handling fee of ten percent (10%). For its purchase of Dendreon Separation Devices, Kirin shall pay Dendreon a transfer price in an amount in U.S. dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of the Separation Devices, plus a handling fee of ten percent (10%). (The Parties acknowledge and agree that Kirin supported the costs of manufacturing development of the Separation Devices so that Kirin is entitled to the purchase price set forth in the preceding sentence.) Kirin shall pay Dendreon fifty percent (50%) of the transfer price for a particular order of Dendreon Components within thirty (30) days of placing its order for such Dendreon Components, and fifty percent (50%) of such transfer price within thirty (30) days of delivery of such Dendreon Components, pursuant to Section 2.4.

(ii) Per Kirin's purchase of Dendreon Antigen PA2024 (which is a Dendreon Component), Kirin shall pay Dendreon the purchase price calculated as follows; for PA2024 manufactured up to and at the 2000L Scale, Kirin shall pay Dendreon a transfer price in U.S. dollars in the amount of Dendreon's Fully-Burdened Manufacturing Costs of PA2024 at the time of its manufacture, plus a handling fee of ten percent (10%). Kirin's transfer price for PA2024 shall equal (in U.S. dollars) the Fully-Burdened Manufacturing Costs of PA2024 last manufactured at the 2000L Scale plus a handling fee of ten percent (10%), even if Dendreon scales up the manufacture of PA2024 to greater than 2000L Scale from time to time. In calculating the transfer price of PA2024 above, all costs shall be excluded for scaling up the manufacture of PA2024 to the 2000L Scale. However, in the event from time to time Dendreon scales up the manufacture of PA2024 to greater than 2000L Scale, Kirin may elect in writing (the "PA2024 Price Election") to purchase PA2024 at a transfer price in U.S. Dollars equal to Dendreon's Fully-Burdened Manufacturing Costs of PA2024 at the time of manufacture at such greater Scale, plus a handling fee of ten percent (10%). Kirin's PA2024 Price Election shall apply to all of Kirin's purchase orders for PA2024 placed from the date the election is made until Kirin gives notice to Dendreon of a new PA2024 Price Election, whereupon, Kirin shall become obligated to pay a transfer price in U.S. Dollars equal to Dendreon's Fully-Burdened

Manufacturing Costs of PA2024 at the time of manufacture at such greater Scale, plus a handling fee of ten percent (10%). Prior to each PA2024 Price Election, Kirin may notify Dendreon in writing of Kirin's good faith tentative intention to make the election, and request a statement from Dendreon of the actual scale-up costs to Dendreon of the scale-up to that manufacturing level. Dendreon shall furnish Kirin with a statement of such scale-up costs no later than thirty (30) days after Kirin requests such statement. Dendreon shall furnish Kirin, at Kirin's request, periodic progress reports on such scale-up costs and efforts. At the time Kirin makes a PA2024 Price Election, Kirin shall become obligated to reimburse to Dendreon as part of the transfer price: (a) ten percent (10%) of the documented cost (in U.S. dollars) to Dendreon of the scale-up to which the PA2024 Price Election and purchase relates and (b) ten percent (10%) of the documented cost (in U.S. dollars) to Dendreon of any lesser scale-up costs not previously reimbursed by Kirin to Dendreon. The full reimbursable amount under the preceding sentence shall be paid as part of the transfer price of the first order placed by Kirin under the PA2024 Price Election. Kirin shall pay Dendreon fifty percent (50%) of the transfer price for a particular order of PA2024 within thirty (30) days of placing its order for PA2024, and fifty percent (50%) of such transfer price within thirty (30) days of delivery of the ordered PA2024, pursuant to Section 2.4.

(b) Dendreon's Purchase of Particular Kirin Components. Per Dendreon's purchase of particular Kirin Components, Dendreon shall pay Kirin for the purchase of such Kirin Components a transfer price in an amount in U.S. Dollars equal to Kirin's Fully-Burdened Manufacturing Costs of such Kirin Components plus a handling fee of twenty percent (20%). Dendreon shall pay Kirin fifty percent (50%) of the transfer price for a particular order of Kirin Components within thirty (30) days of placing its order for such Kirin Components, and fifty percent (50%) of such transfer price within thirty (30) days of delivery of such Kirin Components, pursuant to Section 2.4.

## 5.2 Audit.

(a) Upon the written request of a Party (the "Auditing Party"), and not more than once in each calendar year, the other Party (the "Audited Party") shall permit an independent certified public accounting firm of nationally recognized standing selected by the

Auditing Party, and reasonably acceptable to the Audited Party, at the Auditing Party's expense, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of the Audited Party as may be reasonably necessary to verify the accuracy of (b) the reports of the Audited Party's Fully-Burdened Manufacturing Costs for Components hereunder or (c) Dendreon's claim for reimbursement of scale-up costs under Section 5.1(a)(ii). However, the Audited Party shall only be obligated to maintain and produce records for any calendar year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm shall disclose to the Auditing Party and the Audited Party only whether such reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Auditing Party.

(b) — (d) If such accounting firm concludes that the Audited Party overstated its Fully-Burdened Manufacturing Costs for a particular Component or Components during such period, the Audited Party shall reimburse the Auditing Party the difference between what the Auditing Party paid and what was actually owed, with interest from the date originally due at the prime rate, as published in The Wall Street Journal (Eastern U.S. Edition) on the last business day preceding such date, within thirty (30) days after the date the Auditing Party delivers to the Audited Party such accounting firm's written report. If the amount of the difference is greater than five percent (5%) of the total amount owed, then the Audited Party shall in addition reimburse the Auditing Party for all costs related to such audit.

(e) — (e) The Auditing Party shall treat all information subject to review under this Section 5.2 in accordance with the confidentiality provisions of Article 6 of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the Audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

(d) — (f) If the Audited Party in good faith disputes the conclusion of the accounting firm under subsection (b) above that the Audited Party overstated its Fully-Burdened Manufacturing Costs for a particular Component or Components, or any specific aspect of the conclusion, then the Audited Party shall inform the Auditing Party by written notice within thirty (30) days of receiving a copy of the audit containing such conclusion, specifying in detail the

reasons for the Audited Party's disputing such conclusion. The Parties shall promptly thereafter meet and negotiate in good faith a resolution to such dispute. In the event that the Parties are unable to resolve such dispute within sixty (60) days after such Audited Party notice, the matter shall be resolved in a manner consistent with the procedures set forth in Section 11.7.

### **5.3-5.3 Financing the Development of Dendreon Products.**

(a) As set forth below, Kirin shall have the option, but not the obligation, to provide financial support for the development of Dendreon Products which Dendreon desires Kirin to financially support and which are to be supplied to Kirin hereunder. To exercise its option to support those certain Dendreon Products, Kirin shall notify Dendreon in writing, within thirty (30) days of Kirin's receipt of written notice from Dendreon that Dendreon is developing such a Dendreon Product, that Kirin agrees to pay Dendreon for all of its scale-up and other development costs related to the development of the Dendreon Components for such Dendreon Product up to a total of one million U.S. dollars (\$1,000,000) for such Dendreon Product. All payments due to Dendreon pursuant to this Section 5.3 shall be made by Kirin within thirty (30) days of receipt of Dendreon's invoice therefor. The foregoing option shall be exercised, if at all, on a product-by-product basis as to each Dendreon Product for which Dendreon provides Kirin the applicable notice.

(b) The Parties acknowledge that Kirin has properly exercised its option to provide financial support for Licensed Dendreon Products APC 8015 and APC 8020 within the meaning of Section 5.3(a) of the Agreement and that Kirin has provided its full share of such financial support for purposes of fixing the transfer price of the Separation Devices and PA2024.

## **ARTICLE 6-**

### **ARTICLE 6:**

#### **CONFIDENTIALITY**

6.1-6.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for ten (10) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose to a Third Party or use for any purpose other than as provided for in this

Agreement any Information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "Confidential Information"), except to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

- (a) — (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
- (b) — (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) — (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or
- (d) — (d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

**6.2-6.2 Authorized Disclosure.** Each Party may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed.

**6.3-6.3 Survival.** This Article 6 shall survive the termination or expiration of this Agreement for a period of ten (10) years.

**ARTICLE 7—**  
**ARTICLE 7:**  
**INTELLECTUAL PROPERTY**

Unless specifically and expressly granted herein, no licenses or rights under either Party's intellectual property rights are implied or granted in this Agreement. Each Party shall retain full ownership of all its inventions and intellectual property. The prosecution of any patents, patent applications and any and all other intellectual property rights associated with the manufacture and supply of Components shall be governed by the terms of the Collaborative License Agreement.

**ARTICLE 8—**  
**ARTICLE 8:**  
**REPRESENTATIONS AND WARRANTIES**

**8.1-8.1 General.** Each of the Parties hereby represents and warrants: (a) the Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms; (b) the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound; and (c) the Agreement does not violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

**8.2-8.2 Component Warranty.**

**(a)——(a)** Dendreon warrants to Kirin, for a period of twelve (12) months from delivery for Separation Devices and Reagent, a period of nine (9) months from delivery for recombinant antigen PA 2024 and a period of six (6) months from delivery for Dendreon Antigen other than recombinant antigen PA 2024, that the Separation Devices, Reagent and Dendreon Antigen, as applicable, supplied by Dendreon to Kirin shall: (i) be manufactured in accordance with current Good Manufacturing Practices (for medical devices and drugs as promulgated and amended by the FDA); and (ii) conform with applicable Dendreon specifications at the time of delivery by Dendreon. The preceding warranty specifically excludes, and Dendreon shall not be liable for, any action or omission by Kirin or any other

entity, specifically including any failure to store or transport Dendreon Components in accordance with applicable specifications, which results in the damage or destruction of Dendreon Components after Dendreon has delivered the Dendreon Components to Kirin pursuant to Section 2.4. Kirin's sole remedy for breach of the foregoing warranty as to a particular Dendreon Component shall be repair, replacement or refund of the purchase price paid by Kirin, at Dendreon's sole option.

**(b) — (b)** Kirin warrants to Dendreon, for a period of twelve (12) months from delivery, pursuant to Section 2.4, for any Kirin Components other than Kirin Antigen, and a period of six (6) months from delivery for Kirin Antigen, that the Kirin Components supplied by Kirin to Dendreon shall: (i) be manufactured in accordance with current Good Manufacturing Practices (for medical devices and drugs as promulgated and amended by the FDA); and (ii) conform with applicable Kirin specifications at the time of delivery by Kirin. The preceding warranty specifically excludes, and Kirin shall not be liable for, any action or omission by Dendreon or any other entity, specifically including any failure to store or transport Kirin Components in accordance with applicable specifications, which results in the damage or destruction of Kirin Components after Kirin has delivered the Kirin Components to Dendreon pursuant to Section 2.4. Dendreon's sole remedy for breach of the foregoing warranty as to a particular Kirin Component shall be repair, replacement or refund of the purchase price paid by Dendreon, at Kirin's sole option.

**8.3-8.3 Warranty Disclaimer.** THE EXPRESS WARRANTIES IN THIS ARTICLE 8 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

## **ARTICLE 9**

### **ARTICLE 9:**

#### **TERM AND TERMINATION**

**9.1-9.1 Term.** This Agreement shall commence on the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the expiration or termination of the

Collaborative License Agreement, unless extended upon the mutual, written agreement of the Parties.

**9.2 9.2 Termination.**

(a) — (a) If either Party materially breaches this Agreement at any time, which breach is not cured within thirty (30) days of written notice thereof if such breach is caused by the failure of a Party to meet its financial obligations under this Agreement, or within ninety (90) days of written notice thereof for any other material breach of this Agreement, from the non-breaching Party specifying in detail the nature of the breach, the non-breaching Party shall have the right to terminate the Agreement.

(b) — (b) Either Party may terminate this Agreement, effective immediately upon the giving of written notice, if the other Party shall file a petition for bankruptcy, or shall be adjudicated a bankrupt or insolvent, or shall take advantage of the insolvency laws of any state of the United States or of any country, or shall make an assignment for the benefit of creditors, or shall have a receiver appointed, whether by private instrument or by court officer, for its property which is not dismissed within sixty (60) days, or become subject to an involuntary petition for bankruptcy which is not dismissed within sixty (60) days.

**9.3 9.3 Surviving Obligations.** Termination or expiration of this Agreement shall not (a) affect any other rights of either Party which may have accrued up to the date of such termination or expiration, or (b) relieve Purchaser of its obligation to pay to Supplier sums due in respect of Components delivered and accepted prior to termination or expiration of this Agreement. The provisions of Articles 6, 7 and 10, and Sections 3.9(b), 4.4, 5.2 and 11.6 of this Agreement shall survive termination or expiration of this Agreement.

**9.4 9.4 Termination Without Cause.** This Agreement may be terminated at any time upon mutual, written agreement of the Parties.

**ARTICLE 10**  
**ARTICLE 10:**  
**INDEMNIFICATION**

**10.1-10.1 Indemnification by Dendreon.**

**(a) ——(a)** Subject to compliance with Section 10.3, Dendreon agrees to indemnify, defend and hold harmless Kirin, its Affiliates, and their respective officers, directors, shareholders, representatives, agents and employees (the “Kirin Indemnitees”), from and against any and all losses, liabilities, damages, costs, fees and expenses, including reasonable legal costs and attorneys’ fees (“Losses”) resulting from a Third Party claim, suit or action based upon: (i) death or injury to any person or damage to any property to the extent caused by the defective or negligent manufacture of a Component or Product manufactured by or on behalf of Dendreon and sold to Kirin and its Affiliates hereunder (the “Defective Manufacturing Claim”); (ii) death or injury to any person or damage to any property to the extent caused by the defective or negligent marketing or promotion of a Product by Dendreon or its Affiliates hereunder (a “Defective Marketing Claim”); (iii) harm or damage attributable to or caused by the acts or omissions of Dendreon or its Affiliates or their respective officers, directors, representatives, agents or employees; or (iv) breach of any representation or warranty of Dendreon set forth in Article 8.

**(b) ——(b)** Dendreon shall have no obligation under this Section 10.1 with respect to any Losses resulting from: (i) the negligent or intentionally wrongful act or omission of Kirin, its Affiliates or their respective officers, directors, representatives, agents or employees; (ii) the improper storage, transportation, marketing, training, or handling of a Component or Product by any person or entity other than Dendreon, its Affiliates or their respective officers, directors, representatives, agents or employees; (iii) the improper use of a Component or Product by any person or entity other than Dendreon, its Affiliates or their respective officers, directors, agents or employees; or (iv) any claims based upon death or injury to any person or damage to any property caused by a Component or Product that is attributable to or caused by acts or omissions of Kirin or its sublicensees or their respective Affiliates or their respective officers, directors, representatives, agents or employees. With respect to any Third Party claim, suit or action based

upon death or injury to any person or damage to any property based on use of a Product, Dendreon agrees to provide Kirin, at Kirin's expense, with reasonable assistance in Kirin's defense of such claim, suit or action.

**10.2 Indemnification by Kirin.**

**(a)** Subject to compliance with Section 10.3, Kirin agrees to indemnify and defend Dendreon, its Affiliates, and their respective officers, directors, shareholders, representatives, agents and employees (the "Dendreon Indemnitees"), from and against any and all Losses (as defined in Section 10.1) resulting from a Third Party claim, suit or action based upon: (i) a Defective Manufacturing Claim (as defined in Section 10.1); (ii) a Defective Marketing Claim (as defined in Section 10.1); (iii) harm or damage attributable to or caused by the acts or omissions of Kirin or its Affiliates or their respective officers, directors, representatives, agents or employees; or (iv) breach of any representation or warranty of Kirin in Article 8.

**(b)** Kirin shall have no obligation under this Section 10.2 with respect to any Losses resulting from: (i) the negligent or intentionally wrongful act or omission of Dendreon, its Affiliates or their respective officers, directors, representatives, agents or employees; (ii) the improper storage, transportation, marketing, training, or handling of a Component or Product by entities or persons other than Kirin or its sublicensees or their respective Affiliates, or their respective officers, directors, representatives, agents or employees; (iii) the improper use of a Product or Component, unless caused by Kirin or its sublicensees or their respective Affiliates, or their respective officers, directors, representatives, agents or employees; or (iv) any claims based upon death or injury to any person or damage to any property caused by a Component or Product that is attributable to or caused by acts or omissions of Dendreon or its sublicensees or their respective Affiliates or their respective officers, directors, representatives, agents or employees. With respect to any Third Party claim, suit or action based upon death or injury to any person or damage to any property based on use of a Product, Kirin agrees to provide Dendreon, at Dendreon's expense, with reasonable assistance in Dendreon's defense of such claim, suit or action.

**10.3-10.3 Indemnity Procedure.** In the event that a Party is seeking indemnification under Section 10.1 or 10.2, it shall inform the other Party (the "Indemnifying Party") of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and, at the Indemnifying Party's expense, shall cooperate as reasonably requested in the defense of the claim. The Indemnified Party shall have the right to retain its own counsel, subject to the approval of any such outside counsel by the Indemnifying Party, with the fees and expenses to be paid by the Indemnifying Party if representation of such Party by the counsel retained by Indemnifying Party would be inappropriate due to actual or potential differing interests between such indemnitee and any other Party represented by such counsel in such proceedings. The Indemnifying Party may not settle such action or claim, or otherwise consent to an adverse judgment in such action or claim, without the express written consent of the Indemnified Party if such settlement or adverse judgment diminishes the rights or interests of the Indemnified Party.

## **ARTICLE 11**

### **ARTICLE 11:**

#### **MISCELLANEOUS**

**11.1-11.1 Assignment.** Neither Party shall assign any of its rights and obligations hereunder except (i) as incident to the merger, consolidation, reorganization or acquisition of stock affecting actual voting control or of substantially all of the assets of the assigning Party; or (ii) to an Affiliate; provided, however, that in no event shall either Party's rights and obligations hereunder be assigned without prior written notice to the other Party. In any case, neither Party may make an assignment of its assets which renders it unable to perform its material obligations hereunder. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns.

**11.2-11.2 Retained Rights.** Nothing in this Agreement shall limit in any respect the right of either Party to conduct research and development with respect to, and market products outside of, the Field using such Party's Technology, but no license to use the other Party's technology to do so is granted herein expressly or by implication.

**11.3** **Force Majeure.** Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, in no event shall a Party be required to settle any labor dispute or disturbance.

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

**11.5** **No Trademark Rights.** Except as otherwise provided in the Collaborative License Agreement, no right, express or implied, is granted by the Agreement to use in any manner the name "Dendreon" or "Kirin" or any other trade name or trademark of the other Party in connection with the performance of the Agreement.

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

If to Dendreon, addressed to:

Dendreon Corporation  
3005 1<sup>st</sup> Avenue  
Seattle, WA 98121-1010

Attention: C. S. HenneyGeneral Counsel  
Telephone: (206) 256-4545  
TelexFacsimile: (206) 256-0571

With copy to:

~~Eeoley Godward LLP~~

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McNaul Ebel Nawrot Helgren & Vance P.L.L.C.  
Five Palo AltoOne Union Square, 4th Floor  
Palo Alto, CA 94306  
600 University Street, Suite 2700  
Seattle, WA 98101-3143

Attention: Barelay James KambPeter M. Vial, Esq.  
Telephone: (650) 843-467-50521816  
Telexopy: (650) 857-0663  
Facsimile: (206) 624-5128

If to Kirin, addressed to:

Kirin Brewery Co., Ltd.  
26-1, Jingumae 6-chome  
Shibuya-ku  
Tokyo 150-8011, Japan

Attention: Akihiro ShimosakaGeneral Manager  
Research and Product DevelopmentPlanning Department  
Pharmaceutical Division  
Telephone: (03) 5485-68056292  
Telexopy:

Facsimile: (03) 3499-5485-61526316

With a copy to:

Pennie & Edmonds LLP  
1155 Avenue of the Americas  
New York, NY 10036

Attention: Rory J. Radding, Esq.  
Telephone: (212) 790-9090  
Facsimile: (212) 869-9741

**11.7 Dispute Resolution.** If any dispute, controversy or claim arises out of or in connection with this Agreement, the Parties shall use reasonable efforts to settle it by friendly negotiation within sixty (60) days of notice from one Party to the other of such dispute, controversy or claim, before pursuing any other remedies available to them. If either Party fails or refuses to participate in such negotiations, or if, in any event, the dispute, controversy or claim is not resolved to the satisfaction of both Parties within the sixty (60) day period, any such dispute, controversy or claim shall be settled by arbitration. Any such arbitration shall be

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conducted in accordance with the Japan-American Trade Arbitration Agreement of September 16, 1952. The Parties agree that any such arbitration shall be conducted in the English language in a location within the United States selected by the Party that did not initiate such arbitration, and the Agreement shall be governed by and construed in accordance with the laws of the State of California and the United States of America. The arbitrators shall include one independent ~~un-affiliated~~unaffiliated nominee selected by each Party and a third neutral arbitrator selected by such nominees. The Parties agree that any arbitration panel shall include members knowledgeable as to the evaluation of biopharmaceutical technology. Judgment upon the award rendered may be entered in the highest state or federal court or forum, state or federal, having jurisdiction; *provided, however,* that the provisions of this Section 11.7 shall not apply to any dispute or controversy as to which any treaty or law prohibits such arbitration. The prevailing Party shall be entitled to reasonable attorney's fees and costs to be fixed by the arbitrators.

**11.8-11.8** **Waiver.** Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

**11.9-11.9** **Severability.** If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law.

**11.10-11.10** **Ambiguities.** Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**11.11-11.11** **Entire Agreement.** This Agreement ~~sets~~and any agreements referenced ~~herein~~ set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with regard to the subject matter discussed herein and supersedes and terminates all prior agreements and understanding between the Parties with

regard to the subject matter discussed herein. Specifically, this Agreement supercedes and terminates the Original Supply Agreement and the Memorandum. There are no covenants, promises, agreements, warranties, representations conditions or understandings, either oral or written, between the Parties with regard to the subject matter discussed herein other than as set forth in this Manufacturing and Supply Agreement or any agreements referenced herein. For clarity, a redlined version of this Agreement, showing the changes made to the Original Supply Agreement, is attached hereto as Exhibit A. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

**11.12-11.12 Headings.** The Section and Paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the Section or Paragraphs to which they apply.

**11.13 Undefined Terms.** Terms that are capitalized but undefined in this Manufacturing and Supply Agreement shall be defined as set forth in any other of the Parties' Agreements (and in amendments to the foregoing agreements). Terms that are capitalized but undefined in any amendment to this Manufacturing and Supply Agreement shall be defined as set forth in this Manufacturing and Supply Agreement and in any other of the Parties' Agreements (and in amendments to the foregoing agreements). However, if there is a conflict or inconsistency between the definition of a capitalized term appearing in this Manufacturing and Supply Agreement or in any amendments hereto, on the one hand, and a definition of the same capitalized term appearing in any other of the Parties' Agreements and amendments thereto, on the other, then the definition of the capitalized term set forth in the Collaborative License Agreement and in the amendment hereto shall control.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

DENDREON CORPORATION

By: \_\_\_\_\_

Title: \_\_\_\_\_

KIRIN BREWERY CO., LTD.

By: \_\_\_\_\_

Title: \_\_\_\_\_

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**EXHIBIT A**

**REDLINED AGREEMENT**

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**AMENDED AND RESTATED**

**MANUFACTURING AND SUPPLY AGREEMENT**

**BETWEEN**

**DENDREON CORPORATION**

**AND**

**KIRIN BREWERY CO., LTD.**

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