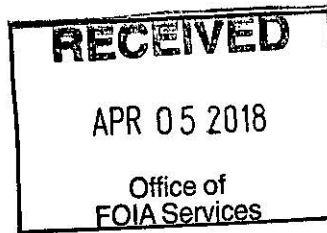


18-03774-E



Debra Smetana
kMINE
940 West Adams
Suite 100
Chicago, IL 60607

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibit 10.2 to Form 8-K filed on 11/13/2001 by Immunex Corp

We authorize \$0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

Debra Smetana



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

Office of FOIA Services

May 2, 2018

Ms. Debra Smetana
ktMINE
940 West Adams, Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03774-E

Dear Ms. Smetana:

This letter is in response to your request dated and received in this office on April 5, 2018, for Exhibit 10.2 to the Form 8-K filed by Immunex Corp. on November 13, 2001.

Your request is granted in full. The 51-page exhibit is enclosed with this letter. Because this exhibit was released in response to a previous FOIA request, no processing fees have been assessed.

If you have any questions, please contact me at Gbenoua@sec.gov or (202) 551-5327. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Jeffery Ovall as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Amy Gbenou

Amy Gbenou
FOIA Research Specialist

Enclosure

10.2

**CONFIDENTIAL TREATMENT
REQUESTED**

COLLABORATION AND GLOBAL SUPPLY AGREEMENT

By and Between

IMMUNEX CORPORATION

and

**AMERICAN HOME PRODUCTS CORPORATION acting through its
WYETH-AYERST PHARMACEUTICALS division**

RECEIVED
OFFICE OF THE SECRETARY
2001 NOV 14 PM 3:07

COLLABORATION AND GLOBAL SUPPLY AGREEMENT

This **COLLABORATION AND GLOBAL SUPPLY AGREEMENT** (the "Agreement") is entered into this 6th day of November, 2001 (the "Effective Date"), by and between **IMMUNEX CORPORATION**, a Washington corporation having its principal place of business at 51 University Street, Seattle, Washington 98101, together with its Affiliates (collectively, "Immunex") and **AMERICAN HOME PRODUCTS CORPORATION**, a Delaware corporation having its corporate headquarters at Five Giralda Farms, Madison, New Jersey 07940, together with its Affiliates (collectively, "AHPC"), acting through its **WYETH-AYERST PHARMACEUTICALS** division, having offices at 555 East Lancaster Avenue, St. Davids, Pennsylvania 19087, together with its Affiliates (collectively, "Wyeth").

Background

WHEREAS, Immunex and AHPC entered into a TNFR License and Development Agreement dated July 1, 1996 (the "TNFR Agreement"), in which they agreed to collaborate as set forth in the TNFR Agreement with regard to Enbrel® (etanercept) ("Enbrel"), a biopharmaceutical product for the treatment of rheumatoid arthritis and other diseases;

WHEREAS, in the TNFR Agreement, the Parties agreed that Immunex would have certain rights to market and sell *Enbrel* in the United States, its territories and possessions (including Puerto Rico), and Canada, and that Wyeth would have certain rights to market and sell *Enbrel* in all other countries;

WHEREAS, Immunex and AHPC entered into a Promotion Agreement dated September 25, 1997, regarding the marketing and promotion of *Enbrel* in the Immunex Territory (the "Promotion Agreement");

WHEREAS, Immunex and AHPC entered into an Enbrel Supply Agreement with Boehringer Ingelheim Pharma KG (including any successor thereto, "BIP") dated November 5, 1998, which agreement was amended by Amendment No. 1 to the Enbrel Supply Agreement dated June 27, 2000, in which BIP agreed to manufacture certain quantities of *Enbrel* and supply those quantities to Immunex and Wyeth;

WHEREAS, Greenwich Holdings, Inc. ("Greenwich"), a wholly-owned subsidiary of AHP Subsidiary Holding Corporation ("AHPS"), a wholly-owned subsidiary of AHPC, owns a manufacturing facility located in West Greenwich, Rhode Island at which *Enbrel* is expected to be manufactured;

WHEREAS, Immunex, AHPC, and AHPS have entered into a Purchase Agreement simultaneously with this Agreement, pursuant to which AHPS is obligated to sell, and Immunex is obligated to purchase, the shares of Greenwich;

WHEREAS, AHP Manufacturing B.V., a wholly-owned indirect subsidiary of AHPC, through its Wyeth Medica Ireland branch, is in the process of constructing a manufacturing facility in Ireland, at which it plans to manufacture *Enbrel*, among other products;

WHEREAS, the Parties entered into a letter agreement regarding the short-term allocation of *Enbrel* supplies dated August 9, 2000 (the "Short-Term Allocation Agreement"), which agreement is attached hereto as Exhibit C;

WHEREAS, the Parties agreed, in a Memorandum of Understanding Regarding Long-Term Allocation of ENBREL Supplies dated August 9, 2000, as amended on April 18, 2001 (the "MOU"), to enter into a Collaboration Agreement regarding the manufacture, inventory, and allocation of supplies of *Enbrel* throughout the world, which MOU is superceded by this Agreement and is of no further force and effect; and

WHEREAS, the Parties now wish to set forth their mutual agreements concerning the manufacture, supply, inventory, and allocation of supplies of *Enbrel* throughout the world.

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

Article 1. Definitions

The following terms, whether used in the singular or the plural, shall have the meaning assigned to them below for purposes of this Agreement.

- 1.1 "Affiliate" shall mean: (a) any corporation or business entity of which a Party owns, directly or indirectly, fifty percent (50%) or more of the assets or outstanding stock; (b) any corporation, or business entity which a Party directly or indirectly controls; (c) any corporation or business entity that is under common control with a Party; (d) any corporation or business entity that owns, directly or indirectly, fifty percent (50%) or more of the assets or outstanding stock of a Party; or (e) any corporation or business entity that directly or indirectly controls a Party. For the purposes of this Agreement, neither Party shall be considered to be an Affiliate of the other Party, even if a Party owns, directly or indirectly, fifty (50%) or more of the assets or outstanding stock of the other Party, directly or indirectly controls the other Party, or is under common control with the other Party.
- 1.2 "Allocable Overhead" shall mean costs allocated to the manufacture of Bulk Drug Substance based on methodology consistently applied in the project accounting system and determined in accordance with GAAP. Allocable Overhead shall include:

- (i) indirect labor, benefits and taxes, indirect supplies, outside laboratory services, laboratory and plant consumables, and other indirect department expenses;
- (ii) facility costs such as rent, depreciation (excluding depreciation of capitalized interest), utilities, facility repair and maintenance and monitoring;
- (iii) other overhead costs, including infrastructure services, purchasing, information systems, accounting, period costs, and other related expenses; and
- (iv) such other costs as the Parties may agree upon in writing from time to time.

An example of the methodology to be used in calculating Allocable Overhead is included in Exhibit A attached hereto. Allocable Overhead shall not include any costs attributable to general corporate activities, including but not limited to executive management, investor relations, business development, legal affairs, and finance.

- 1.3 "BIOS Capacity" shall mean the volume of Bulk Drug Substance that the Parties reasonably expect to be manufactured within bioreactors having a working volume equivalent to the RI Capacity during a Calendar Year.
- 1.4 "BIOS Site" shall mean the portion of the biopharmaceutical manufacturing facility to be built at the Wyeth BioPharma campus at Grange Castle International Business Park, Clondalkin, Dublin 22, Ireland, within which the BIOS Capacity will be manufactured. The BIOS Site shall not include such manufacturing facility with respect to its manufacture of Excluded Supply or products other than the Product.
- 1.5 "BIP Capacity" shall mean the volume of Bulk Drug Substance that Immunex and Wyeth reasonably expect to purchase collectively from BIP pursuant to the Enbrel Supply Agreement during a Calendar Year, excluding any Bulk Drug Substance from Bulk Drug Substance Runs that have been separately negotiated pursuant to an agreement between only one of the Parties hereto and a Third Party customer of BIP on or before March 26, 2001.
- 1.6 "BIP Site" shall mean that portion of BIP's facility at Birkendorfer Straße 65, 88397 Biberach an der Riss, Federal Republic of Germany, within which the BIP Capacity is or will be manufactured, including but not limited to the [H84 Plant and the G104 Plant] during a Calendar Year. In the event that the manufacture of the Product is transferred to another facility of BIP, a BIP Affiliate, or a successor of BIP in accordance with the terms of the Enbrel Supply Agreement, then the BIP Site shall refer to that portion of such successor facility in which the BIP Capacity is manufactured. ★
- 1.7 "Blended Price" shall mean the price for Bulk Drug Substance that is calculated as [the weighted average of the Standard Product Prices] for each of the Sites for a Calendar ★

Year, as further described in Section 9.3 below. An example of the calculation of the Blended Price is set forth on Exhibit A attached hereto.

- 1.8 "Bulk Drug Substance" shall mean etanercept that has been processed to result in bulk drug substance and purified to a concentrated form, and that can be stored in liquid or frozen form under appropriate conditions.
- 1.9 "Bulk Drug Substance Lot" shall mean a single lot of Bulk Drug Substance, produced at a fermentation scale of [eight thousand (8,000) liters, fifteen thousand (15,000) liters, twenty thousand (20,000) liters] or any other scale mutually agreed by the Parties. ★
- 1.10 "Bulk Drug Substance Run" shall mean a single run of the process for manufacturing a Bulk Drug Substance Lot.
- 1.11 "Calendar Quarter" shall mean a three (3)-month period commencing on the first day of January, April, July, and October of each Calendar Year during the Term.
- 1.12 "Calendar Year" shall mean a twelve (12)-month period beginning on January 1 of each year during the Term.
- 1.13 "Catalytica Supply Agreement" shall mean the Supply Agreement, dated October 16, 2000, among Immunex, Wyeth, and Catalytica Pharmaceuticals, Inc. (including any successor thereto, "Catalytica").
- 1.14 "cGMP" shall mean the regulatory requirements for current good manufacturing practices promulgated by the FDA under the FD&C Act, 21 C.F.R. § 210 *et seq.*, and under the PHS Act, Biological Products, 21 C.F.R. §§ 600-610, or the applicable regulatory guidance documents promulgated by the EMEA or Koseisho, as the same may be amended from time to time.
- 1.15 "Collaboration" shall mean the collaborative efforts of the Parties as further described herein.
- 1.16 "Confidential Information" shall mean all proprietary and confidential information of a Party, including, without limitation, trade secrets, technical information, business information, sales information, customer and potential customer lists and identities, product sales plans, license and sublicense agreements, inventions, developments, discoveries, know-how, methods, techniques, formulae, data, processes, and other proprietary ideas, whether or not protectable under patent, trademark, copyright, or other legal principles, that the other Party has access to or receives, but does not include information that (a) is or becomes publicly available through no fault of the receiving Party; (b) was already known to the receiving Party at the time it was disclosed to the receiving Party, as shown in the records of the receiving Party maintained during the ordinary course of business; (c) is independently developed by employees of the receiving Party who had no knowledge of or access to such information, as shown in the records of the receiving Party maintained in the ordinary course of business; or (d)

is received from a Third Party who is under no obligation of confidentiality to the disclosing Party. As used herein, "Confidential Information" shall include, without limitation, any and all technical information regarding the Product, Five-Year Requirement Schedules, Five-Year Capacity Projections, and Five-Year Plans.

- 1.17 "Direct Costs" shall include: (a) direct labor costs, which shall include all wages directly attributable and allocable to labor for the production of Bulk Drug Substance at the RI Site and the BIOS Site, as applicable; and (b) material costs, including the costs of acquiring all materials directly attributable and allocable to the production of Bulk Drug Substance at the RI Site and the BIOS Site, as applicable.
- 1.18 "Drug Product" shall mean Bulk Drug Substance that has been appropriately formulated, compounded, filled into containers and lyophilized (if applicable), but is not labeled (*i.e.*, unlabeled vial or syringe packed in a labeled secondary shipper).
- 1.19 "EMA" shall mean the European Medicines Evaluation Agency, or any successor agency.
- 1.20 "Enbrel Supply Agreement" shall mean the November 5, 1998 agreement among Immunex, BIP, and AHPC for the manufacture of Product at the BIP Facility, as amended on June 27, 2000 and as may be amended from time to time by the parties thereto.
- 1.21 "European Union" shall mean those countries within the jurisdiction of the EMA.
- 1.22 "Excluded Supply" shall mean (a) any quantities of Product manufactured or acquired by Immunex outside of the RI Capacity or BIP Capacity, and (b) any quantities of Product manufactured or acquired by Wyeth outside of the BIOS Capacity or the BIP Capacity.
- 1.23 "FDA" shall mean the United States ("U.S.") Food and Drug Administration, or any successor agency.
- 1.24 "Finished Product" shall mean Drug Product in a vial or syringe that has been appropriately labeled and that is suitable for shipment in bulk packaging to Immunex, Wyeth and/or their respective designee(s) for final commercial packaging and conversion to Product Supply.
- 1.25 "Fully Absorbed Manufacturing Cost" shall have the meanings set forth below:
 - (a) For Bulk Drug Substance manufactured at the RI Site or the BIOS Site, Fully Absorbed Manufacturing Cost shall mean [one hundred percent (100%)] of all costs, expenses, and period costs incurred at the Site for the manufacturing of Bulk Drug Substance incurred by the Party controlling such Site, determined according to GAAP and as mutually agreed upon by the Parties. Such costs shall include Direct Costs and Allocable Overhead at each stage of the process

for manufacturing Bulk Drug Substance at such Site. Fully Absorbed Manufacturing Cost shall also include any other costs borne by the Party controlling such Site for transport, customs clearance and storage of Bulk Drug Substance (if necessary) at the request of another Party or a Third Party (*i.e.*, freight, customs duty, and transportation related insurance). Fully Absorbed Manufacturing Cost shall exclude any losses at the RI Site or BIOS Site resulting from a significant or catastrophic event that would otherwise be covered by property insurance, regardless of whether such insurance is in place. To the extent that the manufacturing capacity at the RI Site or BIOS Site is utilized to manufacture a product other than the Product, the Direct Costs and Allocable Overhead incurred for the manufacture of such other product shall be excluded from the calculation of Fully Absorbed Manufacturing Cost.

- (b) For Bulk Drug Substance manufactured at the BIP Site, Fully Absorbed Manufacturing Cost shall mean the amount paid or payable by a Party to BIP for Bulk Drug Substance purchased by a Party under the Enbrel Supply Agreement, whether purchased in the form of Bulk Drug Substance itself or as incorporated into Drug Product or Finished Product, as the case may be.

An example of the calculation of Fully Absorbed Manufacturing Cost is included in Exhibit A attached hereto.

- 1.26 "GAAP" shall mean U.S. Generally Accepted Accounting Principles consistently applied.
- 1.27 "G104 Plant" shall mean the manufacturing facility that BIP is currently constructing at the BIP Site in which it plans to manufacture Bulk Drug Substance. ★
- 1.28 "H84 Plant" shall mean the manufacturing facility at the BIP Site in which BIP currently manufactures Bulk Drug Substance. ★
- 1.29 "Immunex Territory" shall mean the U.S., its territories and possessions (including Puerto Rico) and Canada.
- 1.30 "Inventory Carrying Costs" shall mean seven percent (7%) per annum of the Fully Absorbed Manufacturing Cost of Bulk Drug Substance manufactured at either the RI Site or the BIOS Site, as applicable, and held in storage by or on behalf of a Party for a period greater than sixty (60) days after release by both Parties, commencing after such sixty (60)-day period has elapsed. ★ ★ ★
- 1.31 "ISP" shall mean the Immunex proprietary process for manufacturing Bulk Drug Substance, which, if used at the RI Site, shall include the hydroxyapatite chromatography step and which process is the subject of a letter agreement among Immunex, Wyeth, and BIP dated May 29, 2001. ★ ★

- 1.32 "Major Markets" shall mean the U.S., the European Union, and Japan.
- 1.33 "Manufacturing Process" shall mean a process for manufacturing Bulk Drug Substance and/or Drug Product, including but not limited to the T1 Process, the ISP, and the T2 Process. ★
- 1.34 "Party" or "Parties" shall refer to Immunex, AHPC, and/or Wyeth, as applicable.
- 1.35 "Phase A Capacity" shall mean the volume of Bulk Drug Substance that the Parties reasonably expect to be manufactured within the eight (8) eight-thousand (8,000) liter nominal volume bioreactors contained in the Phase A Facility during a Calendar Year, or, if Immunex transfers such manufacturing to the Phase B Facility, the volume of Bulk Drug Substance that the Parties reasonably expect to be manufactured within bioreactors of equivalent working volume in the Phase B Facility during a Calendar Year. ★
- 1.36 "Phase A Facility" shall mean the manufacturing plant at the RI Site that Wyeth is currently in the process of retrofitting to manufacture Bulk Drug Substance.
- 1.37 "Phase B Additional Capacity" shall mean the volume of Bulk Drug Substance that the Parties reasonably expect to be manufactured within three (3) twenty-thousand (20,000) liter nominal volume bioreactors in the Phase B Facility per Calendar Year. ★
- 1.38 "Phase B Facility" shall mean the new manufacturing facility that Immunex plans to construct located on the portion of the RI Site that Immunex Manufacturing Corporation has leased from Greenwich pursuant to the Ground Lease between those parties dated March 9, 2001.
- 1.39 "Product" shall mean the pharmaceutical product etanercept, in any form.
- 1.40 "Product Supply" shall mean Finished Product that has been fully packaged and is in final form for distribution for commercial sale or clinical testing in any country in the Immunex Territory or the Wyeth Territory.
- 1.41 "Product Supply Units" shall refer to individual units of Product Supply.
- 1.42 "Production Surplus" shall mean the situation, as may be determined by the JSC from time to time, in which the Parties' forecasted needs for Product Supply in any Calendar Year fall more than seven percent (7%) below the total quantity of Bulk Drug Substance that can be manufactured in the Subject Capacity during such Calendar Year. ★
- 1.43 "Quality Agreement" shall mean the Quality Agreement attached hereto as Exhibit D, as the same may be amended from time to time, setting forth the terms and conditions relating to (a) the quality, safety, efficacy, and purity of the Bulk Drug Substance supplied by each Party to the other hereunder, (b) the respective roles and responsibilities of Immunex and Wyeth relating to quality control, quality assurance,

validation, ongoing manufacturing, materials, standards, and the functions of person(s)-in-the-plant, and (c) procedures for resolving disputes regarding any of the foregoing.

- 1.44 "Regulatory Authority" shall mean (a) the applicable government agency or agencies in a country whose permission, approval, or clearance must be obtained for, or which has jurisdiction over, the manufacturing, production, clinical testing, and/or marketing of the Product, including, but not limited to, the FDA, the EMEA, and Koseisho; and (b) any state, provincial, or local government agency or entity with jurisdiction, to any extent, over the Party supplying the Product, a Site, or the Product.
- 1.45 "Regulatory Filings" shall mean all documents and other information filed with and/or submitted to one or more Regulatory Authorities and which are related to the Product.
- 1.46 "Regulatory Requirements" shall mean (a) all Specifications, methods of manufacture, and other information in one or more Regulatory Filings in a Major Market related in any way to the Product, and (b) all laws, rules, regulations, applicable regulatory guidance documents, and other requirements of any Regulatory Authority in a Major Market that govern the Product, the manufacture of the Product, and use of the Product in or with Finished Products, including, but not limited to, the requirements set forth in the United States Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), 21 U.S.C. Section 301 *et seq.*, the Public Health Service Act (the "PHS Act"), 42 U.S.C. Section 262 *et seq.*, cGMPs, any applicable regulations promulgated by the EMEA, and any applicable regulations promulgated by Koseisho, as the same may be amended from time to time.
- 1.47 "Released Bulk Drug Substance" shall mean, with respect to a particular Site and a particular Calendar Year, Bulk Drug Substance that is, or is expected to be, released at such Site during such Calendar Year, including (a) any such Bulk Drug Substance for which manufacturing was commenced and completed and which was released during such Calendar Year, and (b) any such Bulk Drug Substance released during such Calendar Year that was Work In Process at the end of the prior Calendar Year.
- 1.48 "RI Capacity" shall mean the volume of Bulk Drug Substance that the Parties reasonably expect to be manufactured from the combined capacity of the Phase A Capacity and the Phase B Additional Capacity in a Calendar Year.
- 1.49 "RI Site" shall mean the portion of the biopharmaceutical manufacturing facility in West Greenwich, Rhode Island, currently owned by Greenwich, within which the RI Capacity is or will be manufactured. The RI Site shall not include such manufacturing facility with respect to its manufacture of Excluded Supply or products other than the Product.
- 1.50 "Safety Agreement" means the Memorandum of Understanding between Immunex Drug Safety Surveillance and Wyeth-Ayerst for the Identification, Collection, Evaluation and Regulatory Reporting of Adverse Events and Product Quality and for

the Provision of Medical Information for Enbrel® (etanercept), effective as of December 13, 2000, as the same may be amended from time to time.

- 1.51 "Site" shall mean the BIOS Site, the BIP Site, and/or the RI Site, as applicable.
- 1.52 "Specifications" shall mean a set of specifications for Bulk Drug Substance agreed upon by the Parties pursuant to the Quality Agreement.
- 1.53 "Subject Capacity" shall mean that manufacturing capacity subject to the Collaboration as further set forth in Section 2.2 below.
- 1.54 "Supply Shortage" shall mean the situation, as may be determined by the JSC from time to time, that in one or more of the first three (3) years of a Five-Year Plan approved by the JSC, the total quantity of Bulk Drug Substance that can be manufactured in the Subject Capacity is less than one hundred twenty-five percent (125%) of the Parties' forecasted requirements for Bulk Drug Substance set forth in the applicable Five-Year Requirements Schedules. When a Supply Shortage is in effect, it shall be deemed to be in effect for the first three (3) Calendar Years of a Five-Year Plan.
- 1.55 "T1 Process" shall mean the Immunex proprietary Manufacturing Process used by BIP as of the Effective Date to manufacture Bulk Drug Substance.
- 1.56 "T2 Process" shall mean the Immunex proprietary process for manufacturing Bulk Drug Substance, which process is currently the subject of the T2 Development Agreement: TNFR:FC Process (Phase I), dated January 1, 1999, among Immunex, AHPC, and BIP, as the same may be amended from time to time.
- 1.57 "Territory" shall mean the Immunex Territory or the Wyeth Territory, as applicable, and "Territories" shall mean both the Immunex Territory and the Wyeth Territory, collectively.
- 1.58 "Third Party" shall mean any party other than Immunex, Wyeth, BIP, and their respective Affiliates.
- 1.59 "Total BIOS Facility Capacity" shall mean the BIOS Capacity plus the volume of Excluded Supply that can be produced in the biopharmaceutical manufacturing facility to be built at the Wyeth BioPharma campus at Grange Castle International Business Park, Clondalkin, Dublin 22, Ireland.
- 1.60 "Type" shall mean Bulk Drug Substance produced by a specified Manufacturing Process meeting a defined Specification approved by Immunex and Wyeth pursuant to the provisions of the Quality Agreement.
- 1.61 "Work in Process" shall mean Bulk Drug Substance for which manufacturing has commenced in a Calendar Year but which has not yet been released by the end of such Calendar Year.

1.62 "Wyeth Territory" shall mean all the countries in the world other than those within the Immunex Territory.

Each of the following definitions are found in the body of this Agreement as indicated:

	<u>Section</u>
" <u>Additional Term</u> "	14.1
" <u>Adjusted Standard Product Price</u> "	9.1(b)(iv)
" <u>Base Allocation</u> "	5.2(a)
" <u>Clinical Development Requirements</u> "	5.2(b)
" <u>Cost of Goods</u> "	2.2(d)
" <u>Delivery Dates</u> "	8.2
" <u>Detailed Forecast Schedule</u> "	8.2
" <u>Firm Order</u> "	8.2
" <u>Five-Year Capacity Projection</u> "	4.2(b)
" <u>Five-Year Plan</u> "	4.2(c)
" <u>Five-Year Requirement Schedule</u> "	4.2(a)
" <u>Force Majeure Event</u> "	16.1
" <u>Greater Volume Party</u> "	2.2(d)(i)
" <u>Immunex License Agreements</u> "	10.3
" <u>Indemnitor</u> "	13.3
" <u>Indemnitee</u> "	13.3
" <u>Initial Term</u> "	14.1
" <u>JSC</u> "	3.1
" <u>Kg</u> "	5.2(a)
" <u>Liabilities</u> "	13.1
" <u>Lower Volume Party</u> "	2.2(d)(i)
" <u>Net Sales</u> "	2.2(d)
" <u>Product Development Steering Committee</u> "	5.2(b)
" <u>Product Gross Profits</u> "	2.2(d)
" <u>Production Plan</u> "	4.2(c)(i)
" <u>Publication</u> "	15.4
" <u>Reasonable Steps</u> "	15.1
" <u>RI Approval</u> "	4.1
" <u>Royalties</u> "	2.2(d)
" <u>Standard Product Price</u> "	9.1(a)
" <u>Sublicense Agreements</u> "	10.3
" <u>Supply Plan</u> "	4.2(c)(ii)
" <u>Technology Transfer and License Agreement</u> "	7.3
" <u>Term</u> "	14.1
" <u>Territory Shortage</u> "	2.2(d)

Article 2. Scope of Agreement; Subject Capacity

2.1 Scope of Agreement.

The purpose of the Collaboration is for the Parties to allocate and manage in a collaborative manner the manufacture and supply of Product deriving from the Subject Capacity.

2.2 Subject Capacity.

(a) Included Capacities. The Subject Capacity subject to the Collaboration shall be composed of the following:

- (i) the BIP Capacity;
- (ii) the RI Capacity; and
- (iii) the BIOS Capacity.

(b) Excluded Supply. Each Party shall be free to manufacture quantities of Product in addition to those included in the Subject Capacity, or to contract with a Third Party to manufacture at such Third Party's facilities such additional Product, for use by such Party within its Territory. All such additional quantities of Product Supply in excess of those included in the Subject Capacity, whether manufactured by or for a Party, shall be considered Excluded Supply that is not included within the Subject Capacity and, except as expressly set forth herein, shall not be subject to this Agreement. Without limiting the generality of the foregoing, (i) Immunex may, in its discretion, manufacture additional Product in the Phase B Facility or elsewhere at the RI Site, which additional Product shall be considered Excluded Supply, and (ii) Wyeth may, in its discretion, manufacture additional Product at the BIOS Site in excess of that included in the BIOS Capacity, which additional Product shall be considered Excluded Supply.

(c) ISP. The Parties agree that, through the JSC, they shall cooperate in good faith to ensure that Bulk Drug Substance manufactured using ISP is available from one or more of the Sites, for all markets where the T2 Process has not yet been approved. Without limiting the generality of the foregoing, until the later of June 30, 2006 or the six (6)-month anniversary of the date on which the T2 Process at the RI Site is approved by the FDA, if Wyeth's requirements for Bulk Drug Substance manufactured using the ISP cannot be met by Wyeth's allocated supply from the BIP Site and the BIOS Site hereunder, Immunex shall manufacture that quantity of Bulk Drug Substance at the RI Site to which Wyeth is entitled hereunder using the ISP. After the later of June 30, 2006 or the six (6)-month anniversary of the date on which the T2 Process at the RI Site is approved by the FDA, Immunex shall continue, at the written request of Wyeth, to manufacture Bulk Drug Substance at the RI Site using the ISP at a purchase price equal to Immunex's Fully Absorbed



Manufacturing Cost plus thirty percent (30%) of such Fully Absorbed Manufacturing Cost, and the provisions of Article 9 shall not apply to such purchases. Notwithstanding the foregoing, however, Wyeth shall not under any circumstances be entitled under this Section 2.2(c) to receive more Bulk Drug Substance from the RI Site or the BIP Site than that to which Wyeth is otherwise entitled according to the terms hereof.]

- (d) Equivalency of Capacities. Until [December 31, 2006] all supply within the Subject Capacity shall be allocated as set forth in this Agreement and purchased by the Parties for the prices set forth in Article 9 (except as set forth in Section 2.2(c)), without regard for whether the bioreactor working volume available from the RI Site is equivalent to the bioreactor working volume available from the BIOS Site. If, at any time after [December 31, 2006] the RI Site and the BIOS Site have and continue to have substantially equivalent bioreactor working volumes within the Subject Capacity, all supply within the Subject Capacity shall be allocated as set forth in this Agreement and purchased by the Parties for the prices set forth in Article 9 (except as set forth in Section 2.2(c)). Notwithstanding anything to the contrary in this Agreement, if, at any time after [December 31, 2006] the RI Site and the BIOS Site do not have and continue not to have substantially equivalent bioreactor working volumes within the Subject Capacity, all supply within the Subject Capacity shall be allocated as set forth in this Agreement and purchased by the Parties at the following prices:

- (i) Supply from Equivalent Bioreactor Working Volumes. All supply from an equivalent bioreactor working volume within the Subject Capacity from the RI Site or the BIOS Site, as applicable, shall be purchased by the Parties for the prices set forth in Article 9 (except as set forth in Section 2.2(c)). If a Party (the "Lower Volume Party") has a lower total bioreactor working volume in the Subject Capacity than the total bioreactor working volume of the other Party (the "Greater Volume Party") in the Subject Capacity with respect to all or a portion of a particular Calendar Year after [2006] the supply from the Greater Volume Party to the Lower Volume Party priced in accordance with Article 9 (except as set forth in Section 2.2(c)) for such portion of such Calendar Year shall equal [the quantity of Bulk Drug Substance allocated to the Lower Volume Party for such period pursuant to the applicable Five-Year Plan, less any Bulk Drug Substance supplied to the Lower Volume Party from its own Site and the BIP Site during such period, multiplied by a fraction of which the numerator is the total bioreactor working volume in the amount equivalent to the total bioreactor working volume of the Lesser Volume Party in the Subject Capacity, and the denominator is the total bioreactor working volume of the Greater Volume Party in the Subject Capacity during such period.]

(ii) Supply from Additional Bioreactor Working Volumes. Quantities of Bulk Drug Substance allocated to the Lesser Volume Party in the applicable Five-Year Plan in excess of the quantities supplied to the Lower Volume Party from its own Site and the BIP Site and quantities purchased pursuant to subsection (i) above shall be purchased by the Lesser Volume Party from the Greater Volume Party, and shall be priced as follows:

(A) Supply Shortage and Territory Shortage. If both a Supply Shortage and a Territory Shortage are in effect with respect to all or a portion of a particular Calendar Year after 2006, then such Bulk Drug Substance purchased by the Lesser Volume Party shall be priced as follows for that portion of such Calendar Year in which such Supply Shortage and Territory Shortage are in effect:

(1) If Wyeth is the Lesser Volume Party, then Wyeth shall pay Immunex for such Bulk Drug Substance the sum of: (a) the Standard Product Price determined as set forth in Section 9.1; and (b) the lower of (i) fifty-five percent (55%), or (ii) the percentage Immunex would be entitled to receive under Article 10 of the Promotion Agreement if Product Supply containing such Bulk Drug Substance were sold in the Immunex Territory at such time (including, for such purposes, the calculation set forth in Section 10.1(e) thereunder), of what would have been Immunex's applicable Product Gross Profits

(2) If Immunex is the Lesser Volume Party, then Immunex shall pay Wyeth for such Bulk Drug Substance the sum of: (a) the Standard Product Price determined as set forth in Section 9.1; and (b) the higher of (i) fifty-five percent (55%), or (ii) the percentage Immunex would be entitled to receive under Article 10 of the Promotion Agreement if Product Supply containing such Bulk Drug Substance were sold in the Immunex Territory at such time (including, for such purposes, the calculation set forth in Section 10.1(e) thereunder), of what would have been Immunex's applicable Product Gross Profits

(B) Absence of Supply Shortage and/or Territory Shortage. If either a Supply Shortage or a Territory Shortage is not in

effect, or if neither a Supply Shortage nor a Territory Shortage is in effect, then such Bulk Drug Substance purchased by the Lesser Volume Party shall be priced as follows:

- (1) the Fully Absorbed Manufacturing Cost allocated to the manufacture of such Bulk Drug Substance; plus
- (2) thirty percent (30%) of such Fully Absorbed Manufacturing Cost

As used in this Section 2.2(d), "Territory Shortage" shall mean the situation in which the total quantity of Bulk Drug Substance allocated to the Greater Volume Party pursuant to the applicable Five-Year Plan is less than the quantity of Bulk Drug Substance required to meet demand for Product Supply in the Greater Volume Party's Territory in a given time period. As used in this Section 2.2(d), "Product Gross Profits" shall mean Net Sales of Product Supply Units, less the sum of Cost of Goods and Royalties. As used in this Section 2.2(d), "Cost of Goods" shall mean, with respect to Product Supply Units, the total cost of finished goods, including, but not limited to, the Bulk Drug Substance at the Standard Product Price, other bulk materials, fill and finish, quality control, labeling, packaging, and shipping to a Party or its agent, and storage. As used in this Section 2.2(d), "Net Sales" shall mean the gross invoice price of Product Supply Units sold in a Party's Territory by a Party, its Affiliates, sublicensees, distributors, or other designees to a Third Party after deducting, if not already deducted in the amount invoiced or not otherwise accounted for in Cost of Goods: (a) the standard inventory cost (actual acquisition cost) of devices used for dispensing or administering such Product Supply Units and that accompany such Product Supply Units as they are sold; (b) then normal or customary trade, cash, and/or quantity discounts; (c) returns, allowances, free goods, rebates, and chargebacks; (d) retroactive price reductions applicable to sales of such Product Supply Units; (e) fees paid to distributors, selling agents (excluding any sales representatives of a Party or any of its Affiliates), group purchasing organizations, or managed care entities; (f) sales taxes, excise taxes, tariffs, and duties; and (g) two percent (2%) of the amount invoiced to cover bad debt, freight, or other transportation charges, insurance charges, additional special packaging, and other governmental charges. As used in this Section 2.2(d), "Royalties" shall mean all running royalties paid to Third Parties or to the other Party pursuant to Sublicense Agreements under patent or technology licenses that are necessary or desirable in order to manufacture, import, use, sell, or distribute Product, provided that such royalties for purposes of the calculation of Product Gross Profits shall be capped at sixteen percent (16%) of Net Sales, and any royalties above such amount shall be for the account of the Party that sold such Product.

Article 3. Governance

3.1 Joint Steering Committee.

The Parties hereby establish a Joint Steering Committee (the "JSC") to manage the Collaboration. Each Party shall designate two (2) senior executives to serve on the JSC on the basis of their expertise in pharmaceutical manufacturing and supply management. The initial members of the JSC are listed on Exhibit B attached hereto. A Party shall be free to change either or both of its designated representatives upon reasonable written notice to the other Party. The Parties shall be free to increase the number of their respective representatives upon mutual agreement of the Parties in writing. The JSC shall appoint a chairperson from among its members, provided that the chairperson shall alternate between the Immunex members and the Wyeth members on an annual basis.

3.2 Role of JSC.

The JSC shall be responsible for general management of the Collaboration. Its responsibilities shall include, without limitation, the following:

- (a) Reviewing and approving the Five-Year Requirement Schedules, as further described in Section 4.2(a) below;
- (b) Reviewing and approving the Five-Year Capacity Projections, as further described in Section 4.2(b) below;
- (c) Establishing, maintaining, and updating the Five-Year Plan, as further described in Section 4.2(c) below;
- (d) Overseeing the management of the Parties' joint relationship with BIP, with other contractors performing services related to the Product with regard to the Subject Capacity, and with suppliers of raw materials and other supplies for the Product with regard to the Subject Capacity;
- (e) Serving as the initial forum for resolution of disputes between the Parties related to matters within the scope of the Collaboration, as set forth in Section 3.4 below;
- (f) Establishing the quantities of safety inventories of Product to be maintained by the Parties, except as set forth in Section 5.5 below;
- (g) Establishing the operating guidelines pursuant to which the Parties will allocate tasks to accomplish the effective functioning of the Collaboration;
- (h) Creating a quality review board and such other subcommittees as the JSC deems necessary or appropriate for the effective functioning of the Collaboration;

- (i) Enforcing the responsibilities of and resolving disputes between the finance representatives designated by the Parties as set forth in Section 9.5(b);
- (j) Making decisions regarding process improvements as set forth in Section 7.4(a)(i); and
- (k) Performing the other tasks specifically set forth herein, as well as any other tasks that the JSC deems necessary or appropriate for the effective functioning of the Collaboration.

Except as expressly set forth herein, or as determined by the JSC, the Parties shall be bound by the decisions made by the JSC hereunder. Each Party shall cause its members of the JSC to act in accordance with, and perform the functions of the JSC required by, this Agreement.

3.3 Meetings.

The JSC shall meet as frequently as necessary to manage the Collaboration effectively, but at least semi-annually. The Chairperson shall send notices and agendas for all regular meetings to all JSC members. The location of regularly scheduled meetings shall alternate between the offices of the Parties. Meetings may be held telephonically, by video conference, or by any other media agreed to by the JSC. Members of the JSC shall have the right to participate in and vote at meetings by telephone or proxy. Each Party shall have one (1) vote on all matters within the jurisdiction of the JSC. The Party hosting any meeting shall appoint a person to record the minutes of the meeting; such minutes shall be circulated to the Parties promptly following the meeting for review, comment, ratification, and distribution. Each Party shall bear its own travel and related costs incurred in participation in the JSC. The JSC may invite additional participants from relevant functions to attend JSC meetings when appropriate for the issues being addressed at the meeting.

3.4 Dispute Resolution.

The JSC shall endeavor to reach a consensus on all matters within its purview. In the event that the JSC cannot reach consensus on a matter, or in the event that a disputed matter between the Parties is referred to the JSC, the JSC shall strive to resolve such matter within a period of ten (10) calendar days after the disputed matter is identified or referred to the JSC in writing for resolution. If the JSC cannot reach a resolution within the applicable time period (or earlier at the election of either Party), the matter shall be referred to resolution in accordance with Article 18 below.

Article 4. Allocation; Five-Year Plans

4.1 Short-Term Allocation.

Until either the FDA or EMEA has approved manufacture of Bulk Drug Substance at the RI Site ("RI Approval"), the supply of Bulk Drug Substance shall be allocated as follows:

- (a) Product Manufactured at the BIP Site. Until RI Approval, Wyeth shall have the right to receive such quantities of Bulk Drug Substance as set forth in the Short-Term Allocation Agreement, pursuant to the terms of the Short-Term Allocation Agreement, and any written agreements involving both of the Parties relating to importation of Product Supply Units from Immunex's customers into the Wyeth Territory.
- (b) Clinical Trial Material Manufactured at RI Site. In the event that Bulk Drug Substance manufactured at the RI Site, prior to RI Approval, is used in Product Supply for the Parties' clinical trials, and such use permits additional Product manufactured at the BIP Site to be allocated for use and used for the commercial market, the amount of additional Product obtained for the commercial market because of such substitution shall be divided equally between the Parties. The JSC shall determine the amount of such Product, if any, subject to such allocation.

4.2 Five-Year Planning.

- (a) Five-Year Requirement Schedules. On November 30, 2001 each Party shall provide the JSC with a written five-year requirement schedule (a "Five-Year Requirement Schedule") for the period beginning January 1, 2002 of its projected requirements for Bulk Drug Substance from the Subject Capacity for its Territory, net of Bulk Drug Substance reasonably expected to be satisfied from Excluded Supply, according to Type, divided into monthly increments for the first Calendar Year and divided into yearly increments for the remaining four (4) Calendar Years. By each May 30 thereafter, each Party shall submit to the JSC an updated Five-Year Requirement Schedule for the period beginning January 1 of the following Calendar Year. Within thirty (30) days after each such submission, the JSC shall review the Five-Year Requirement Schedules, and either, at its discretion, approve the Five-Year Requirement Schedules, or request additional information from the Parties as needed to use the Five-Year Requirement Schedules to establish the Five-Year Plan. At the JSC's discretion and request, the Parties shall update their Five-Year Requirement Schedules by each November 30 thereafter. Each Five-Year Requirement Schedule provided hereunder shall include, for each Calendar Year included therein:

- (i) total Bulk Drug Substance requirements from the Subject Capacity, separated according to Type, on a region-by-region basis;


- (ii) Bulk Drug Substance requirements by indication on a Territory-wide basis, separated according to Type;
 - (iii) a schedule of expected dates of submission and approval by Regulatory Authorities, on a country-by-country basis within such Party's Territory, of initial marketing applications for the Product, and supplemental submissions for additional indications to be added to the Product labeling;
 - (iv) information concerning sales of Product during the preceding six (6) months on a Territory-wide basis; and
 - (v) any other information reasonably requested by the JSC.
- (b) Five-Year Capacity Projections. On [November 30, 2001] each Party shall provide the JSC with a written five-year capacity projection (a "Five-Year Capacity Projection") beginning [January 1, 2002] for the Subject Capacity from each of its Sites according to Type, divided into monthly increments for the first Calendar Year of a Capacity Projection and divided into yearly increments for the remaining four Calendar Years of a Capacity Projection. Immunex shall submit the Five-Year Capacity Projection for the BIP Site and the RI Site, and Wyeth shall submit the Five-Year Capacity Projection for the BIOS Site. By each [May 30] thereafter, each Party shall submit to the JSC an updated Five-Year Capacity Projection for the period beginning [January 1] of the following Calendar Year. Within thirty (30) days after each such submission, the JSC shall review the Five-Year Capacity Projections, and either, at its discretion, approve the Five-Year Capacity Projections, or request additional information from the Parties as needed to use the Five-Year Capacity Projections to establish the Five-Year Plan. At the JSC's discretion and request, the Parties shall update their Five-Year Capacity Projections by each [November 30] thereafter. Each Five-Year Capacity Projection provided hereunder shall include, for each year included therein:
- (i) the total quantity of Bulk Drug Substance that can reasonably be expected to be produced and released at the Site within bioreactors included in the Subject Capacity, separated according to Type;
 - (ii) the projected Standard Product Price for Released Bulk Drug Substance at the Site within bioreactors included in the Subject Capacity, according to Type, which price shall be non-binding on the Parties;
 - (iii) a schedule of expected dates of submissions to and approval by Regulatory Authorities, of Regulatory Filings regarding additional

Sites to manufacture the Product and process and other changes, on a regional or country-by-country basis;


- (iv) inventory of Product on hand from the Subject Capacity, separated according to Type, on a region-by-region basis, as of one month before the date of submission of the such Five-Year Capacity Projection; and
 - (v) any other information reasonably requested by the JSC.
- (c) Five-Year Plan. By December 31, 2001, and by each June 30 thereafter during the Term, the JSC shall establish the "Five-Year Plan" for the upcoming five (5) Calendar Years. The JSC shall determine, in its discretion, whether it is necessary to adjust each such Five-Year Plan after receiving submissions from the Parties by each November 30 and, shall make any such necessary adjustments. The Five-Year Plan shall include, for each Calendar Year included therein, a Production Plan and a Supply Plan, as further described below.
- (i) Production Plan. Each Five-Year Plan shall indicate the quantity of Bulk Drug Substance separated according to Type reasonably expected to be manufactured and released at each specific Site within the Subject Capacity (the "Production Plan"). The Production Plan shall be established on a Calendar Year basis within the applicable Five-Year Plan.
 - (ii) Supply Plan. Each Five-Year Plan shall indicate: (A) the quantity of Bulk Drug Substance reasonably expected to be supplied to each of the Territories separated according to Type; and (B) the quantity of Bulk Drug Substance reasonably expected to be manufactured at each specific Site separated according to Type to be supplied to each of the Parties for their respective Territories (the "Supply Plan"). The Supply Plan shall be established on a monthly basis for the first Calendar Year included in the Five-Year Plan, and on a Calendar Year basis for the remaining four (4) Calendar Years within the Five-Year Plan, on a Territory-wide basis.
 - (iii) Reconciliation. In establishing a Five-Year Plan, the JSC shall review the Bulk Drug Substance that was actually distributed to the Parties from the Subject Capacity during the preceding Calendar Year to determine whether the capacity actually received by each Party during the preceding Calendar Year equaled the capacity to which each Party was entitled pursuant to this Agreement. If one Party did not receive the capacity from the Subject Capacity to which such Party was entitled under the Five-Year Plan for such preceding Calendar Year, the JSC shall make any appropriate adjustments to the Five-Year Plan that it is establishing to account for such discrepancy.

4.3 General Principles of Allocation.

In the absence of a Supply Shortage or a Production Surplus, the JSC shall be guided by the following principles in establishing the Five-Year Plans.

- (a) The JSC shall use its best efforts to prevent any out-of-stock situation in any Major Market, including but not limited to resolving any short supply issues for each Type. The JSC shall use its commercially reasonable efforts to prevent any out-of-stock situation in any non-Major Market, including but not limited to resolving any short supply issues for each Type.
- (b) [The JSC shall use its best efforts to ensure that minimal contractual obligations to BIP under the Enbrel Supply Agreement are met.] 
- (c) The JSC shall use its best efforts to prevent out-dating of Bulk Drug Substance.
- (d) The JSC shall use its best efforts to minimize costs to the extent they impact the Blended Price.
- (e) The JSC shall use its best efforts to allocate supply such that each Party receives the Type of Bulk Drug Substance that such Party requires.

4.4 Binding Portion of Five-Year Plan.

The [first Calendar Year] of each Five-Year Plan shall be binding on the Parties. Notwithstanding anything herein to the contrary, the initial Five-Year Plan shall not become effective nor bind the Parties until RI Approval, and prior to that time, the supply of Bulk Drug Substance shall be allocated according to Section 4.1 above. The JSC shall not change a binding portion of a Five-Year Plan. The Parties shall be obligated to utilize the capacity and to purchase the quantities of Bulk Drug Substance set forth in the binding portion of the Five-Year Plan. The remaining portions of a Five-Year Plan shall not be binding on the Parties, but the Parties shall use such Five-Year Plan for joint planning purposes. 

4.5 Specific Product Purchases.

The Parties shall purchase Product from each other in the quantities specified in the Five-Year Plan, according to the terms set forth in this Agreement.

- (a) BIP Site. Under the Enbrel Supply Agreement, the Parties have the option to receive Bulk Drug Substance Lots manufactured by BIP; the remainder of the Bulk Drug Substance manufactured by BIP is converted by BIP to Drug Product and/or Finished Product that is sold to the Parties thereunder.
 - (i) In the event that a Party desires to receive Bulk Drug Substance from BIP, such Party shall so specify in its Five-Year Requirement Schedule submitted to the JSC. The JSC shall approve any such request that complies with the Enbrel Supply Agreement or, if necessary, shall limit

the quantities of Bulk Drug Substance requested by one or both Parties to ensure such compliance. Any Party who requests Bulk Drug Substance from BIP shall pay BIP the cost therefor under the Enbrel Supply Agreement and shall bear the cost of and the risk of loss during the fill-finish, labeling, packaging, and other services necessary to convert such Bulk Drug Substance to Product Supply.

- (ii) In the event that a Party requests Drug Product or Finished Product from BIP, such Party shall pay BIP the cost therefor under the Enbrel Supply Agreement and shall bear the cost of the labeling, packaging, and other services necessary to convert such Product to Product Supply.

(b) RI Site.

- (i) For the quantities of Bulk Drug Substance that Wyeth receives from the RI Site, Wyeth shall purchase the Bulk Drug Substance form of the Product and shall pay Immunex therefor in accordance with Article 9 below. Wyeth may enter into an agreement with Immunex or a Third Party pursuant to which Immunex or a Third Party would perform certain fill-finish, labeling, packaging, and other services necessary to convert such Bulk Drug Substance to Product Supply on terms and conditions mutually agreed upon in writing by Wyeth and Immunex, or a Third Party, as applicable.
- (ii) When (A) more than three (3) twenty-thousand (20,000) liter nominal volume bioreactors are used to produce Bulk Drug Substance in the Phase B Facility in a given Calendar Year, or, (B) if the Phase A Capacity is moved to the Phase B Facility, more than seven (7) twenty-thousand (20,000) liter nominal volume bioreactors are used to produce Bulk Drug Substance in the Phase B Facility in a given Calendar Year, the quantity of Bulk Drug Substance subject to allocation and purchase in accordance with the applicable Five-Year Plan shall equal the total quantity of Bulk Drug Substance released in the Phase B Facility multiplied by a fraction in which the numerator is either three (3) or seven (7), as applicable based on subsections (A) and (B) above, and the denominator is the number of twenty thousand (20,000) liter nominal volume bioreactors used to produce Bulk Drug Substance in the Phase B Facility in the applicable Calendar Year.

(c) BIOS Site.

- (i) For the quantities of Bulk Drug Substance that Immunex receives from the BIOS Site, Immunex shall purchase the Bulk Drug Substance form of the Product and shall pay Wyeth therefor in accordance with Article 9 below. Immunex may enter into an agreement with Wyeth or a Third Party pursuant to which Wyeth or a Third Party would perform certain fill-

finishing, labeling, packaging, and other services necessary to convert such Bulk Drug Substance to Product Supply on terms and conditions mutually agreed upon in writing by Immunex and Wyeth, or a Third Party, as applicable.

- (ii) If a greater number of bioreactors than those included in the BIOS Capacity are used to produce Bulk Drug Substance in the Total BIOS Facility Capacity in a given Calendar Year, the quantity of Bulk Drug Substance subject to allocation and purchase in accordance with the applicable Five-Year Plan shall equal the total quantity of Bulk Drug Substance released in the Total BIOS Facility Capacity multiplied by a fraction in which the numerator shall be the total nominal volume included in the BIOS Capacity and the denominator shall be the total nominal volume included in the Total BIOS Facility Capacity in the applicable Calendar Year

Article 5. Product Allocation During Supply Shortage

5.1 Scope.

Except as set forth in Section 5.6 below, in the event that there is a Supply Shortage, the JSC shall allocate the total quantity of Bulk Drug Substance manufactured in the Subject Capacity as set forth in this Article 5, for each of the Calendar Years for which the Supply Shortage is in effect pursuant to Section 1.54 above.

5.2 Allocation of Combined BIP Capacity and Phase A Capacity.

The total volume of Bulk Drug Substance available from the combined BIP Capacity and Phase A Capacity shall be allocated as follows, in the following priority:

- (a) **Base Allocation.** The first three hundred ten (310) Kilograms ("Kg") of Bulk Drug Substance available from the combined BIP Capacity and Phase A Capacity (the "**Base Allocation**") shall be allocated as follows:

- (i) Immunex shall receive two hundred fifty (250) Kg; and
 - (ii) Wyeth shall receive sixty (60) Kg.

In the event that fewer than 310 Kg of Bulk Drug Substance are available from the combined BIP Capacity and Phase A Capacity, then Immunex shall receive eighty and six-tenths of a percent (80.6%) and Wyeth shall receive nineteen and four-tenths of a percent (19.4%) of the available quantities.

- (b) **Clinical Development Requirements.** Additional volumes of Bulk Drug Substance above the Base Allocation that are available from the combined BIP Capacity and Phase A Capacity, if any, shall be used to satisfy any

ongoing clinical trials being conducted by the Parties, as well as any new clinical trials agreed upon by the "Product Development Steering Committee" under the TNFR Agreement (as that term is defined therein) (collectively, the "Clinical Development Requirements"). [In the event that there is insufficient Bulk Drug Substance from these combined Capacities to satisfy all Clinical Development Requirements, the Parties shall negotiate in good faith to determine to which clinical trials the available supplies shall be allocated.] To the extent that the Parties agree that excess quantities of Bulk Drug Substance from the quantities allocated to the Clinical Development Requirements are available from time to time, such quantities shall be allocated as follows:

- (i) If the Base Allocation has not been satisfied as set forth in Section 5.2(a) in the Calendar Years in which the Parties agree that excess quantities are available, the excess quantities shall be allocated as set forth in Section 5.2(a).
- (ii) If the Base Allocation has already been satisfied as set forth in Section 5.2(a) in the Calendar Years in which the Parties agree that excess quantities are available, the excess quantities shall be allocated as set forth in Section 5.2(c).
- (c) Additional Quantities. Additional quantities of Bulk Drug Substance that are available from the combined BIP Capacity and Phase A Capacity, if any, above that necessary to satisfy the Base Allocation and the Clinical Development Requirements, shall be allocated as follows:

	Immunex	Wyeth
First [50] Kg or portion thereof	[75%]	[25%]
Next [50] Kg or portion thereof	[70%]	[30%]
Next [50] Kg or portion thereof	[60%]	[40%]
Next [50] Kg or portion thereof	[55%]	[45%]
All additional supplies from the combined BIP Capacity and Phase A Capacity	[50%]	[50%]

- (d) Example. By way of example only, the following table demonstrates how the quantities of total Bulk Drug Substance available from the BIP and Phase A Capacity, as shown below, would be allocated during a Supply Shortage. (The numbers shown below have been rounded to the nearest 0.5 Kg.)

Clinical

	Immunex	Wyeth	Development Requirements
Total Supply from BIP Capacity and from Phase A Capacity	Kg	Kg	Kg
[310]	[250]	[60]	[0]
[360]	[272.5]	[67.5]	[20]
[410]	[308.5]	[81.5]	[20]
[460]	[340.5]	[99.5]	[20]
[510]	[369]	[121]	[20]
[610]	[420]	[170]	[20]

5.3 Allocation of Phase B Additional Capacity.

In the event of a Supply Shortage, the volume of Bulk Drug Substance available from the Phase B Additional Capacity shall be allocated [seventy percent (70%)] to Immunex and [thirty percent (30%)] to Wyeth.

5.4 Allocation of BIOS Capacity.

In the event of a Supply Shortage, the volume of Bulk Drug Substance available from the BIOS Capacity shall be allocated [seventy percent (70%)] to Wyeth and [thirty percent (30%)] to Immunex.

5.5 Safety Stock.

During any period of Supply Shortage, each Party shall be responsible for maintaining its own inventory of safety stock from among the quantities it is allocated pursuant to this Article 5.

5.6 Sale of Product between Parties.

If there is a Supply Shortage and the allocation of Bulk Drug Substance according to this Article 5 provides a Party with excess supply above that required to meet such Party's supply needs, as determined in such Party's sole discretion, such Party shall have the right, but not the obligation, to sell additional Bulk Drug Substance to the other Party beyond that allocated to such other Party according to this Article 5; provided, however, that any such quantities of Bulk Drug Substance that derive from the Subject Capacity and are sold by one Party to the other Party shall be sold at a price that does not exceed the applicable Blended Price established for such Bulk Drug Substance during the Calendar Year in which the sale occurs.

5.7 Allocation According to Type.

In establishing a Five-Year Plan, the JSC shall use its best efforts to allocate to a Party the Type of Bulk Drug Substance required by such Party. If the JSC is bound, according to this Article 5, to allocate a certain percentage of Bulk Drug Substance from one Site or a portion thereof to a Party, and such Site manufactures a particular Type of Bulk Drug Substance that is not required by such Party, the JSC shall substitute an equivalent quantity of Bulk Drug Substance from a different Site

that produces a Type required by such Party, and shall make any necessary corresponding adjustments to maintain compliance with Article 5.

Article 6. Product Allocation During Production Surplus

6.1 Allocation.

In the event that there is a Production Surplus, the total quantity of Bulk Drug Substance that can be manufactured in the Subject Capacity shall be allocated as set forth below.

(a) BIP Obligations. [The JSC shall first allocate production to the BIP Capacity to the extent necessary to satisfy minimal contractual obligations to BIP under the Enbrel Supply Agreement.]

(b) Additional Supply Needs. If there is additional demand for Product Supply beyond the quantities produced as a result of the allocation to the BIP Capacity under Section 6.1(a) above, then production shall be allocated among the RI Capacity and the BIOS Capacity according to the following formula.

[(i) A fraction will be created as follows:

(A) the numerator will be the RI Capacity or the BIOS Capacity, as applicable; and

(B) the denominator will be the RI Capacity plus the BIOS Capacity.

(ii) The fraction created in Section 6.1(b)(i) shall be multiplied by a number representing the remaining worldwide capacity to be filled, which number shall be calculated by subtracting:

(A) the quantity of Bulk Drug Substance allocated to the BIP Site under Section 6.1(a) above

from

(B) the total worldwide demand for Bulk Drug Substance, as established in the most recent Five-Year Plan.]

(c) Example. By way of example only, assume that the respective capacities of the Subject Capacities as follows:

BIP Capacity: [200 Kg]

RI Capacity: [450 Kg]

BIOS Capacity: [400 Kg]

Total: [1050 Kg]

Assume further that (i) the worldwide demand for Product Supply is [800 Kg] per year, and (ii) the Parties must purchase [200 Kg] from BIP to meet their minimum contractual obligation under the Enbrel Supply Agreement. Production shall be allocated as follows:

BIP Capacity: [200 Kg]

RI Capacity: [450/850 (53%) x 600 Kg (800 Kg-200 Kg) = 318 Kg]

BIOS Capacity: [400/850 (47%) x 600 Kg (800 Kg-200 Kg) = 282 Kg]

Article 7. Manufacturing Strategy

7.1 Regulatory Approvals.

The Parties shall cooperate in good faith and use all commercially reasonable efforts to obtain approval from the applicable Regulatory Authorities for each Site to manufacture Bulk Drug Substance for each of the Major Markets. Immunex shall be responsible for all Regulatory Filings for each Site to enable each Site to manufacture Bulk Drug Substance for countries within the Immunex Territory as deemed necessary by Immunex, and Wyeth shall be responsible for all Regulatory Filings for each Site to enable each Site to manufacture Bulk Drug Substance for countries within the Wyeth Territory as deemed necessary by Wyeth. Each Party shall offer its reasonable assistance to the other Party in preparing any such Regulatory Filings. Each Party shall reimburse the other for [all reasonable out-of-pocket costs and expenses] incurred by such other Party in connection with the performance of such other Party's obligations under the preceding sentence. The Parties shall attempt to obtain such approvals as quickly as practicable. The Parties shall attempt to qualify the Subject Capacity in those Major Markets where the qualification is reasonably likely to be obtained the earliest, as agreed upon by Immunex and Wyeth; provided, however, that the Parties shall simultaneously use all commercially reasonable efforts to qualify the Subject Capacity for manufacturing Bulk Drug Substance for use in the United States, the European Union, and Japan.

7.2 Raw Materials and Supplies.

- (a) General. Each Site shall be responsible for purchasing the raw materials and other supplies necessary to manufacture Bulk Drug Substance, Drug Product, and/or Finished Product, as applicable, at its location. The Parties shall, however, cooperate with regard to purchasing from specific suppliers, particularly sole source suppliers, and shall, when reasonably practicable, enter into joint contracts or other purchasing arrangements with suppliers, with the objective of obtaining more favorable pricing and other terms than if

such Party was purchasing alone. In addition, the Parties shall cooperate in working with BIP in purchasing from such suppliers. The JSC shall direct the Parties' management of the relationship with common suppliers, and in the event that entering into a joint purchasing arrangement with a sole source supplier is not reasonably practicable, then the JSC shall oversee and direct each Party's individual contractual relationship with such supplier. Section 5.3 of the Quality Agreement addresses quality issues related to raw materials.

- (b) Shortage. [If a worldwide shortage develops of a particular raw material ingredient or other item necessary to manufacture the Product, then the JSC shall be responsible for allocating among the Sites the quantities to be purchased of such item. The JSC shall make such allocation in its discretion and shall consider factors including but not limited to (i) how to ensure that contractual obligations under the Enbrel Supply Agreement can be met by all Parties, and (ii) how to facilitate the ability of each Site to meet its obligations under the applicable Five-Year Plan. Neither Party shall take any action with respect to a particular raw material used in the manufacture of Product that such Party knows would interfere with fulfillment of a Five-Year Plan established hereunder.]

7.3 Technology Transfer and License.

Immunex and Wyeth shall enter into a technology transfer and license agreement simultaneously herewith setting forth the terms and conditions simultaneously herewith pursuant to which transfer of the technology for the Manufacturing Process to Wyeth will occur (the "Technology Transfer and License Agreement").

7.4 Changes to the Product.

(a) Process Changes.

- (i) The Parties shall collaborate with regard to any process improvement efforts for the Manufacturing Process. The JSC shall make all decisions regarding joint investments for development work for process improvements, allocating costs of such development work if such costs are to be allocated other than as set forth in Section 3.05 of the TNFR Agreement, whether to implement any such jointly funded process improvements into the Manufacturing Process, the timing of such implementation at the various Sites, [and the negotiation with BIP regarding implementation of such changes at the BIP Site.] The JSC shall consider the requirements of all countries within the Territories in determining whether to jointly fund development work for process improvements.
- (ii) The Parties, through the JSC, shall cooperate in good faith to help ensure that, as improvements to the Manufacturing Process are implemented, [(i) Product manufactured using such improvements is available from one or more Sites to support the Major Markets where such improvements have been approved, (ii) Product manufactured using previous Manufacturing

Processes remains available from one or more Sites to support the Major Markets where such improvements have not yet been approved, and (iii) Product inventory is managed appropriately at the various Sites to accomplish (i) and (ii) above and to implement changes as efficiently as possible

(iii) Implementation of process changes is also addressed in Article 10 of the Quality Agreement.

(b) Other Changes. The Parties' technical, production scheduling, regulatory and other appropriate personnel shall work together to coordinate other changes to the Product, including but not limited to formulation changes, presentation changes (e.g., vial vs. prefilled syringe) and assay changes. The JSC shall provide general direction to the Parties with respect to the implementation and timing of such changes, with the objective of ensuring that (i) Product incorporating a particular change is available from one or more of the Sites to support the Major Markets where such change is approved, (ii) to the extent commercially practicable, Product not incorporating a particular change is available from one or more of the Sites to support the Major Markets where such change is not approved, and (iii) Product inventory is managed appropriately to accomplish (i) and (ii) above and to implement changes as efficiently as possible. Implementation of such changes is also addressed in Article 10 of the Quality Agreement.

7.5 Manufacturing Strategy.

The Parties shall use commercially reasonable efforts to manufacture Bulk Drug Substance to meet the most stringent Regulatory Requirements in the Major Markets. Notwithstanding the foregoing, if after manufacture, a Bulk Drug Substance Lot fails to meet the most stringent Regulatory Requirements in the Major Markets, it shall be allocated for use, within the scope of the applicable Five-Year Plan, to a Party for use in a country in which the manufactured Bulk Drug Substance Lot meets the applicable Regulatory Requirements, if such Party agrees to such allocation. Any disputes regarding the foregoing shall be resolved as set forth in the Quality Agreement.

7.6 Quality Agreement.

Immunex and Wyeth shall comply with the provisions of the Quality Agreement. To the extent possible, the provisions of the Quality Agreement shall be interpreted consistently with the provisions of this Agreement.

Article 8. Supply of Bulk Drug Substance Between Immunex and Wyeth

8.1 Supply of Bulk Drug Substance.

Immunex shall supply Bulk Drug Substance to Wyeth from the RI Site, and Wyeth shall supply Bulk Drug Substance to Immunex from the BIOS Site, subject to the terms and conditions of this Agreement and the Quality Agreement. All Bulk Drug

Substance supplied by Immunex or Wyeth hereunder shall conform to the provisions of the Quality Agreement, including, without limitation, the Specifications for such Bulk Drug Substance set forth in the Quality Agreement.

8.2 Forecasts.

On the thirtieth (30th) day after each Five-Year Plan is established pursuant to Section 4.2(c), each of Immunex and Wyeth shall provide to the other a One Year "Detailed Forecast Schedule" for the amount of Kg of Bulk Drug Substance, separated according to Type, to be delivered on delivery dates (the "Delivery Dates"), by month for the following Calendar Year. The Detailed Forecast Schedule shall be considered a "Firm Order" in accordance with the binding portion of the Five Year Plan.

8.3 Delivery.

- (a) Delivery Terms. Wyeth and Immunex shall each arrange for shipment of the Bulk Drug Substance to the other Party and/or its respective designee at the purchasing Party's expense, F.O.B. the purchasing Party's designated carrier, and in accordance with the purchasing Party's instructions, including instructions as to designated carrier(s) to utilize. Title to, and risk of loss of, the Bulk Drug Substance shall remain with the supplying Party until delivery to the designated carrier specified by the purchasing Party, at which time the purchasing Party shall assume risk of loss of the Bulk Drug Substance.
- (b) Filling Firm Orders. The supplying Party shall fulfill each Firm Order submitted pursuant to Section 8.2 above, for such quantities of Bulk Drug Substance specified in such Firm Order for each purchasing Party, on or before the specified Delivery Date applicable thereto and in accordance with any instructions of the purchasing Party; provided, however, that the Parties shall deliver Bulk Drug Substance in whole Bulk Drug Substance Lots. Notwithstanding anything herein to the contrary, if supply from a Bulk Drug Substance Lot is lower than expected, the deficiency shall not constitute a breach of an obligation to fulfill a Firm Order. If a Supply Shortage is in effect when such deficiency occurs, Immunex and Wyeth shall receive a reduced quantity of Bulk Drug Substance to accommodate such deficiency proportionately based on the allocation set forth in the applicable Five-Year Plan on a monthly basis. If a Supply Shortage is not in effect when such deficiency occurs, the deficient quantity shall be placed on backorder.
- (c) Delivery Schedule. The Parties will cooperate to maintain a non-binding rolling six (6)-month delivery schedule. Such schedule shall be updated at least monthly and will specify the quantity of and delivery dates for Bulk Drug Substance to be delivered in the next six (6) calendar months.
- (d) Compliance. Each Party shall comply with all applicable laws and regulations regarding the transportation and shipment of the Bulk Drug Substance for all deliveries made by such Party pursuant to this Agreement.

8.4 Division of Orders for and Delivery of Allocated Supply.

The Parties will use commercially reasonable efforts to deliver Product in accordance with the binding forecast (as described in Section 4.4) in each month of the Detailed Forecast Schedule, unless otherwise agreed by the Parties in writing.

8.5 Product Warranties.

- (a) Warranties by Wyeth. Wyeth hereby warrants to Immunex that the Bulk Drug Substance that Immunex purchases from Wyeth under this Agreement, at the time of sale and shipment by Wyeth: (i) shall conform to the provisions of the Quality Agreement, including, without limitation, the applicable Specifications for such Bulk Drug Substance; (ii) shall have been manufactured in compliance with all Regulatory Requirements in the United States; and (iii) shall be transferred free and clear of any liens or encumbrances of any kind related to Wyeth's activities hereunder.
- (b) Warranties by Immunex. Immunex hereby warrants to Wyeth that the Bulk Drug Substance that Wyeth purchases from Immunex under this Agreement, at the time of sale and shipment by Immunex: (i) shall conform to the provisions of the Quality Agreement, including, without limitation, the applicable Specifications for such Bulk Drug Substance; (ii) shall have been manufactured in compliance with all Regulatory Requirements in the Major Markets; and (iii) shall be transferred free and clear of any liens or encumbrances of any kind related to Immunex's activities hereunder.
- (c) Continuing Warranties. The warranties set forth in this Section 8.5(a) and (b) shall be continuing warranties and shall be applicable to all of the Bulk Drug Substance delivered by Wyeth or Immunex to the other Party pursuant to this Agreement.
- (d) Disclaimer. THE WARRANTIES SET FORTH IN SECTIONS 8.5(a) AND 8.5(b) ABOVE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY AND ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. EXCEPT FOR THE WARRANTIES EXPRESSED IN SECTIONS 8.5(a) AND 8.5(b) ABOVE, NEITHER PARTY MAKES ANY OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT.

8.6 Validation.

Product and process validation shall be governed by Article 11 of the Quality Agreement.

8.7 Claims.

- (a) Notice of Claims. In the event that any of the Bulk Drug Substance supplied hereunder shall fail to conform with any warranty set forth in Section 8.5(a) or Section 8.5(b) hereof, the purchasing Party may reject the same by giving written

notice thereof to the supplying Party within sixty (60) days after shipment (or in the case of a latent defect, within thirty (30) days after discovery of such latent defect, but in no case later than one year after delivery to the designated carrier specified by the purchasing Party), which notice shall specify the manner in which such Bulk Drug Substance fails to conform to any warranty. In the alternative, rather than initially issuing a notice of rejection, the purchasing Party may give written notice to the supplying Party within the time period specified in this Section 8.7(a) of a decision by the purchasing Party to investigate whether a potentially nonconforming shipment should be rejected, which investigation shall, unless otherwise agreed upon by the Parties, be completed within the time period set forth in this Section 8.7(a).

- (b) No Supplier Liability. If it is determined by agreement of Immunex and Wyeth (or in the absence of such agreement, by a mutually acceptable qualified Third Party whose determination shall be binding on Immunex and Wyeth and whose fees shall be paid by the non-prevailing Party) that the nonconformity is due to damage to the Bulk Drug Substance caused by the purchasing Party or its agents subsequent to delivery of such Bulk Drug Substance by the supplying Party, the supplying Party shall have no liability to Purchaser with respect thereto.
- (c) Supplier Liability; Replacement Product. If it is determined by agreement of Immunex and Wyeth (or in the absence of such agreement, by a mutually acceptable qualified Third Party whose determination shall be binding on Immunex and Wyeth and whose fees shall be paid by the non-prevailing Party) that the nonconformity is caused by the supplying Party, the supplying Party shall as soon as reasonably possible replace such nonconforming Bulk Drug Substance with conforming Bulk Drug Substance, at no additional cost to the purchasing Party, and the supplying Party shall pay the full cost of disposal or return of such Bulk Drug Substance to the supplying Party.
- (d) Disposition of Nonconforming Product. In any case where a purchasing Party expects to make a claim against a supplying Party with respect to damaged or otherwise nonconforming Bulk Drug Substance, the purchasing Party shall not dispose of or allow to be disposed such Product without written authorization and instructions of the supplying Party either to dispose of or return to the supplying Party such Bulk Drug Substance. Upon written request by the purchasing Party, the supplying Party agrees promptly to give the purchasing Party such authorization and instructions within a reasonable period of time.

8.8 Manufacturing Audits, Regulatory Matters.

- (a) Manufacturing Audits. The Parties shall have the right to perform manufacturing audits as set forth in Sections 8.4 and 8.5 of the Quality Agreement.
- (b) Records. Each Party shall maintain records relating to the production of the Product hereunder in accordance with Section 7.6 of the Quality Agreement. Each Party agrees that, in response to any complaint or in the defense by the other Party of any

litigation, hearing, regulatory proceeding or investigation relating to the Product, it shall use reasonable efforts to make available to the other Party during normal business hours and upon reasonable prior written notice, such Party's employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections. Each Party shall reimburse the other for [all reasonable out-of-pocket costs and expenses incurred] by such other Party in connection with the performance of such other Party's obligations under the preceding sentence. ★

- (c) Notification to Other Party of Regulatory Correspondence. Within [three (3)] business days after receiving or finalizing such document, each of Immunex and Wyeth shall promptly notify the other Party in writing of, and shall provide each other with copies of, any correspondence and other documentation received or prepared by such Party in connection with receipt of a regulatory letter, warning, or similar item, from any Regulatory Authority related to an inspection of the RI Site or the BIOS Site, as applicable, that could affect production of the Product; (ii) any recall, market withdrawal or correction of any lot of any Product provided by such Party to the other Party hereunder; and (iii) any comments by a Regulatory Authority concerning the Product requiring a response or action by Immunex or Wyeth. ★

8.9 Recalls.

- (a) Immunex Territory. Each Party shall notify the other Party promptly (and, in any event, within [three (3)] business days of receipt of written notice) if any Bulk Drug Substance, Finished Product, Drug Product, or Product Supply is alleged or proven to be the subject of a recall, market withdrawal or correction in any country in the Immunex Territory. Immunex and Wyeth shall cooperate in the handling and disposition of such recall, market withdrawal or correction in the Immunex Territory; provided, however, that in the event of disagreement as to any matters related to such recall, market withdrawal or correction, other than the determination of who shall bear the costs as set forth in the immediately following sentence, Immunex, after consultation with Wyeth, shall have final authority with respect to such matters in the Immunex Territory, which authority shall be exercised reasonably in and in good faith. Immunex shall bear the cost of all recalls, market withdrawals, or corrections of Bulk Drug Substance, Finished Product, Drug Product, or Product Supply in the Immunex Territory unless such recall, market withdrawal or correction shall have been the result of any breach of Wyeth's covenants, representations, or warranties set forth in this Agreement or shall have been the result of Wyeth's grossly negligent breach of any of its obligations hereunder, in which case Wyeth shall, upon substantiation, bear the cost of such recall, market withdrawal, or correction. Immunex or its agent shall in all events be responsible for conducting any recalls, market withdrawals or corrections with respect to ★

Bulk Substance, Finished Product, Drug Product, or Product Supply in the Immunex Territory.

- (b) Wyeth Territory. Each Party shall notify the other Party promptly (and, in any event, within three (3) business days of receipt of written notice) if any Bulk Drug Substance, Finished Product, Drug Product, or Product Supply is alleged or proven to be the subject of a recall, market withdrawal or correction in any country in the Wyeth Territory. Immunex and Wyeth shall cooperate in the handling and disposition of such recall, market withdrawal or correction in the Wyeth Territory; provided, however, that in the event of disagreement as to any matters related to such recall, market withdrawal or correction, other than the determination of who shall bear the costs as set forth in the immediately following sentence, Wyeth, after consultation with Immunex, shall have final authority with respect to such matters in the Wyeth Territory, which authority shall be exercised reasonably in and in good faith. Wyeth shall bear the cost of all recalls, market withdrawals, or corrections of Bulk Drug Substance, Finished Product, Drug Product, or Product Supply in the Wyeth Territory unless such recall, market withdrawal or correction shall have been the result of any breach of Immunex's covenants, representations, or warranties set forth in this Agreement or shall have been the result of Immunex's grossly negligent breach of any of its obligations hereunder, in which case Immunex shall, upon substantiation, bear the cost of such recall, market withdrawal, or correction. Wyeth or its agent shall in all events be responsible for conducting any recalls, market withdrawals or corrections with respect to Bulk Substance, Finished Product, Drug Product, or Product Supply in the Wyeth Territory.

8.10 Safety Agreement.

Immunex and Wyeth shall comply with the provisions of the Safety Agreement. To the extent possible, the provisions of the Safety Agreement shall be interpreted consistently with the provisions of this Agreement. In the event of a conflict between the provisions of the Safety Agreement and the provisions of this Agreement, the provisions of this Agreement shall control.

Article 9. Pricing of Product Between the Parties

9.1 Standard Product Prices.

- (a) Calculation. For each Calendar Year (or portion thereof remaining in the Term) for which a Five-Year Plan is in effect, a "Standard Product Price" for Bulk Drug Substance manufactured at each of the Sites will be established, on a per Kg basis] as further described below. A separate Standard Product Price shall be calculated for Bulk Drug Substance manufactured using [ISP] Bulk Substance manufactured using the T1 Process, and Bulk Drug Substance manufactured using the T2 Process, if each such Manufacturing Process is

being used at one or more Sites, and all references to calculation or adjustment of the Standard Product Price shall include all such Standard Product Prices, if applicable.

- (i) RI Site and BIOS Site. For the RI Site and the BIOS Site, the Standard Product Price shall be calculated, for a particular Calendar Year, by dividing

(A) the cumulative Fully Absorbed Manufacturing Cost for all Released Bulk Drug Substance completed at the Site during such Calendar Year, plus the applicable Inventory Carrying Costs,

by

(B) the total number of Kg of Released Bulk Drug Substance completed at the Site during such Calendar Year.]

In such calculation, the Fully Absorbed Manufacturing Cost shall first be allocated between all Released Bulk Drug Substance for which the release is completed during such Calendar Year and Bulk Drug Substance that is Work In Process at the end of such Calendar Year. The Fully Absorbed Manufacturing Cost for all Released Bulk Drug Substance for which the release is completed during such Calendar Year shall be included, and the Fully Absorbed Manufacturing Cost for Bulk Drug Substance that is Work In Process at the end of such Calendar Year shall be carried over and used in calculating the Standard Product Price in the Calendar Year that such Bulk Drug Substance is released. The Standard Product Price for the RI Site and the BIOS Site shall not include any Excluded Supply, unless the Excluded Supply is manufactured in the same manufacturing facility at the Site as the Subject Capacity, in which case Excluded Supply shall be included in both subsections (A) and (B) of the calculation above.

- (ii) BIP Site. For Product manufactured at the BIP Site, the Standard Product Price for Bulk Drug Substance will be calculated, for a particular Calendar Year, by dividing

(A) the cumulative cost of all Bulk Drug Substance that the Parties plan to purchase from BIP in such Calendar Year,

by

(B) the total number of Kg of Bulk Drug Substance that the Parties plan to purchase from BIP in such Calendar Year.]

The Standard Product Price shall be calculated for Bulk Drug Substance to be purchased by the Parties, whether purchased in the form of Bulk Drug Substance itself or as incorporated into Drug Product or Finished Product. If incorporated into Drug Product or Finished Product, the Standard Product Price will be calculated based on the portion of the price attributable to Bulk Drug Substance.

(b) Schedule for Establishing Standard Product Prices.

(i) BIP Site. Within thirty (30) days after the Effective Date, and thereafter on or before July 31 of each Calendar Year, the Parties shall submit to each other in writing the total quantity of Product that each plans to purchase from BIP during the following Calendar Year in accordance with the binding Supply Allocation for such Calendar Year in the Five-Year Plan, along with the cost of the Bulk Drug Substance used in such Product in U.S. dollars. The Parties shall cooperate in good faith in using such information to determine the Standard Product Price for Bulk Drug Substance for the BIP Site.

(ii) RI and BIOS Sites. Immunex shall be responsible for establishing the Standard Product Price for the RI Site. Wyeth shall be responsible for establishing the Standard Product Price for the BIOS Site. Within thirty (30) days after the Effective Date, and thereafter on or before July 31 of each Calendar Year, each Party shall submit to the other in writing (A) the Standard Product Price for the following Calendar Year for the Site(s) for which it bears responsibility according to the previous sentence, and (B) its planned purchases from the Site owned by the other Party (pursuant to the applicable Five-Year Plan issued by the JSC) during the following Calendar Year, and (c) the quantity of Bulk Drug Substance deriving from the Subject Capacity at its own Site that such Party plans to manufacture for its own use.

(iii) Finalizing Standard Product Prices and Projected Blended Price. Within thirty (30) days after receiving the initial submissions pursuant to Section 9.1(b)(i) and (ii) above, and thereafter by no later than August 31 of each subsequent Calendar Year, the Parties shall agree upon in writing (A) the Standard Product Prices for all of the Sites for the upcoming Calendar Year, and (B) the projected Blended Price for the upcoming Calendar Year. The JSC shall resolve any disputes between the Parties with regard to the Standard Product Prices and the projected Blended Price, and the Parties shall agree upon in writing no later than December 1 of each Calendar Year the Standard Product Prices for all Sites and the projected Blended Price for the upcoming Calendar Year. The Standard Product Prices and Blended Price shall be established in U.S. dollars, and the Parties' finance representatives shall negotiate in good faith to determine the exchange rate to be used in calculating the Standard Product Prices for the BIP Site and the BIOS Site. Each Party

may enter into hedging contracts related to currency exchange, but such contracts will not be considered in calculation of the quarterly settlement pursuant to Section 9.3 below.

- (iv) Updating Standard Product Prices and Blended Price. Each Party shall quarterly submit to the other Party any necessary adjustments to (a) the Standard Product Price for its Site, (b) the quantity and timing of its purchases from the BIP Site or the other Party's Site for the then-current Calendar Year, or (c) the quantity of Bulk Drug Substance deriving from the Subject Capacity at its own Site that such Party plans to manufacture for its own use. Each Party shall make such submissions updating such information for past, then-current, and future Calendar Quarters in the then-current Calendar Year by no later than February 28, May 31, August 31, November 30, and December 31. Based upon any such updated information, the Parties shall agree upon any updated Standard Product Prices (the "Adjusted Standard Product Price") and projected Blended Price for the then-ongoing Calendar Year.

- (c) Example. An example of the calculation of Standard Product Prices is set forth on Exhibit A1 attached hereto.

9.2 Purchase Price.

A Party purchasing Bulk Drug Substance from one of the Sites hereunder during a Calendar Year shall pay the Standard Product Price applicable to such Site and to the form of the Manufacturing Process used to manufacture such Bulk Drug Substance (e.g., ISP the T1 Process, or the T2 Process) for such Calendar Year, as established pursuant to Section 9.1(b)(iii) above. Notwithstanding the foregoing, if the Standard Product Price for Bulk Drug Substance for the BIP Site differs from the applicable price due to BIP under the Enbrel Supply Agreement, the Party purchasing from BIP shall pay the amount therefor set forth in the Enbrel Supply Agreement. If, during such Calendar Year, the Standard Product Price for a Site is adjusted pursuant to Section 9.1(b)(iv) above, the original Standard Product Price established pursuant to Section 9.1(b)(iii) above shall continue to apply to purchases of Bulk Drug Substance from such Site, and settlement to the Adjusted Standard Product Price shall occur during the quarterly settlements described in Section 9.3(b) below.

9.3 Blended Price; Quarterly Settlement.

- (a) Adjustments to Projections. Within ten (10) days following the end of each Calendar Quarter, each Party shall submit to the other Party the following information, if applicable and if not already submitted pursuant to Section 9.1(b)(iv) above:
 - (i) Any adjustments to the quantity or price of Bulk Drug Substance for Product that such Party purchased from BIP, compared to the projections

of such purchases that were used in calculating the Standard Product Price for the BIP Site for the applicable Calendar Year;

- (ii) Any adjustments to the quantity of Bulk Drug Substance that such Party purchased from the Site owned by the other Party, or to the quantity of Bulk Drug Substance manufactured at such Party's own Site for its own use, compared to the previous projections of such purchases that were used in calculating the Blended Price for the current Calendar Year; and
- (iii) Any adjustments to the Fully Absorbed Manufacturing Cost for Bulk Drug Substance manufactured at the Site owned by such Party, or the applicable Inventory Carrying Costs, compared to the projections made in calculating the Standard Product Price for such Site for such Calendar Year.

In addition, if a Party at any other time becomes aware of a material variance in actual performance, compared to projections used in calculating the Standard Product Price, for any of the items set forth in Sections 9.3(a)(i)-(iii) above, then such Party shall provide written notice to the other Party of such variance as soon as reasonably practicable, and the JSC shall make any necessary adjustments to the Standard Product Price and the Blended Price.

- (b) Settlement to Adjusted Standard Product Price. Each Calendar Quarter, according to the schedule set forth in Section 9.4 below, the finance representatives designed by the Parties as set forth in Section 9.5(b) shall settle Calendar Year-to-date purchases of Bulk Drug Substance, made at the initial Standard Product Prices, to the Adjusted Standard Product Prices. The settlement due from one Party to the other Party shall be calculated by:
 - (i) determining the difference between (A) Calendar Year-to-date purchases, multiplied by the Adjusted Standard Product Price, and (B) Calendar Year-to-date purchases, multiplied by the Standard Product Price, and
 - (ii) subtracting therefrom the previous Calendar Year-to-date settlements made to the Adjusted Standard Product Price under this Section 9.3(b).
- (c) Calculation of Blended Price and Settlement. Each Calendar Quarter, according to the schedule set forth in Section 9.4 below, the finance representatives designated by the Parties as set forth in Section 9.5(b) shall jointly make the following calculations.
 - (i) The finance representatives shall calculate the Blended Price applicable to such Calendar Quarter, based on the weighted average of the cumulative Calendar Year-to-date purchases of Bulk Drug Substance by both Parties multiplied by the applicable Adjusted Standard Product



Prices. A separate Blended Price shall be calculated for Bulk Drug Substance manufactured using [ISP], Bulk Substance manufactured using the T1 Process, and Bulk Drug Substance manufactured using the T2 Process, if each such Manufacturing Process is being used at one or more Sites.

- (ii) The finance representatives shall determine the settlement due from one Party to another by calculating:
 - (A) the difference between (I) the cumulative Calendar Year-to-date purchases of Bulk Drug Substance purchased by each Party from all Sites, multiplied by the Blended Price as calculated in Section 9.3(c)(i) above, and (II) the cumulative Calendar Year-to-date purchases of Bulk Drug Substance purchased by each Party from all Sites multiplied by the applicable Adjusted Product Prices,
 - (B) and subtracting therefrom the previous Calendar Year-to-date settlements made to the Blended Price under this Section 8.3(c).

An example of the calculation of the Blended Price Settlement is set forth on Exhibits A2 and A3 attached hereto.

9.4 Consolidated Reporting and Forecasting.

The finance representatives designated by the Parties as set forth in Section 9.5(b) shall jointly perform consolidated reporting for the Collaboration. The finance representatives will provide each other with financial information prepared in accordance with the terms contained in this Agreement for preparation of the consolidated reports according to the schedule set forth herein. The finance representatives shall negotiate in good faith to resolve any issues arising during the preparation of consolidated reports, if the issue cannot be resolved, shall refer such dispute to the JSC. Subject to resolution of any issues by the JSC, the consolidated reporting shall be binding on the Parties, subject to Section 11.2 below, and the Party who owes the other Party a cash settlement shall pay the other Party the amount owed no later than [sixty (60)] days following the close of the Calendar Quarter at issue, as further set forth in Section 11.1 below.


9.5 Accounting and Financial Reporting.

- (a) Reporting. Each Party shall report costs in a manner consistent with GAAP, the terms hereof and such Party's project cost system. Each Party's financial representative will disclose the project cost system methodologies used, as well as any material changes thereto, to the other Party's financial representative.
- (b) Finance Representatives. Each Party shall appoint a representative from its finance department with expertise in the areas of accounting, cost allocation, budgeting, and financial reporting to assist in the matters addressed by this



Article 9. Each such representative shall act as its Party's finance manager hereunder reporting to the JSC, with authority and responsibility for determining financial accounting and reporting methods, reports, budgets and forecasts. Such representatives shall also provide services to and consult with the JSC in order to address any financial, budgetary and accounting issues that arise in connection with each Five-Year Plan. Each Party may designate a substitute financial representative to perform such functions temporarily or may replace its designated financial representative at any time by providing notice thereof to the other Party.

Article 10. Relationship with BIP, Catalytica, and Third Party Licensors

10.1 Relationship with BIP.

Immunex and Wyeth shall enter into a back-to-back agreement setting forth the obligations of Immunex and Wyeth with respect to the Enbrel Supply Agreement. 

10.2 Relationship with Catalytica.


The Catalytica Supply Agreement sets forth the terms by which either Immunex or Wyeth shall submit Firm Orders and Semi-Firm Orders (as each term is defined therein) on behalf of both Immunex and Wyeth to Catalytica. During the term of the Catalytica Supply Agreement, the Parties shall abide by the terms thereof in submitting such Firm Orders on behalf of each other. Neither Party shall take any action with Catalytica that such Party knows would interfere with fulfillment of a Five-Year Plan established hereunder. 


10.3 Third Party Royalties.

Immunex has entered into certain license agreements that require royalties to be paid upon sales of Product Supply Units (collectively, the "Immunex License Agreements"). Immunex shall enter into sublicense agreements with Wyeth, pursuant to which Wyeth will receive certain rights and licenses to use the technology of the licensors' in the Immunex License Agreement (the "Sublicense Agreements"). Each Sublicense Agreement will state any fees or other obligations owed by Wyeth to Immunex in consideration for such rights and licenses.

Article 11. Payment of Amounts Due; Audit

11.1 Payment of Amounts Due.

(a) Invoices; Payment. Each Party shall invoice the other Party for any amounts owed pursuant to Article 9 hereunder. Subject to Section 11.1(c) below, such invoices shall be paid within thirty (30) days after receipt thereof. Section 9.4 shall govern the procedure for payments between the Parties related to settlement to Blended Price; no invoices shall be required. All payments made by the Parties hereunder shall be made in U.S. dollars by bank wire transfer in immediately available funds to an account designated by the Party receiving payment. 

- (b) Disputes. Any disputes concerning amounts due shall be referred to the finance representatives designated by the Parties as set forth in Section 9.5(b). The finance representatives shall negotiate in good faith to resolve any such disputes. If the finance representatives are unable to resolve any disputes concerning amounts due, they will refer such disputes to the JSC for resolution.
- (b) Late Payments. For any amounts that one Party owes to the other Party according to Section 9.4 or 11.1(a) above, and which the paying Party has not paid within the time period set forth in such section, the paying Party shall increase the amount otherwise due and payable by adding interest thereon, computed at the rate of seven percent (7%) per annum, as of the date on which payment was due. ★

11.2 Audits and Interim Review.

Each Party shall maintain accurate books and records in accordance with GAAP and the terms hereof, supporting the calculation of Standard Product Prices, Adjusted Standard Product Prices, quantities of Product purchased and sold by such Party, Blended Prices, and amounts invoiced and paid by such Party pursuant to Section 11.1 above, for three (3) years following the end of the Calendar Year to which such records pertain, or for such longer period required by an Immunex License Agreement, provided that Immunex notifies Wyeth of such longer period in writing. The period subject to audit will extend for a maximum period of three (3) years preceding the then current Calendar Year. A Party, or its independent public accountants reasonably acceptable to the other Party, may have access to the books and records subject to audit of the other Party during normal business hours to conduct a review or audit of such books and records, solely and to the extent necessary to confirm the accuracy of the amounts reported and calculated in accordance with the terms hereof; provided, however, that a Party conducting such an audit must provide the other Party at least thirty (30) days' prior written notice and may not conduct such an audit more than once in any four (4) consecutive Calendar Quarters during the Term or more than once following the Term. Any payment made by the Party being audited to the other Party as a result of such an audit shall include interest from the date due, calculated as set forth in Section 11.1(b) above. Any such inspection or audit shall be at the expense of the Party conducting it; provided, however, that if such accountants reasonably determine that the Party conducting the audit has overpaid or underpaid the other Party by an amount equal to or greater than ten percent (10%) in the period of time within the scope of the audit, the other Party shall pay all reasonable fees and expenses incurred by such accountants in making such determination. Any accounting firm conducting such an audit shall enter into a confidentiality agreement reasonably acceptable to both Parties limiting the disclosure and use of information contained in such books and records. In the event that an audit performed in accordance with this Section 11.2 does not resolve the dispute between the Parties, then such dispute shall be referred to the JSC pursuant to Section 3.4 above. ★ ★

Article 12. Representations and Warranties; Limitation of Liabilities

12.1 Wyeth.

Wyeth hereby represents and warrants to Immunex that:

- (a) Wyeth has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and
- (b) Wyeth has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of Wyeth, and constitutes a legal, valid, binding obligation, enforceable against Wyeth in accordance with its terms.

12.2 Immunex.

Immunex hereby represents and warrants to Wyeth that:

- (a) Immunex has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and
- (b) Immunex has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of Immunex, and constitutes a legal, valid, binding obligation, enforceable against Immunex in accordance with its terms.

Article 13. Indemnification

13.1 Indemnification by Immunex.

Immunex shall indemnify, defend, and hold Wyeth, its Affiliates, and its and their respective directors, officers, employees and agents, harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs, and expenses (including, without limitation, reasonable attorneys' fees and expenses) (collectively, the "Liabilities") to the extent such Liabilities arise out of or result from (i) any claim, lawsuit or other action by a Third Party caused by the manufacture, use, handling, distribution, marketing, or sale of the Bulk Drug Substance, Drug Product, Finished Product, or Product Supply in the Immunex Territory, (ii) any material breach by Immunex of its representations, warranties, and covenants made hereunder, and/or (iii) Immunex's grossly negligent acts or omissions or willful misconduct. Notwithstanding the foregoing, Immunex's indemnification obligation hereunder shall not apply to the extent that any particular Liability arises out of or results from (y) any material breach by Wyeth of its representations, warranties, or covenants made hereunder, and/or (z) Wyeth's grossly negligent acts or omissions or willful misconduct.

13.2 Indemnification by Wyeth.

Wyeth shall indemnify, defend, and hold Immunex, its Affiliates, and their respective directors, officers, employees, and agents harmless from and against all Liabilities arise out of or result from (i) any claim, lawsuit, or other action by a Third Party caused by the manufacture, use, handling, distribution, marketing, or sale of the Bulk Drug Substance, Drug Product, Finished Product, or Product Supply in the Wyeth Territory, (ii) any material breach by Wyeth of its representations, warranties, and covenants made hereunder, and/or (iii) Wyeth's grossly negligent acts or omissions or willful misconduct. Notwithstanding the foregoing, Wyeth's indemnification obligation hereunder shall not apply to the extent that any particular Liability arises out of or results from (y) any material breach by Immunex of its representations, warranties, or covenants made hereunder, and/or (z) Immunex's grossly negligent acts or omissions or willful misconduct.

13.3 Indemnification Procedures.

A person (the "Indemnatee") which intends to claim indemnification under Section 13.1 or 13.2 hereof shall promptly notify the Party indemnifying hereunder (the "Indemnitor") in writing of any claim, lawsuit or other action in respect of which the Indemnatee or any of its directors, officers, employees, agents or Affiliates intend to claim such indemnification. The Indemnatee shall permit, and shall cause its directors, officers, employees, agents, and Affiliates to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement does not adversely affect the Indemnatee's rights hereunder or impose any obligations on the Indemnatee in addition to those set forth herein in order for it to exercise such rights. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnatee, its directors, officers, employees, agents and Affiliates shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification. The Indemnatee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

Article 14. Term and Termination

14.1 Term.

The initial term (the "Initial Term") of this Agreement shall begin as of the Effective Date and shall continue, unless earlier terminated as set forth in Section 14.2 below, until the later of (a) twelve (12) years after the Effective Date, or (b) the expiration or termination of the Enbrel Supply Agreement. The Parties may extend this Agreement beyond the Initial Term for periods of one (1) year or more (any such period, an "Additional Term"), by mutual written agreement entered

into by the Parties at least three (3) years prior to the expiration of the Initial Term or Additional Term, as applicable. If an Additional Term is for a period of less than three (3) years, the Parties may extend the Agreement beyond such Additional Term for periods of one (1) year or more by mutual written agreement entered into by the Parties at least six (6) months prior to the expiration of the Additional Term. The Initial Term plus any Additional Terms shall constitute the "Term" of this Agreement.

14.2 Termination.

This Agreement may be terminated prior to the period set forth in Section 14.1 above as follows:

- (a) Mutual Agreement. This Agreement may be terminated in its entirety at any time upon mutual written agreement between Immunex and Wyeth signed by a duly authorized executive officer of each Party.
- (b) Material Breach.
 - (i) This Agreement may be terminated in its entirety by either Immunex or Wyeth upon written notice to the other Party in the event of a material breach by the other Party which is not cured within sixty (60) days from written notice to the breaching Party specifying in reasonable detail the nature of such breach or longer if the breaching Party delivers a certificate that such material breach is not reasonably capable of being cured within sixty (60) days and that the breaching Party is working diligently to cure such breach, but in no event shall the time for curing such breach exceed an additional sixty (60) days.
 - (ii) Except as expressly stated otherwise herein, remedies hereunder are cumulative, and nothing in this Agreement shall prevent either Party, in the case of a breach, from not terminating this Agreement and seeking to enforce its rights hereunder.

14.3 Consequences of Termination.

- (a) Amounts Outstanding. Expiration or termination of this Agreement for any reason shall not exempt either Immunex or Wyeth from paying to the other Party any amounts due to such Party under this Agreement and outstanding at the time of such expiration or termination.
- (b) Transitional Supply Obligation. In the event of termination of this Agreement by either Party pursuant to Section 14.2(b) above, the breaching Party shall, at the request of the non-breaching Party, continue to supply the Product to the non-breaching Party until such time as a new supplier for the Product has been approved by the applicable regulatory authorities in the non-breaching Party's Territory; provided, however, that unless otherwise agreed upon, the breaching Party shall not be required to supply the Product longer than for the duration of the Five-Year Plan in effect at the time of termination, which Five-Year Plan

shall, unless otherwise agreed, become binding on the Parties for the entire five (5) year-period included therein. The breaching Party shall supply the non-breaching Party with the quantities of Product that the breaching Party is obligated to supply according to the Supply Allocation included in such Five-Year Plan.

- (c) Willful Breach. In the event that either Party willfully breaches its obligation to supply Product to the other Party in accordance with the terms set forth in Articles 4, 5, or 6 hereof, the non-breaching Party shall be entitled to recover its incidental, special, and consequential damages incurred as result of such willful breach, in addition to any other remedies that the non-breaching Party may have at law or in equity. EXCEPT AS SET FORTH IN THE PRECEDING SENTENCE, NEITHER PARTY SHALL HAVE THE RIGHT TO RECOVER INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES ARISING FROM OR RELATED TO BREACH BY THE OTHER PARTY OF THIS AGREEMENT.

14.4 Specific Performance.

The Parties agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof and that the Parties shall be entitled to specific performance of the terms of this Agreement, in addition to any other remedy at law or equity.

14.5 Rights Not Exclusive.

All rights to terminate, all rights upon termination, and all rights to seek specific performance are in addition to other remedies in law or equity that may be available to either Party.

Article 15. Confidentiality

15.1 Confidentiality Obligations.

Except as permitted elsewhere under this Agreement, each Party agrees to take Reasonable Steps (as defined in this Section 15.1) (a) to receive and maintain the Confidential Information of the other Party in confidence, (b) not to disclose such Confidential Information to any Third Party without the written consent of the disclosing Party, and (c) to promptly notify the disclosing Party upon learning of any law, rule, regulation, or court order that purports to compel disclosure of any Confidential Information of the disclosing Party and to reasonably cooperate with the disclosing Party, at the disclosing Party's expense, in the exercise of the disclosing Party's right to protect the confidentiality of such Confidential Information. Neither Party hereto shall use all or any part of the Confidential Information of the other Party for any purpose other than to perform its obligations under this Agreement. The Parties will take Reasonable Steps (as defined in this Section 15.1) to ensure that their employees, representatives, and agents comply with this provision, and will be responsible for any breach by such employees, representatives, and agents. As used herein, "Reasonable Steps"

means at least the same degree of care that the receiving Party uses to protect its own Confidential Information, and in, any event, no less than reasonable care.

15.2 Exclusions.

Nothing contained herein shall prevent a Party from disclosing Confidential Information pursuant to any applicable law, rule, regulation, or court order; provided, however, that such Party complies with the notice provisions of Section 15.1(c) to the extent permissible under applicable laws, rules, regulations, or court orders. Such disclosure shall not alter the status of such information hereunder for all other purposes as Confidential Information.

15.3 Remedies.

Each Party acknowledges and agrees that the provisions of this Article 15 are reasonable and necessary to protect the other Party's interests in its Confidential Information, that any breach of the provisions of this Article 15 may result in irreparable harm to such other Party, and that the remedy at law for such breach may be inadequate. Accordingly, in the event of any breach or threatened breach of the provisions of this Article 15 by a party hereto, the other Party, in addition to any other relief available to it at law in equity or otherwise, shall be entitled to seek temporary and permanent injunctive relief restraining the breaching Party from engaging in and/or continuing any conduct that would constitute a breach of this Article 15, without the necessity of proving actual damages or posting a bond or other security.

15.4 Publications.

No announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, the subject matter herein, or either Party's performance hereunder (collectively, a "Publication") shall be made without the other Party's prior approval; provided, however, that either Party may make such Publication or disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with federal or state laws or regulations. Each Party agrees to submit such Publication it proposes to make to the other Party for purposes of such other Party's review and comment or, if required pursuant to this Section 15.4, approval. Any such disclosure will not contain confidential business or technical information of the other Party, unless if disclosure of such confidential business or technical information is required by law or regulation, in which case the disclosing Party will redact if permissible by such law or regulation, or otherwise make reasonable efforts to minimize such disclosure and obtain confidential treatment for any such information which is disclosed by requirement of such law or regulation. Except as otherwise required by such law or regulation, the Party whose Publication has been reviewed shall consider in good faith the removal of any information the reviewing Party reasonably deems to be inappropriate for disclosure. Each Party further agrees to respond as promptly as reasonably practicable to a proposed Publication in accordance with timelines agreed upon by the Parties, and likewise agrees that it shall not unreasonably withhold approval of such Publication.

Article 16. Force Majeure

16.1 Effects of Force Majeure.

Neither Immunex nor Wyeth shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due hereunder) occasioned by any act of God, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining energy or other utilities, labor disputes of whatever nature or any other reason beyond the control and without the fault or negligence of the Party affected thereby (a "Force Majeure Event"). Such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance hereunder.

16.2 Notice of Force Majeure.

Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations hereunder. Each Party further agrees to use reasonable efforts to correct the Force Majeure Event as quickly as possible and to give the other Party prompt written notice when it is again fully able to perform such obligations.

16.3 Supply Shortage Caused by Force Majeure.

If a Force Majeure Event occurs, the JSC shall determine whether it has caused a Supply Shortage, and if so, the JSC shall make any corresponding adjustments to the then-current Five-Year Plan.

Article 17. Assignment

17.1 Assignment.

This Agreement shall be binding upon the successors and assigns of each Party and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that either Party may assign its interest under this Agreement, without the prior written consent of the other Party, (a) to an Affiliate, so long as the assigning Party unconditionally guarantees the obligations of such Affiliate or (b) to a successor to the assigning Party's business by reason of merger, sale of all or substantially all of its assets or other form of acquisition, provided that such successor agrees in writing to assume all of the obligations of the assigning Party under this Agreement. Any purported assignment without a required consent shall be void. No assignment shall relieve either Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

Article 18. Dispute Resolution

18.1 Dispute Resolution.

The Parties recognize that a *bona fide* dispute as to certain matters may from time to time arise during the term of this Agreement that relates to a Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by written notice to the other Party, have such dispute referred to their respective officers designated below, or their designees, for attempted resolution by good faith negotiations within thirty (30) days after such written notice is received. Such designated officers are as follows:

For Immunex – Chief Operating Officer

For Wyeth – President

In the event the designated officers are not able to resolve such dispute within such thirty (30)-day period, or such other period of time as the Parties may mutually agree in writing, each Party shall have the right to pursue any and all remedies available at law or in equity.

- 18.2 Certain Disputes. Notwithstanding the foregoing, this Article 18 shall not apply to any disputes arising under Article 13 (Indemnification) or Article 15 (Confidentiality) hereunder. Disputes arising under the Quality Agreement shall be governed by the process set forth in Article 9 therein.

Article 19. Miscellaneous

19.1 Notices.

Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with the original promptly sent by any of the foregoing manners), to the addresses or facsimile numbers of the other Party set forth below, or at such other addresses as may from time to time be furnished by similar notice by either Party. The effective date of any notice hereunder shall be the date of receipt by the receiving Party.

If to Immunex: Immunex Corporation
 51 University Street
 Seattle, Washington 98101
 Attention: Chief Operating Officer
 Fax: (206) 292-9271
 Phone: (206) 587-0430

with a copy to: Immunex Corporation
51 University Street
Seattle, Washington 98101
Attention: General Counsel
Fax: (206) 292-9271
Phone: (206) 587-0430

If to Wyeth: Wyeth-Ayerst Laboratories
555 E. Lancaster
St. Davids, Pennsylvania 19807
Attention: Senior Vice President, Global Business Development
Fax: (610) 688-9498
Phone: (610) 971-5809

with a copy to: American Home Products Corporation
Five Giralda Farms
Madison, New Jersey 07940
Attention: General Counsel
Fax: (973) 660-7050
Phone: (973) 660-6040

19.2 Applicable Law.

This Agreement shall be construed and the respective rights of the Parties determined in accordance with the laws of the State of New Jersey, without regard to conflicts of law. The Parties expressly exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

19.3 Headings.

The table of contents and all headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement.

19.4 Exhibits.

All exhibits referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

19.5 Severability.

Both Parties hereby expressly agrees that they have no intention to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or either Party hereto, in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as

enforcement of the remainder does not violate the Parties' overall intentions in this transaction.

19.6 Waiver.

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

19.7 Construction.

The Parties agree that each Party and its counsel has reviewed this Agreement and that any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not apply to the interpretation of this Agreement.

19.8 Counterparts.

This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed to be an original and all of which shall constitute the same instrument.

19.9 Entirety; Amendments.

This Agreement, including any exhibits attached hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof, and no terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless it is hereafter made in writing and signed by both Parties. The MOU is superceded by this Agreement and is of no further force and effect. After RI Approval, the Short-Term Allocation Agreement shall be superceded by this Agreement and shall be of no further force and effect. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any purchase order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein. In the event of a conflict between this Agreement and the exhibits hereto, the terms of this Agreement shall control. In the event of a conflict between this Agreement and the terms of the TNFR Agreement, the terms of this Agreement shall control. In the event of a conflict between this Agreement and the terms of the Enbrel Supply Agreement, the terms of the Enbrel Supply Agreement shall control. This Agreement may be amended and supplemented only by a written instrument signed by both Parties.

[This space is intentionally left blank.]

IN WITNESS WHEREOF, Immunex and Wyeth have caused this Agreement to be executed as of the Effective Date.

IMMUNEX CORPORATION

By: *David A. Mann*
Name: David A. Mann
Executive Vice President
Title: Chief Financial Officer
Date: November 6, 2001

**AMERICAN HOME PRODUCTS
CORPORATION, acting through its
Wyeth-Ayerst Laboratories division**

By: *Kenneth J. Martin*
Name: Kenneth J. Martin
Title: Senior Vice President, Finance
Date: November 6, 2001

