

Complaint

IN THE MATTER OF

AMGEN INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-4056; File No. 0210059

Complaint, July 12, 2002--Decision, September 3, 2002

This consent order addresses the merger of Respondent Amgen Inc. and Respondent Immunex Corporation, two pharmaceutical manufacturers. The order, among other things, requires the respondents to divest all of Respondent Immunex's assets relating to Leukine – a neutrophil regeneration factor used to treat neutropenia (the suppression of production of certain white blood cells known as “neutrophils”), which often results from chemotherapy – to Schering AG. The order also requires the respondents to license certain Amgen patents relating to its tumor necrosis factor (“TNF”) receptor to Serono S.A. In addition, the order requires the respondents to license certain Amgen and Immunex patents relating to the development of Interleukin-1 (“IL-1”) receptors to Regeneron Pharmaceuticals Inc., thereby enabling Regeneron to continue to develop its IL-1 Trap product – an IL-1 inhibitor used to treat rheumatoid arthritis – in competition with the respondents.

Participants

For the Commission: *Elizabeth A. Jex, James J. Hegarty, Kari A. Wallace, David von Nirschl, Jennifer Lee, Kristen M. Gorzelany, Stephanie Richard, Ann Malester, Christina Sarris, Elizabeth A. Piotrowski, Hajime Hadeishi, and Michael G. Vita.*

For the Respondents: *John M. Nannes, Skadden, Arps, Slate, Meagher & Flom, and Daniel M. Wall and J. Thomas Rosch, Latham & Watkins.*

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COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that Respondent Amgen Inc. (“Amgen”), a corporation subject to the jurisdiction of the Commission, has agreed to merge with Respondent Immunex Corporation (“Immunex”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. DEFINITIONS

1. “Abbott” means Abbott Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the state of Illinois, with its offices and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064.
2. “Celltech” means Celltech Group plc, a corporation organized, existing, and doing business under and by virtue of the laws of the United Kingdom, with its offices and principal place of business located at 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.
3. “FDA” means the United States Food and Drug Administration.
4. “IL-1 Inhibitor” or “IL-1 Inhibitor product” means any molecule capable of binding to human Interleukin-1 (“IL-1”), thereby reducing the binding of IL-1 to the target cell membrane receptors, which molecule is comprised of all of, or an IL-1 binding portion of, an IL-1 receptor (Type I or Type II) and all of, or an active portion of, the IL-1 accessory protein.

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5. “Johnson & Johnson” means Johnson & Johnson, a corporation organized, existing, and doing business under and by virtue of the laws of the state of New Jersey, with its offices and principal place of business located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

6. “Merger Agreement” means the Amended and Restated Agreement and Plan of Merger by and among Amgen, AMS Acquisition Inc., and Immunex dated December 16, 2001.

7. “Neutrophil Regeneration Product” means a colony stimulating factor produced, at least in part, by recombinant DNA technology, that stimulates the proliferation and differentiation of human neutrophil cells, commonly referred to as white blood cells, including, but not limited to, granulocytes and macrophages.

8. “Pharmacia” means Pharmacia Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its offices and principal place of business located at 100 Route 206 North, Peapack, New Jersey 07977.

9. “RA” means rheumatoid arthritis.

10. “Regeneron” means Regeneron Pharmaceuticals Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the state of New York, with its offices and principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

11. “Serono” means Serono International S.A., a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation, with its offices and principal place of business located at 15bis, Chemin des Mines, Case Postale 54, CH-1202 Geneva, Switzerland.

12. “TNF Inhibitor” or “TNF Inhibitor product” means any recombinant human tumor necrosis factor (“TNF”) binding

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protein that binds to TNF, thereby reducing the binding of TNF to target cell membrane receptors.

II. RESPONDENTS

13. Respondent Amgen is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen, among other things, is engaged in the research, development, manufacture, and sale of human pharmaceutical products, including, among other things, Neutrophil Regeneration Products, TNF Inhibitors, and IL-1 Inhibitors.

14. Respondent Immunex is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Washington, with its office and principal place of business located at 51 University Street, Seattle, Washington 98101. Immunex, among other things, is engaged in the research, development, manufacture, and sale of human pharmaceutical products, including, among other things, Neutrophil Regeneration Products, TNF Inhibitors, and IL-1 Inhibitors.

15. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED MERGER

16. On December 16, 2001, Amgen and Immunex entered into a Merger Agreement whereby Amgen agreed to acquire, through its wholly-owned subsidiary, AMS Acquisition Inc., 100 percent of all issued and outstanding shares of Immunex (“Merger”). Amgen intends to pay consideration such that each issued and outstanding share of Immunex common stock will be converted

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into the right to receive 0.44 shares of Amgen common stock and about \$4.50 in cash. The parties estimate the aggregate value of the transaction to be approximately \$16 billion. After the completion of the transaction, Amgen will be the surviving corporate entity.

IV. THE RELEVANT MARKETS

17. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Merger are:

- a. the research, development, manufacture, and sale of Neutrophil Regeneration Products;
- b. the research, development, manufacture, and sale of TNF Inhibitors; and
- c. the research, development, manufacture, and sale of IL-1 Inhibitors.

18. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger in the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

19. Amgen and Immunex are the only two companies competing in the \$1.2 billion neutrophil regeneration market. Amgen is developing and marketing Neupogen, a granulocyte colony stimulating factor ("G-CSF") that stimulates the production of granulocytes to treat cancer chemotherapy patients suffering from neutropenia, as well as for other indications. Amgen is also marketing Neulasta, a new, longer-lasting formulation of the G-CSF product for those same indications. Immunex is developing and marketing Leukine, a granulocyte macrophage colony stimulating factor that stimulates the production of macrophages and granulocytes to treat cancer chemotherapy patients (especially acute myelogenous leukemia

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cancer patients) suffering from neutropenia, as well as for other indications.

20. In the United States, Amgen and Immunex are the only companies clinically developing or marketing soluble TNF receptor products, two of only four companies clinically developing subcutaneously delivered TNF Inhibitors, and two of only five companies clinically developing TNF Inhibitors to treat RA and other autoimmune diseases by blocking the activity of the pro-inflammatory cytokine TNF. There are two TNF Inhibitors approved by the FDA for the treatment of RA: (1) Enbrel, Immunex's soluble TNF receptor; and (2) Remicade, Johnson & Johnson's chimeric monoclonal antibody targeting the TNF cell surface receptor. In the United States, there are three TNF Inhibitors in clinical development: (1) Amgen is in late Phase II trials with PEG-sTNFr, a soluble receptor product very similar to Immunex's Enbrel; (2) Abbott recently submitted a Biologic License Application to the FDA for its humanized monoclonal antibody, D2E7, targeting the TNF cell surface receptor; and (3) Pharmacia and Celltech are jointly in Phase II trials with a humanized monoclonal antibody, CDP 870, targeting the TNF cell surface receptor. Serono also is developing a soluble TNF receptor, Onercept, for use in Europe, but it does not possess the patent rights necessary to market the product in the United States.

21. Amgen and Immunex are two of only three companies clinically developing or marketing IL-1 Inhibitor products to treat RA and other autoimmune diseases by blocking the activity of the pro-inflammatory cytokine IL-1. Amgen's product, Kineret, was the first IL-1 Inhibitor approved by the FDA. Amgen also has research and development efforts directed at second generation IL-1 Inhibitors. Immunex is in Phase I trials of its IL-1 Inhibitor product, known as IL-I Type II. Regeneron, the only other company in clinical development of an IL-1 Inhibitor, is about to begin Phase II trials of its IL-1 Inhibitor product called IL-1 Trap. It appears that Immunex is likely to succeed in its efforts to preclude Regeneron's successful commercialization of its IL-1 Trap product through patent infringement litigation for the

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following reasons: (1) Immunex has the ability to block Regeneron by using patent litigation; (2) Regeneron has indicated that such litigation, even were it to ultimately yield a favorable outcome for Regeneron, could foreclose its ability to commercialize its IL-1 Trap; and (3) the likelihood of threatened patent litigation by Immunex will jeopardize and could effectively preclude commercialization of Regeneron's IL-1 Trap.

VI. ENTRY CONDITIONS

22. Amgen and Immunex each control substantial proprietary rights necessary to commercialize Neutrophil Regeneration Products, TNF Inhibitor products, and IL-1 Inhibitor products in the United States, and possess the technological, manufacturing, clinical and regulatory expertise, and manufacturing capability to commercially develop Neutrophil Regeneration Products, TNF Inhibitor products, and IL-1 Inhibitor products.

23. Entry into the United States neutrophil regeneration, TNF Inhibitor, and IL-1 Inhibitor product markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the merger. FDA regulations covering these products create long lead times for the introduction of new products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry.

24. Entry into the neutrophil regeneration, TNF Inhibitor, and IL-1 Inhibitor product markets requires lengthy preclinical and clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the FDA. Clinical development and FDA approval can extend from 6 to 10 years and cost over \$200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. No company can reach advanced stages of development in the relevant market without: (1) scientific research that

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requires years to complete; (2) patent rights sufficient to provide the company with reasonable assurances of freedom to operate; (3) commercial scale product manufacturing expertise and capacity, regulatory approvals; and (4) clinical expertise. The necessary intellectual property includes the respective DNA sequences, methods of making and using neutrophil regeneration, TNF Inhibitor, and IL-1 Inhibitor products.

VII. EFFECTS OF THE MERGER

25. The effects of the Merger, if consummated, may be to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Amgen and Immunex in the neutrophil regeneration market;
- b. by increasing the merged firm's ability to exercise market power unilaterally in the neutrophil regeneration market;
- c. by reducing innovation competition in the research, development, and commercialization of (a) neutrophil regeneration, (b) TNF Inhibitor, and (c) IL-1 Inhibitor products; and
- d. by eliminating potential competition in the (a) TNF Inhibitor and (b) IL-1 Inhibitor product markets.

VIII. VIOLATIONS CHARGED

26. The Merger Agreement described in Paragraph 16 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

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27. The Merger described in Paragraph 16, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twelfth day of July, 2002, issues its Complaint against said Respondents.

By the Commission.

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DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger of Respondent Amgen Inc. (“Amgen”) and Respondent Immunex Corporation (“Immunex”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

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1. Respondent Amgen is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

2. Respondent Immunex is a corporation organized, existing and doing business under and by virtue of the laws of the State of Washington, with its office and principal place of business located at 51 University Street, Seattle, Washington 98101-2936.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Amgen” means Amgen Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Amgen Inc. (including, but not limited to, AMS Acquisition, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Immunex” means Immunex Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Immunex Corporation (including, but not limited to, Immunex Manufacturing Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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- C. “Respondents” means Amgen and Immunex, individually and collectively.
- D. “Merger” means the proposed merger of AMS Acquisition Inc., a wholly-owned subsidiary of Amgen, and Immunex by means of an Amended and Restated Agreement and Plan of Merger dated as of December 16, 2001, by and among Amgen, AMS Acquisition Inc., and Immunex.
- E. “Commission” means the Federal Trade Commission.
- F. “Regeneron” means Regeneron Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its offices and principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591.
- G. “Schering” means Schering Aktiengesellschaft, a stock corporation organized under the laws of The Federal Republic of Germany with its offices and principal place of business located at Mullerstrasse 178, 13353 Berlin, Germany.
- H. “Serono” means Serono International, S.A., a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation, with its offices and principal place of business located at 15bis, Chemin des Mines, Case Postale 54, CH-1202 Geneva, Switzerland.
- I. “Agency(ies)” means any governmental regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s) or permit(s) for any aspect of the research, development, manufacture, marketing, distribution or sale of a Product. The term “Agency” includes, but is not limited to, the United States Food and Drug Administration (“FDA”).

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- J. “BLA” means the Biologic License Application or Establishment License Application/Product License Application filed or to be filed with the FDA for Leukine pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, or its foreign Agency equivalent, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the FDA or other Agency relative thereto.
- K. “Bothell Facility” means that portion of the Immunex facility located at 21511 23rd Drive SE, Bothell, Washington that is described in Exhibits A-2 and B (and which constitutes a portion of the larger facility that is legally described in Exhibit A-1) of the Lease by and among Immunex and Schering, which Lease is attached as Exhibit H to the Leukine Asset Purchase Agreement.
- L. “Business Day” means any day excluding Saturday, Sunday and any United States Federal holiday.
- M. “Closing Date” means the date on which Respondents and a Commission-approved Acquirer close on a transaction to divest, license, or otherwise convey relevant assets pursuant to this Order.
- N. “Commission-approved Acquirer” means an entity approved by the Commission to acquire the Leukine Assets.
- O. “Confidential Business Information” means all information owned by Respondents that is not in the public domain related to the research, development, manufacture, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support, or use of Leukine.
- P. “Divestiture Agreement” means any agreement between Respondents and a Commission-approved Acquirer (or between a trustee appointed pursuant to Paragraph VI of this

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Order and a Commission-approved Acquirer) and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Leukine Assets to be divested that have been approved by the Commission to accomplish the requirements of this Order.

- Q. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph VI.A. of this Order.
- R. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority who issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Leukine Trademarks required to be divested.
- S. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to Leukine.
- T. “Effective Date” means the date the Merger is consummated by filing articles of merger with the Secretary of State of the State of Washington.
- U. “Governmental Entity” means any Federal, state, local or non-U.S. government or any court, legislature, governmental agency or governmental commission or any judicial or regulatory authority of any government.
- V. “IL-1 Inhibitor” means any recombinant human Interleukin-1 (“IL-1”) binding protein that binds to IL-1, thereby reducing the binding of IL-1 to the target cell membrane receptors.
- W. “IL-1 Trap” means a molecule capable of binding to IL-1, thereby reducing the binding of IL-1 to the target cell membrane receptors, which molecule is comprised of all of, or an IL-1 binding portion of, an IL-1 receptor (Type I or

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Type II) and all of, or an active portion of, the IL-1 accessory protein.

- X. “IL-1 License Agreement” means the license agreement between Immunex and Regeneron dated June 26, 2002, attached hereto as non-public Appendix IV.
- Y. “IND” means an Investigational New Drug Application filed with the FDA for Leukine pursuant to 21 C.F.R. 312.1, et seq., for which Immunex is the “Sponsor” (as defined in 21 C.F.R. 312.3), and all supplements, amendments and revisions thereto.
- Z. “Leukine” means the Product that contains the active ingredient generically known as sargramostim, *i.e.*, a certain modified human granulocyte-macrophage colony stimulating factor produced by recombinant DNA technology, that is or was researched, developed, manufactured, marketed and sold by Respondent Immunex prior to the divestiture of the Leukine Assets. The term “Leukine” also includes Products in development by Respondent Immunex on or before the Effective Date that have a similar amino acid sequence and mechanism of action to that of Leukine, *i.e.*, that stimulate production of granulocytes and macrophages.
- AA. “Leukine Assets” means all of Respondent Immunex’s rights, title and interest, in the United States and Canada, in and to all assets related to Leukine to the extent legally transferable, including the research, development, manufacture, distribution, marketing or sale of Leukine including, without limitation, the following:
 - 1. all Leukine Intellectual Property;
 - 2. the Product and Product Registrations;
 - 3. the Leukine Trade Dress;

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4. the existing lists of all current customers for Leukine and the pricing of Leukine for such customers;
5. at the Commission-approved Acquirer's option, each of the Leukine Assumed Contracts;
6. all Leukine Marketing Materials;
7. all Website(s) related to Leukine;
8. rights to use the NDC Numbers related to Leukine;
9. rights of reference to the Drug Master Files;
10. rights of reference (if such rights exist) to information similar to the Drug Master Files submitted to any Agency (including any Agency outside the United States and Canada) other than the FDA;
11. Leukine Scientific and Regulatory Material;
12. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders is to be provided to the Commission-approved Acquirer within two Business Days after the Closing Date);
13. Leukine Manufacturing Technology, and Leukine manufacturing and manufacturing processes;
14. at the Commission-approved Acquirer's option, all inventories in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Leukine specific packaging and labels;
15. the cell bank inventories related to Leukine owned by Respondent Immunex, including, but not limited to, Master Cell Bank Lot BVL-0002; Working Cell Bank Lot: BAG/010138; Working Cell Bank Lot: BAG/A03184;

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Original Host Source Material: XV2181 diploid; and one (1) vial of yeast haploid strain named: 79 containing the same plasmid PIXY15;

16. the Leukine Microbial Manufacturing Facility, *provided, however*, that, in lieu of a sale of this facility to the Commission-approved Acquirer, the Respondents may offer a lease to the facility, for a term of not less than three (3) years from the Closing Date and renewable, at the Commission-approved Acquirer's option, for at least five (5) additional terms of one (1) year each;
17. all manufacturing and other equipment located at the Leukine Microbial Manufacturing Facility that was used in, or suitable for use in, the research, development or manufacture of Leukine;
18. at the Commission-approved Acquirer's option, the Bothell Facility including the real property and buildings; *provided, however*, if the Commission-approved Acquirer so elects, the Respondents may provide a long-term lease to the Bothell Facility in lieu of a sale of the facility to the Commission-approved Acquirer;
19. at the Commission-approved Acquirer's option, all quality control equipment used or held for use for the manufacture of Leukine that is located at the Bothell Facility;
20. all permits from any Governmental Entity that are required to manufacture or sell Leukine, to the extent transferable; and
21. all Respondents' books, records and files related to the foregoing, including, but not limited to, the following specified documents: the Product Registrations; rights of reference to Drug Master Files, including, but not limited to, the pharmacology and toxicology data contained in all INDs and BLAs; all data submitted to and all

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correspondence with the FDA and other Agencies; all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, sales force call activity, and physician prescription activity (to the extent Respondents have the right to transfer such information), for Leukine on a per-physician basis from January 1, 1997, through the Closing Date, and quality control histories pertaining to Leukine owned by Respondents, in each case such as is in existence, and in the possession or control of Respondents, as of the Closing Date.

Provided, however, that in cases in which documents or other materials included in the Leukine Assets contain information that (i) relates both to Leukine and to other Products or businesses of Respondent Immunex, and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to Leukine, the Respondent Immunex shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Commission-approved Acquirer, the Commission-approved Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondents provide the Commission-approved Acquirer with the above-described information without requiring Respondents completely to divest themselves of information that, in content, also relates to Products and businesses other than Leukine.

- BB. “Leukine Asset Purchase Agreement” means the “Asset Purchase Agreement by and between Immunex Corporation as Seller, and Schering Aktiengesellschaft as Purchaser” dated May 2, 2002, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Leukine Assets to be divested that have been approved by the Commission to accomplish the requirements of this

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Order. The Leukine Asset Purchase Agreement is attached to this Order as non-public Appendix II.

- CC. “Leukine Assumed Contracts” means all contracts or agreements:
1. pursuant to which any third party purchases Leukine from Immunex;
 2. pursuant to which Immunex purchases any materials from any third party for use in connection with the manufacture of Leukine;
 3. relating to any clinical trial involving Leukine;
 4. constituting the material transfer agreements involving the transfer of Leukine;
 5. relating to the marketing of Leukine or educational matters relating to the Leukine business;
 6. relating to the manufacture (including finish or fill) of Leukine;
 7. constituting confidentiality agreements involving Leukine;
 8. involving any royalty, licensing or similar arrangement involving Leukine;
 9. pursuant to which any services are provided to Immunex with respect to Leukine or the Leukine business, including consultation arrangements; and/or
 10. pursuant to which any third party collaborates with Immunex in performance of research or development of Leukine or the Leukine business.

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Provided, however, that where any such contract or agreement also relates to Product(s) of Respondent Immunex other than Leukine, Respondents shall assign the Commission-approved Acquirer all such rights under the contract or agreement as are related to Leukine, but concurrently may retain similar rights for the purposes of the other Product(s).

- DD. “Leukine Bothell Microbial Facility Project Employees” means all employees of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the planning, engineering, procurement, or analysis of the means to produce Leukine at Immunex’s facility in Bothell, Washington within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.
- EE. “Leukine Copyrights” means rights to all original works of authorship of any kind related to Leukine and any registrations and applications for registrations thereof, including, but not limited to, the following: all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and development of Leukine or of any materials used in the research, development, manufacture, marketing or sale of Leukine, including all raw data relating to clinical trials of Leukine, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, Leukine sales forecasting models, medical education materials, sales training materials, Website content and advertising and display materials; all records relating to employees that accept employment with the Commission-approved

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Acquirer (excluding any personnel records the transfer of which is prohibited by applicable law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to Leukine or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

- FF. “Leukine Core Employees” means the Leukine Bothell Microbial Facility Project Employees, Leukine Manufacturing Employees, Leukine Marketing Employees, Leukine Patent Attorneys, and Leukine Research and Development Employees.
- GG. “Leukine Intellectual Property” means all of the following related to Leukine:
1. Patents;
 2. Leukine Copyrights;
 3. Leukine Software;
 4. Leukine Trademarks, including the goodwill of the business symbolized thereby and associated therewith;
 5. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, development and other information, and all rights in any jurisdiction to limit the use or disclosure thereof;

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6. rights to obtain and file for Patents and registrations thereof;
and
7. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing.

Provided, however, “Leukine Intellectual Property” does not include the name “Immunex” or related logos to the extent used on other of Respondent Immunex’s Products.

- HH. “Leukine Manufacturing Employees” means all employees of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the manufacture of Leukine, including, but not limited to, those involved in the quality assurance and quality control of Leukine, within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.
- II. “Leukine Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability and shelf life of Leukine, including Leukine’s formulation, in existence and in the possession of Respondents as of the Closing Date, including, but not limited to, manufacturing records, sampling records, standard operating procedures and batch records related to the manufacturing process, and supplier lists.
- JJ. “Leukine Marketing Employees” means all executives of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion of Leukine in the United States and Canada within the eighteen (18) month period immediately prior to the Closing Date. These employees include, without limitation, all executives having any responsibilities in the areas of sales management, brand

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management, sales training, market research, managed care contracting, hospital market and other specialty markets, but excluding administrative assistants. These employees are identified in non-public Appendix I.

- KK. “Leukine Marketing Materials” means all marketing materials used anywhere in the world related to Leukine as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, price lists, mailing lists, sales materials (e.g., detailing reports; vendor lists; sales data; reimbursement data), marketing information (e.g., competitor information; research data; market intelligence reports; statistical programs (if any) used for marketing and sales research; customer information, including customer sales information; sales forecasting models; medical educational materials; Website content and advertising and display materials; speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to Leukine.
- LL. “Leukine Microbial Manufacturing Facility” means the third floor of Immunex’s facility located at 51 University Street, Seattle, Washington that has been used by Immunex to research and develop Leukine and to manufacture Leukine bulk drug substance.
- MM. “Leukine Patent Attorneys” means all employees of Respondent Immunex who are attorneys and who performed legal work (irrespective of the portion of working time involved) on Patents related to Leukine within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.
- NN. “Leukine Research and Development Employees” means all employees of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the research, development, regulatory approval

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process, or clinical studies of Leukine within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.

- OO. “Leukine Sales Employees” means all of Respondent Immunex’s worldwide oncology sales force personnel, including all sales representatives, sales managers, national account managers, reimbursement managers, oncology medical associates and oncology nurse educators. These employees are identified in non-public Appendix I.
- PP. “Leukine Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to Leukine, and all rights thereto, in any and all jurisdictions.
- QQ. “Leukine Seller Disclosure Letter” means the disclosure letter from Immunex to Schering dated May 2, 2002, and signed by Edward V. Fritzky, Chief Executive Officer of Immunex, and referred to in the Leukine Asset Purchase Agreement. This letter is attached to this Order and contained in non-public Appendix II.
- RR. “Leukine Software” means computer programs, including all software implementations of algorithms, models, and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any Website; *provided, however*, that “Leukine Software” does not include software that is readily purchasable or licensable and which has not been modified in a manner material to the use or function thereof (other than through user preference settings).

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- SS. “Leukine Trade Dress” means the current trade dress of Leukine, including, but not limited to, product packaging associated with the sale of Leukine worldwide and the lettering of Leukine’s trade name or brand name.
- TT. “Leukine Trademarks” means all trademarks, trade names and brand names including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for Leukine.
- UU. “NDC Numbers” means the National Drug Code numbers(s) assigned by the FDA to a Product.
- VV. “Neupogen” or “Neulasta” means the Neutrophil Regeneration Products developed and marketed by Respondent Amgen.
- WW. “Neutrophil Regeneration Product” means a Product that is a colony stimulating factor produced, at least in part, by recombinant DNA technology, that stimulates the proliferation and differentiation of human neutrophil cells, commonly referred to as white blood cells, including, but not limited to, granulocytes and macrophages.
- XX. “Ownership Interest” means any and all rights, present or contingent, of Respondents to hold any voting or nonvoting stock, share capital, equity or other interests or beneficial ownership in an entity.
- YY. “Patents” mean all patents, patent applications and statutory invention registrations, in each case existing as of the Effective Date, and including all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all

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rights to obtain and file for patents and registrations thereto in the world, related to any Product of or owned by Respondents as of the Closing Date.

- ZZ. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.
- AAA. “Product Registrations” means all registrations, permits, licenses, consents, authorizations and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, development, manufacture, distribution, finishing, packaging, marketing or sale of the Product worldwide, including all INDs or BLAs in existence for the Product as of the Closing Date.
- BBB. “TNFbp-I” means a molecule capable of binding to tumor necrosis factor (“TNF”), thereby reducing the binding of TNF to target cell membrane receptors, which molecule is comprised of the soluble portion of TNF Receptor Type-I, and which is also known as soluble TNF Receptor Type-I.
- CCC. “TNF Settlement and Cross-License Agreement” means the license agreement between Serono and Amgen dated June 28, 2002, attached hereto as non-public Appendix III.
- DDD. “Washington University” means Washington University located in Saint Louis, Missouri.
- EEE. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondents. “Website” shall not include content owned by third parties and other Leukine Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), except to the

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extent that Respondents can transfer their rights, if any, therein.

II.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) Business Days after the Effective Date, Respondents shall divest the Leukine Assets as an ongoing business to Schering pursuant to and in accordance with the Leukine Asset Purchase Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Schering or to reduce any obligations of Respondents under such agreement), and such agreement, if approved by the Commission as the Divestiture Agreement for the Leukine Assets, is incorporated by reference into this Order and made part hereof as non-public Appendix II. If Respondents do not divest the Leukine Assets to Schering within ten (10) Business Days after the Effective Date, the Commission may appoint a Divestiture Trustee to divest the Leukine Assets. *Provided, however*, that if Respondents have divested the Leukine Assets to Schering prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Schering is not an acceptable purchaser of the Leukine Assets or that the manner in which the divestiture was accomplished is not acceptable, then Respondents shall immediately rescind the transaction with Schering and the Commission may appoint a Divestiture Trustee to divest the Leukine Assets to a Commission-approved Acquirer.
- B. Failure to comply with all terms of the Leukine Asset Purchase Agreement, if approved by the Commission, shall constitute a failure to comply with this Order. Any Divestiture

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Agreement between Respondents (or a Divestiture Trustee) and a Commission-approved Acquirer of the Leukine Assets shall be deemed incorporated by reference into this Order, and any failure by Respondents to comply with the terms of such Divestiture Agreement shall constitute a failure to comply with this Order.

- C. Respondents shall include in any Divestiture Agreement related to the Leukine Assets the following provisions, and Respondents shall commit that, upon reasonable notice and a request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner:
1. assistance and advice to enable the Commission-approved Acquirer to obtain all necessary permits and approvals from any Agency or Governmental Entity to manufacture and sell Leukine;
 2. assistance to the Commission-approved Acquirer to manufacture Leukine in substantially the same manner and quality employed or achieved by Respondent Immunex; and
 3. consultation with knowledgeable employees of Respondents and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer receives certification from the FDA for the manufacture of Leukine at the Leukine Microbial Manufacturing Facility (if such certification is required), sufficient to satisfy management of the Commission-approved Acquirer that its personnel are adequately trained in the manufacture of Leukine.
- D. Respondents shall not seek or obtain, directly or indirectly, alone or in collaboration with a third party, an assignment or exclusive license right under any Patent relating to the use of Leukine for the treatment of Crohn's disease (including,

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but not limited to, Patent Application WO 00/47195 “Stimulating Neutrophil Function to Treat Inflammatory Bowel Disease”), that is owned or controlled by Washington University as of the Closing Date. In addition, Respondents shall not interfere with the Commission-approved Acquirer’s ability to acquire rights under such Patent(s) and shall remove any impediments within the control of Respondents that may inhibit the Commission-approved Acquirer’s ability to secure such rights.

- E. Respondents shall submit to the Commission-approved Acquirer, at Respondents’ expense, all Confidential Business Information related to Leukine. *Provided, however*, this provision shall not apply to any Confidential Business Information related to Leukine that Respondent Amgen can demonstrate it obtained without the assistance of Respondent Immunex prior to the Effective Date.
- F. Respondents shall not use, directly or indirectly, any Confidential Business Information related to the research, development, manufacturing, marketing, or sale of Leukine, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer. This provision shall not apply to any Confidential Business Information related to Leukine that Respondent Amgen can demonstrate it obtained without the assistance of Respondent Immunex prior to the Effective Date.
- G. Respondents shall provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Leukine Sales Employees and the Leukine Core Employees for a period of six (6) months from the Closing Date (“the Access Period”), provided that such contracts are contingent upon the Commission’s approval of the Divestiture Agreement.

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- H. Respondents shall provide the Commission-approved Acquirer an opportunity to inspect the personnel files and other documentation related to the Leukine Sales Employees and the Leukine Core Employees, to the extent permissible under applicable laws, at the request of the Commission-approved Acquirer, at any time after execution of the Divestiture Agreement until the end of the Access Period.
- I. During the Access Period, Respondents shall not interfere with the hiring or employing by the Commission-approved Acquirer of Leukine Sales Employees or Leukine Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to a Leukine Sales Employee or Leukine Core Employee who receives a written offer of employment from the Commission-approved Acquirer.

Provided, however, that this Paragraph III. does not prohibit the Respondents from making offers of employment to or employing any Leukine Sales Employee or Leukine Core Employee during the Access Period where the Commission-approved Acquirer has notified the Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee.

Provided further, that if the Respondents notify the Commission-approved Acquirer in writing of their desire to make an offer of employment to a particular Leukine Core Employee or Leukine Sales Employee, and the Commission-approved Acquirer does not make an offer of employment to that employee within twenty (20) Business Days of the date the Commission-approved Acquirer receives such notice, the

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Respondents may make an offer of employment to that employee.

- J. Respondents shall provide all Leukine Core Employees and all Leukine Sales Employees with reasonable financial incentives to continue in their positions until the Closing Date in accordance with Section 3.13(a)(i) of the Leukine Seller Disclosure Letter, which identifies employees and their respective coverage under the Immunex Corporation Retention Plan, as adopted December 16, 2001 ("Retention Plan"). Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Leukine Assets has occurred, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law). In addition to the foregoing, Respondents shall provide to each Leukine Manufacturing Employee who (i) is not included in levels one through six of the Retention Plan as disclosed in Section 3.13(a)(i) of the Leukine Seller Disclosure Letter and (ii) accepts employment with the Commission-approved Acquirer, an incentive equal to three (3) months of such employee's base annual salary to be paid upon the employee's completion of one (1) year of employment with the Commission-approved Acquirer.

Provided, however, that nothing in this Paragraph II.J. or in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee.

- K. For a period of one (1) year following the date the divestiture is accomplished, Respondents shall not, directly or indirectly, solicit or otherwise attempt to induce any employees of the Commission-approved Acquirer with any amount of responsibility related to Leukine to terminate their employment relationship with the Commission-approved Acquirer; *provided, however,* a violation of this provision will not occur if: (i) Respondents advertise for employees in newspapers, trade publications or other media

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not targeted specifically at the employees, or (ii) Respondents hire employees who apply for employment with Respondents, as long as such employees were not solicited by Respondents in violation of this paragraph. During the one-year period following the divestiture, Respondents shall not, directly or indirectly, hire or enter into any arrangement for the services of any employee employed by the Commission-approved Acquirer with any amount of responsibility related to Leukine, unless the individual's employment has been terminated by the Commission-approved Acquirer.

- L. Respondents shall secure, prior to divestiture, all consents and waivers from all private entities that are necessary for the divestiture of the Leukine Assets to the Commission-approved Acquirer, or for the continued research, development, manufacture, sale, marketing or distribution of Leukine by the Commission-approved Acquirer.
- M. For the periods as set forth in this Paragraph II. M. (collectively, the "Moratorium/Waiting Period"), Respondents will not market or promote Neupogen or Neulasta or any other Neutrophil Regeneration Product in the United States or Canada using the services of any employee who has directly participated in the marketing, contracting, promotion or sale of Leukine, regardless of the portion of work time expended on Leukine, within the eighteen (18) month period immediately prior to the Closing Date. The Moratorium/Waiting Period shall be as follows:
 - (i) six (6) months from the Closing Date with respect to Leukine Sales Employees; and (ii) twelve (12) months from the Closing Date for all Leukine Marketing Employees.
- N. Respondents shall require, as a condition of continued employment post-divestiture, that each Leukine Sales Employee and each Leukine Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Leukine Confidential

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Business Information (including, without limitation, all field experience) strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents.

- O. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to Leukine by Respondents' personnel and of the restrictions on the sale of Neupogen or Neulasta or any other Neutrophil Regeneration Product by certain Immunex personnel to all of Respondents' employees who (i) are or were involved in the research, development, manufacturing, distribution, sale or marketing of Leukine, (ii) are involved in the research, development, manufacturing, distribution, sale or marketing of Neupogen or Neulasta or any other Neutrophil Regeneration Product and/or (iii) may have Confidential Business Information related to Leukine. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall also obtain from each employee covered by this Paragraph II. O. an agreement to abide by the applicable restrictions. Such agreement and notification shall be in substantially the form set forth in the "Notice of Divestiture and Employee Agreement to Maintain Non-Public Business Information Related to Leukine Confidential" attached as Appendix V to this Order and as Appendix A to the Order to Maintain Assets. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their sales forces of all applicable restrictions, including the provision of written reminders to all such sales personnel at three (3) month

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intervals until the expiration of the time periods set forth in all Divestiture Agreements, including those in the Leukine Asset Purchase Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order. Respondents shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- P. At the time of divestiture, Respondents shall make available to the Commission-approved Acquirer such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Leukine Assets, and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA, and able to manufacture Leukine. At the time of divestiture, Respondents shall also divest any additional, incidental assets of Respondents and make any further arrangements for transitional services within the first twelve (12) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Leukine Assets.
- Q. Pending divestiture of the Leukine Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Leukine Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Leukine Assets except for ordinary wear and tear.
- R. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to the Commission-approved Acquirer and may have access to original documents (under circumstances where copies of

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documents are insufficient or otherwise unavailable) provided to the Commission-approved Acquirer in order to:

1. comply with any Divestiture Agreement, this Order, any law, (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Governmental Entity, or any taxation requirements; or
2. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Leukine Assets or Leukine business; *provided, however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement.

Provided further, however:

1. Respondents shall require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Commission-approved Acquirer; *provided, however*, that Respondents shall not be deemed to have violated this Paragraph if the Commission-approved Acquirer withholds such agreement unreasonably; and
 2. Respondents shall use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.
- S. The purpose of the divestiture of the Leukine Assets is to ensure the continued use of the Leukine Assets in the same business in which the Leukine Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

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III.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Effective Date, Respondents shall grant to Serono rights and immunities under certain Patents controlled by Respondents sufficient to allow Serono freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and non-glycosylated fragments, derivatives and analogs thereof in the United States in accordance with the TNF Settlement and Cross-License Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order), which is incorporated by reference into this Order and made part hereof as non-public Appendix III.
- B. The purpose of the requirements in Paragraph III.A. is to ensure the continuation of TNFbp-I research and development for additional TNFbp-I Products to be approved by the FDA for sale in the United States and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

IV.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Effective Date, Respondents shall grant to Regeneron rights and immunities under certain Patents controlled by Respondents sufficient to allow Regeneron freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of IL-1 Trap Products in the United States in accordance with the IL-1 License Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order),

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which is incorporated by reference into this Order and made part hereof as non-public Appendix IV.

- B. Not later than four (4) years from the Effective Date, Respondents shall divest all their Ownership Interest in Regeneron, including, but not limited to, all of the shares of Regeneron common stock owned by Respondent Amgen prior to the Effective Date, pursuant to the following conditions (the purpose of which is to insure that the Respondents dispose of such Ownership Interest in a manner that avoids disruption of the market for Regeneron stock or share capital):
1. during the first and second years following the Effective Date, Respondents shall not sell more than 250,000 shares of Regeneron common stock during any calendar quarter; *provided, however*, during the first year, Respondents shall not sell more than a total of 500,000 of such shares;
 2. thereafter, Respondents shall not sell more than the greater of (1) 500,000 shares or (2) the average weekly reported volume of Regeneron common stock traded over the National Association of Securities Dealers Automated Quotation System during any calendar quarter; and
 3. any public announcement made by Respondents regarding such sales shall state that such sales are being made pursuant to the divestiture requirements of this Order.

Provided, however, that the limitation on the number of shares of Regeneron common stock that the Respondents may sell in any period shall be adjusted to reflect any Regeneron stock split.

Provided further, however, that nothing in this Paragraph shall be construed to prohibit the Respondents from (1) accepting a general offer made for all of the issued stock or share capital of Regeneron; (2) selling stock in a private sale to which Regeneron has consented in writing; or (3) after the second

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year following the Effective Date, selling such stock in an underwritten public offering that was initiated by Regeneron.

- C. Respondents shall not, directly or indirectly:
1. exercise dominion or control over, or otherwise seek to influence, the management, direction or supervision of the business of Regeneron, including, but not limited to, any participation in the formulation, determination or direction of any business decisions of Regeneron;
 2. propose corporate action requiring the approval of Regeneron shareholders;
 3. nominate candidates for, or in any other way seek to or obtain representation on, the Board of Directors of Regeneron;
 4. have any of their directors, officers or employees serve simultaneously as an officer or director of Regeneron;
 5. exercise any voting rights attached to any Ownership Interest in Regeneron; *provided, however*, that in any matter to be voted on by the shareholders of Regeneron, Respondents shall cast the votes related to their Ownership Interest in each class of Regeneron stock in an amount and manner proportional to the vote of all other votes cast by other Regeneron shareholders entitled to vote on such matter;
 6. seek or obtain access to any confidential, proprietary, or other non-public information of Regeneron relating to the research or development of IL-1 and not otherwise necessary to comply with this Order; *provided, however*, that this shall not be construed to prohibit Respondents from seeking or obtaining discovery in any litigation or other proceeding to resolve a claim between Respondents and Regeneron in accordance with the procedures of the forum

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before which the dispute is pending. With respect to any such discovery, Respondents shall enter into a protective order to prevent any information from being used for any purpose other than providing legal representation or evidence as to the particular dispute and to prevent any information from being disclosed to any person(s) not necessary to the resolution of such dispute; or

7. take any action or omit to take any action in a manner that would be incompatible with the status of Respondents as passive investors in Regeneron.

The requirements of this Paragraph IV.C. shall continue and remain in effect so long as Respondents retain any Ownership Interest in Regeneron.

- D. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any additional or greater Ownership Interest in Regeneron than that which exists as of the Closing Date, or any other interest(s), in whole or in part, in any Patents owned by Regeneron and related to IL-1 Trap. Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of the Notification to the Commission at least thirty (30) days prior to consummating any such transaction

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(hereinafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. *Provided, however*, that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

- E. The purpose of the requirements of Paragraph IV is to ensure the continuation of IL-1 Inhibitor research and development for additional IL-1 Inhibitor Products to be approved by the FDA for sale in the United States and to remedy the lessening of competition resulting from the Merger as alleged in the Commission’s Complaint.

V.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and by the Order to Maintain Assets (collectively, “the Orders”).
- B. If an Interim Monitor is appointed pursuant to this Paragraph or pursuant to Paragraph III.A. of the Order to Maintain Assets in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

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1. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
2. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the terms of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
3. Within ten (10) days after appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant terms of the Orders in a manner consistent with the purposes of the Orders.
4. The Interim Monitor shall serve until the later of:
 - a. when the Leukine Assets have been divested in a manner that fully satisfies the requirements of the Orders and the Commission-approved Acquirer is fully capable of, independently of Respondents, producing Leukine acquired pursuant to a Divestiture Agreement; or
 - b. when the last obligation under the Orders pertaining to the Interim Monitor's service has been fully performed.

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Provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

5. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the Leukine Assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
6. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Interim Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission. The Commission may, among other things, require the Interim Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

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7. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
8. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or Paragraph III.A. of the Order to Maintain Assets in this matter.
9. The Commission may on its own initiative or at the request of the Interim Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
10. Respondents shall report to the Interim Monitor in accordance with the requirements of Paragraph VII.A. of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders or the Divestiture Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning compliance by Respondents with the provisions of the Orders.

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11. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- C. The Interim Monitor appointed pursuant to Paragraph III.A. of the Order to Maintain Assets in this matter may be the same Person appointed as Divestiture Trustee pursuant to Paragraph VI.A. of this Order.

VI.**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations specified in Paragraph II of this Order, the Commission may appoint a trustee to divest the assets required to be divested pursuant to Paragraph II in a manner that satisfies the requirements of Paragraph II. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Paragraph VI.A. of this Order, Respondents shall consent to the following terms and conditions regarding

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the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the assets that are required by this Order to be divested.
3. Within ten (10) days after appointment of the Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Order.
4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph VI.B.3. to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *provided*,

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however, the Commission may extend the divestiture period only two (2) times.

5. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
6. The Divestiture Trustee shall use best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such entity within five (5) Business Days after receiving notification of the Commission's approval.
7. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the

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Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

8. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
9. If the Divestiture Trustee ceases to act or fails to act diligently, a substitute Divestiture Trustee shall be appointed in the same manner as provided in Paragraph VI.A. of this Order.
10. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or

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at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

11. In the event that the Divestiture Trustee determines that he or she is unable to divest the relevant assets required to be divested in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, development, manufacture, distribution, marketing, promotion, sale, or after-sales support of Leukine, the Divestiture Trustee may divest such additional assets of Respondents and effect such arrangements as are necessary to satisfy the requirements of this Order.
 12. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
 13. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 14. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- C. The Divestiture Trustee appointed pursuant to Paragraph VI.A. of this Order may be the same Person appointed as Interim Monitor pursuant to Paragraph III.A. of the Order to Maintain Assets in this matter.

VII.

Decision and Order

IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with Paragraph II.A., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraph II.A. of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the Leukine Assets and the identity of all parties contacted. Respondents shall include in their reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- B. One (1) year from the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in either corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any

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other change in the corporation that may affect compliance obligations arising out of the Order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order will terminate on September 3, 2012.

By the Commission.

Decision and Order

APPENDIX I (non-public)
Leukine Core Employees

[Redacted From Public Record Version]

APPENDIX II (non-public)
Leukine Asset Purchase Agreement

[Redacted From Public Record Version]

APPENDIX III (non-public)
TNF Settlement and Cross-License Agreement

[Redacted From Public Record Version]

APPENDIX IV (non-public)
IL-1 License Agreement

[Redacted From Public Record Version]

Decision and Order

**APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS****APPENDIX V
TO THE DECISION AND ORDER****NOTICE OF DIVESTITURE AND EMPLOYEE
AGREEMENT TO MAINTAIN NON-PUBLIC BUSINESS
INFORMATION RELATED TO LEUKINE
CONFIDENTIAL**

On [date], Amgen Inc. (“Amgen”) and Immunex Corporation (“Immunex”), hereinafter referred to collectively as “Respondents,” entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission (“FTC”) relating to the divestiture of certain assets. That Consent Agreement includes two orders: (i) the Decision and Order, and (ii) the Order to Maintain Assets. The Decision and Order requires the divestiture of assets relating to the Leukine business of Immunex. These assets are hereinafter referred to as the “Leukine Assets.” The Order to Maintain Assets requires Respondents to maintain the Leukine Assets pending divestiture of these assets. Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Leukine Assets will be disclosed to or used by any employee of the combined entity formed by the merger of Amgen and Immunex (“Combined Entity”), except under specified circumstances. In particular, this restriction is to protect such information from being used in any way for the research, development, sale or manufacture of Neupogen or Neulasta or any other Neutrophil Regeneration Product that may be commercialized by the Combined Entity after the proposed merger. The Decision and Order also requires the divestiture of documents (including electronically stored material) that contain Confidential Business Information related to the Leukine Business. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information.

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Under the Decision and Order, the Respondents are required to divest all of the Leukine Assets to an acquirer that must be approved by the FTC. Schering Aktiengesellschaft has been proposed to the FTC as the acquirer for these assets. Until the divestiture of all of the Leukine Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to insure the continued marketability, viability and competitive vigor of the Leukine Assets. This includes preserving the work force that performs functions related to the Leukine Assets.

You are receiving this notice because you (i) have work responsibilities related to Leukine, (ii) have work responsibilities related to Neulasta or Neupogen, or (iii) might have Confidential Business Information in your possession related to Leukine.

All Confidential Business Information related to Leukine must be retained and maintained by the persons involved in the operation of that business on a confidential basis. Such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Leukine Assets (such as persons with job responsibilities related to Amgen's Neupogen or Neulasta businesses). In addition, any person who possesses such Confidential Business Information related to the Leukine Assets and who becomes involved in the Combined Entity's business related to Neupogen, Neulasta or any other Neutrophil Regeneration Product must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, if you have documents that you believe might be considered Confidential Business Information related to Leukine and have not received specific instructions as to how the documents in your possession should be disposed of, you should contact the contact person identified at the end of this notice.

For the purposes herein, "Confidential Business Information" means all information owned or controlled by Immunex that is not in the public domain related to the research, development,

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manufacturing, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support or use of Leukine.

Any violation of the Decision and Order or the Order to Maintain Assets may subject Amgen, Immunex, or the Combined Entity to civil penalties and other relief as provided by law.

CONTACT PERSON

If you have questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact

_____ at ____ - ____ - _____, e-mail
address:_____.

ACKNOWLEDGMENT

I, _____ (print name),

hereby acknowledge that I have read the above notification and
agree to abide by its provisions.

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ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed merger between Respondent Amgen Inc. (“Amgen”) and Respondent Immunex Corporation (“Immunex”), hereinafter referred to as “Respondents,” and the Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing the proposed Decision and Order, an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

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1. Respondent Amgen is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.
2. Respondent Immunex is a corporation organized, existing and doing business under and by virtue of the laws of the state of Washington, with its office and principal place of business located at 51 University Street, Seattle, Washington 98101.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the definitions used in the Consent Agreement and the attached Decision and Order shall apply.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final:

- A. Respondents shall take such actions as are reasonably necessary to maintain the viability, marketability, and competitive vigor of the Leukine Assets, and shall prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer or impairment of the Leukine Assets, except for ordinary wear and tear and as otherwise would occur in the ordinary course of business.

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- B. Respondents shall maintain the operations of the Leukine Assets in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the Leukine Assets) and shall use their best efforts to preserve the existing relationships with suppliers, vendors, customers, employees, and others having business relations with the Leukine Assets. Respondents' responsibilities shall include, but are not limited to:
1. providing the Leukine Assets with sufficient working capital to operate the Leukine Assets at least at current rates of operation, to meet all capital calls with respect to the Leukine Assets and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Leukine Assets;
 2. continuing, at least at their scheduled pace, any additional expenditures for the Leukine Assets authorized prior to the date the Consent Agreement was signed by Respondents;
 3. making available for use by the Leukine Assets funds sufficient to perform all necessary routine maintenance to, and replacements of, the Leukine Assets;
 4. providing the Leukine Assets with such funds as are necessary to maintain the viability, competitive vigor, and marketability of the Leukine Assets;
 5. providing such support services to the Leukine Assets as are being provided to this business by Respondent Immunex as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force equivalent in size, training, and expertise to what has been associated with the Leukine Assets.

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- D. Respondents shall provide all Leukine Core Employees and all Leukine Sales Employees with reasonable financial incentives to continue in their positions until the Closing Date in accordance with Section 3.13(a)(i) of the Leukine Seller Disclosure Letter, which identifies employees and their respective coverage under the Immunex Corporation Retention Plan, as adopted December 16, 2001 (“Retention Plan”). Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Leukine Assets has occurred, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law). In addition to the foregoing, Respondents shall provide to each Leukine Manufacturing Employee who (i) is not included in levels one through six of the Retention Plan as disclosed in Section 3.13(a)(i) of the Leukine Seller Disclosure Letter and (ii) accepts employment with the Commission-approved Acquirer, an incentive equal to three (3) months of such employee’s base annual salary to be paid upon the employee’s completion of one (1) year of employment with the Commission-approved Acquirer.

Provided, however, this Paragraph shall not be construed to require the Respondents to terminate the employment of any employee.

- E. Prior to the Closing Date, Respondents shall not interfere with the hiring or employing of Leukine Sales Employees and Leukine Core Employees by Schering, or any entity subsequently proposed by the Respondents or a Divestiture Trustee to the Commission as an acquirer of the Leukine Assets (“Proposed Acquirer”), and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment related to the Leukine Assets with Schering or the Proposed Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be

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employed by either Schering or the Proposed Acquirer. In addition, Respondents shall not make any counteroffer to a Leukine Sales Employee or Leukine Core Employee who receives a written offer of employment from Schering or the Proposed Acquirer.

Provided, however, that this Paragraph I.E. does not prohibit the Respondents from making offers to any Leukine Sales Employee or Leukine Core Employee where either Schering or the Proposed Acquirer has notified the Respondents in writing that it does not intend to make an offer of employment to that employee.

Provided further, that if the Respondents notify Schering or the Proposed Acquirer in writing of their desire to make an offer of employment to a particular Leukine Core Employee or Leukine Sales Employee, and Schering or the Proposed Acquirer does not make an offer of employment to that employee within twenty (20) Business Days of the date Schering or the Proposed Acquirer receives such notice, the Respondents may make an offer of employment to that employee.

- F. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to Leukine by Respondents' personnel and of the restrictions on the sale of Neupogen or Neulasta or any other Neutrophil Regeneration Product by certain Immunex personnel to all of Respondents' employees who (i) are involved in the research, manufacturing, distribution, sale or marketing of Leukine, (ii) are involved in the research, manufacturing, distribution, sale or marketing of Neupogen or Neulasta or any other Neutrophil Regeneration Product and/or (iii) may have Confidential Business Information related to Leukine. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to Schering or the Proposed Acquirer.

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Respondents shall also obtain from each employee covered by this Paragraph II. F. an agreement to abide by the applicable restrictions. Such agreement and notification shall be in substantially the form set forth in the “Notice of Divestiture and Employee Agreement to Maintain Non-Public Business Information Related to Leukine Confidential” attached as Appendix A to this Order and as Appendix V to the Decision and Order. Respondents shall maintain complete records of all such agreements at Respondents’ corporate headquarters and shall provide an officer’s certification to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their sales forces of all applicable restrictions, including the provision of written reminders to all such sales personnel at three (3) month intervals until the expiration of the time periods set forth in all Divestiture Agreements, including those in the Leukine Asset Purchase Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order. Respondents shall provide Schering or the Proposed Acquirer with copies of all certifications, notifications and reminders sent to Respondents’ personnel.

- G. Respondents shall adhere to and abide by the Divestiture Agreement incorporated by reference into this Order to Maintain Assets and made a part hereof.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as

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required by this Order to Maintain Assets and by the Decision and Order (collectively, “the Orders”).

- B. If an Interim Monitor is appointed pursuant to Paragraph III.A. of this Order to Maintain Assets or Paragraph V.A. of the Decision and Order in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
 2. The Interim Monitor shall have the power and authority to monitor the Respondents’ compliance with the terms of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 3. Within ten (10) days after appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents’ compliance with the relevant terms of the Orders in a manner consistent with the purposes of the Orders.
 4. The Interim Monitor shall serve until the later of:

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- a. when the Leukine Assets have been divested in a manner that fully satisfies the requirements of the Orders and the Commission-approved Acquirer is fully capable of, independently of Respondents, producing Leukine acquired pursuant to a Divestiture Agreement; or
- b. when the last obligation under the Orders pertaining to the Interim Monitor's service has been fully performed.

Provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

5. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and any other relevant information as the Interim Monitor may reasonably request, relating to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations relating to the Leukine Assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
6. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Interim Monitor shall account for all

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expenses incurred, including fees for services rendered, subject to the approval of the Commission. The Commission may, among other things, require the Interim Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

7. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
8. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in Paragraph III.A. of this Order to Maintain Assets or Paragraph V.A. of the Decision and Order in this matter.
9. The Commission may on its own initiative or at the request of the Interim Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
10. Respondents shall report to the Interim Monitor in accordance with the requirements of Paragraph VII.A. of the Decision and Order and/or as otherwise provided in

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any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders or the Divestiture Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning compliance by Respondents with the provisions of the Orders.

11. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- C. The Interim Monitor appointed pursuant to Paragraph III.A. of this Order to Maintain Assets may be the same Person appointed as Divestiture Trustee pursuant to Paragraph VI.A. of the Decision and Order in this matter.

IV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in either corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order to Maintain Assets.

V.

IT IS FURTHER ORDERED that, for the purposes of determining or securing compliance with this Order to Maintain

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Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representatives of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order to Maintain Assets; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

VI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the divestiture of all of the Leukine Assets, as described in and required by the attached Decision and Order, is completed.

By the Commission.

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**APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS****APPENDIX V
TO THE DECISION AND ORDER****NOTICE OF DIVESTITURE AND EMPLOYEE
AGREEMENT TO MAINTAIN NON-PUBLIC BUSINESS
INFORMATION RELATED TO LEUKINE
CONFIDENTIAL**

On [date], Amgen Inc. (“Amgen”) and Immunex Corporation (“Immunex”), hereinafter referred to collectively as “Respondents,” entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission (“FTC”) relating to the divestiture of certain assets. That Consent Agreement includes two orders: (i) the Decision and Order, and (ii) the Order to Maintain Assets. The Decision and Order requires the divestiture of assets relating to the Leukine business of Immunex. These assets are hereinafter referred to as the “Leukine Assets.” The Order to Maintain Assets requires Respondents to maintain the Leukine Assets pending divestiture of these assets. Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Leukine Assets will be disclosed to or used by any employee of the combined entity formed by the merger of Amgen and Immunex (“Combined Entity”), except under specified circumstances. In particular, this restriction is to protect such information from being used in any way for the research, development, sale or manufacture of Neupogen or Neulasta or any other Neutrophil Regeneration Product that may be commercialized by the Combined Entity after the proposed merger. The Decision and Order also requires the divestiture of documents (including electronically stored material) that contain Confidential Business Information related to the Leukine Business. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information.

Order

Under the Decision and Order, the Respondents are required to divest all of the Leukine Assets to an acquirer that must be approved by the FTC. Schering Aktiengesellschaft has been proposed to the FTC as the acquirer for these assets. Until the divestiture of all of the Leukine Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to insure the continued marketability, viability and competitive vigor of the Leukine Assets. This includes preserving the work force that performs functions related to the Leukine Assets.

You are receiving this notice because you (i) have work responsibilities related to Leukine, (ii) have work responsibilities related to Neulasta or Neupogen, or (iii) might have Confidential Business Information in your possession related to Leukine.

All Confidential Business Information related to Leukine must be retained and maintained by the persons involved in the operation of that business on a confidential basis. Such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Leukine Assets (such as persons with job responsibilities related to Amgen's Neupogen or Neulasta businesses). In addition, any person who possesses such Confidential Business Information related to the Leukine Assets and who becomes involved in the Combined Entity's business related to Neupogen, Neulasta or any other Neutrophil Regeneration Product must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, if you have documents that you believe might be considered Confidential Business Information related to Leukine and have not received specific instructions as to how the documents in your possession should be disposed of, you should contact the contact person identified at the end of this notice.

For the purposes herein, "Confidential Business Information" means all information owned or controlled by

Order

Immunex that is not in the public domain related to the research, development, manufacturing, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support or use of Leukine.

Any violation of the Decision and Order or the Order to Maintain Assets may subject Amgen, Immunex, or the Combined Entity to civil penalties and other relief as provided by law.

CONTACT PERSON

If you have questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact

_____ at ____ - ____ - _____, e-mail
address: _____.

ACKNOWLEDGMENT

I, _____ (print name),

hereby acknowledge that I have read the above notification and

agree to abide by its provisions.

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a proposed Consent Order from Amgen Inc. (“Amgen”) and Immunex Corporation (“Immunex”) that is designed to remedy the anticompetitive effects of the merger of Amgen and Immunex. Under the terms of the agreement, the companies would be required to: (1) divest all of Immunex’s assets relating to Leukine (a neutrophil regeneration factor) to Schering AG (“Schering”); (2) license certain Amgen patents relating to its tumor necrosis factor (“TNF”) receptor to Serono S.A. (“Serono”); and (3) license certain Amgen and Immunex patents relating to the development of Interleukin-1 (“IL-1”) receptors to Regeneron Pharmaceuticals Inc. (“Regeneron”).

The proposed Consent Order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and any comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed Consent Order.

In their merger agreement of December 16, 2001, Amgen and Immunex propose to combine their two companies in a transaction valued at approximately \$16 billion. Thereafter, the merged entity will be called Amgen Inc. The proposed Complaint alleges that the proposed merger, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the markets for: (1) neutrophil regeneration factors; (2) TNF inhibitors; and (3) IL-1 inhibitors. The proposed Consent Order would remedy the alleged violations by replacing the lost competition in each of these markets that would result from the merger.

Analysis

Neutrophil Regeneration Factors

Neutrophil regeneration factors are used to treat neutropenia, the suppression of production of certain white blood cells (known as “neutrophils”) which often results from chemotherapy. Immunex’s product, Leukine, stimulates the production of both granulocytes and macrophages, two types of neutrophils, while Amgen’s products, Neupogen and Neulasta, stimulate the production of granulocytes. The use of these products to stimulate neutrophil regeneration allows patients to maintain a robust immune system while continuing with their chemotherapy regimens. Annual U.S. sales of neutrophil regeneration factors total approximately \$1.2 billion.

The market for neutrophil regeneration factors is highly concentrated. Amgen and Immunex are the only companies with neutrophil regeneration factors approved for sale in the United States. Amgen’s Neupogen is the leading product in this market, with 2001 sales of approximately \$1.05 billion in the United States. In January 2002, Amgen launched Neulasta, an extended-release version of Neupogen. Immunex’s 2001 sales for Leukine were \$109 million.

Entry into the neutrophil regeneration factor market requires lengthy preclinical and clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the Food and Drug Administration (“FDA”). Clinical development and FDA approval can extend from 6 to 10 years and cost over \$200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. No company can reach advanced stages of development in the relevant market without: (1) clinical trial expertise; (2) patent rights sufficient to provide the company with reasonable assurances of freedom to operate; (3) commercial scale product manufacturing expertise and capacity; and (4) regulatory approvals.

Analysis

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. neutrophil regeneration market by eliminating actual, direct, and substantial competition between the only two firms in the market. As a result, cancer patients that need these drugs would likely pay higher prices for neutrophil regeneration factors.

The proposed Consent Order maintains competition in the market for neutrophil regeneration factors by requiring that Immunex sell its Leukine business to Schering so that Schering can maintain the present competition against Amgen as well as the continued research and development of Leukine for future competition.

TNF Inhibitors

TNF is a cytokine that promotes the inflammation of human tissues. TNF inhibitors may be used to prevent the binding of TNF proteins with TNF receptors, thereby blocking the triggering of the inflammation cascade. TNF inhibitors are used primarily to treat rheumatoid arthritis, Crohn's disease, and psoriatic arthritis, but they also are being examined for a host of other autoimmune diseases. Annual U.S. sales of TNF inhibitors total approximately \$1.4 billion.

The market for TNF inhibitors is highly concentrated. Immunex, which makes Enbrel, and Johnson & Johnson ("J&J"), which makes Remicade, are the only companies with TNF inhibitors on the market. In 2001, Immunex sold over \$760 million of Enbrel in the United States and Canada, while Remicade accounted for the rest of the market in the United States. There are only three other companies with TNF inhibitors in clinical development in the United States. Amgen has a TNF inhibitor similar to Enbrel in clinical development that it expects to launch in 2005. Abbott recently submitted a Biologic License Application to the FDA for its D2E7 product. Pharmacia and Celltech are jointly in Phase II trials for their TNF inhibitor, CDP870. Additionally, Serono is developing a TNF inhibitor for

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use in Europe, but it does not possess the patent rights necessary to market the product in the United States.

New entry into the research, development, manufacture, and sale of TNF inhibitors is difficult, expensive, and time-consuming. As with other pharmaceutical markets, entry requires identifying a preclinical compound, performing animal safety tests, clinically developing the product in humans, securing FDA approval of commercial scale production facilities, and obtaining FDA approval to market the drug in the United States. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture, and sell a TNF inhibitor. *De novo* entry has been estimated to take from 8 to 10 years and cost over \$400 million. New entry sufficient to deter or counteract the anticompetitive effects of the proposed merger would not occur in a timely manner.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. TNF inhibitor market by eliminating potential competition from Amgen's TNF inhibitor in development. Immunex and Amgen are the only two firms that market or are developing soluble TNF receptor products in the United States and two of only five firms that are developing any type of TNF inhibitor for the U.S. market. As a result of the merger, consumers of these drugs would likely pay higher prices and have fewer alternatives for TNF inhibitors for the treatment of rheumatoid arthritis and other diseases.

The proposed Consent Order maintains competition in the TNF inhibitor market by requiring that Amgen license certain patents to Serono, a Swiss biotechnology company with a soluble TNF inhibitor in clinical development that otherwise likely would not be sold in the United States due to blocking patents held by Amgen. This license would assure Serono that it has the freedom of operation necessary to market its TNF inhibitor in the U.S. Amgen retains the rights to pursue development of its TNF inhibitor either as a monotherapy or in combination with an IL-1 inhibitor.

Analysis

IL-1 Inhibitors

IL-1 is another cytokine that promotes the inflammation of human tissues. IL-1 inhibitors prevent the binding of IL-1 proteins with IL-1 receptors, thereby blocking the triggering of the inflammation cascade. IL-1 inhibitors are used to treat rheumatoid arthritis.

The market for IL-1 inhibitors is highly concentrated. Amgen's Kineret, approved by the FDA in November of 2001, is the only IL-1 inhibitor on the U.S. market. Sales to date have exceeded \$2.4 million. Immunex and Regeneron are the only other companies with IL-1 inhibitors in clinical trials in the United States. Regeneron's development and commercialization of its IL-1 Trap, however, may be delayed or foreclosed by patents owned by Immunex. It appears that Immunex is likely to succeed in its efforts to preclude Regeneron's successful commercialization of its IL-1 Trap product through patent infringement litigation for the following reasons: (1) Immunex has indicated that it will seek to block Regeneron by using patent litigation; (2) Regeneron has indicated that such litigation, even were it to yield an outcome favorable to Regeneron, could foreclose its ability to commercialize its IL-1 Trap; and (3) the likelihood of threatened patent litigation by Immunex will jeopardize and could effectively preclude commercialization of Regeneron's IL-1 Trap.

New entry into the research, development, manufacture, and sale of IL-1 inhibitors is difficult, expensive, and time-consuming. As with other pharmaceutical markets, entry requires identifying a preclinical compound, performing animal safety tests, clinically developing the product in humans, securing FDA approval of commercial scale production facilities, and obtaining FDA approval to market the drug in the United States. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture, and sell an IL-1 inhibitor. *De novo* entry has been estimated to take between 6 to 10 years and cost over \$200 million. New entry sufficient to deter or counteract the

Analysis

anticompetitive effects of the merger would not occur in a timely manner.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. IL-1 inhibitor market by eliminating Amgen's most significant (and likely only) potential competitor, Immunex. By consolidating the IL-1 patents of both companies, Amgen would be more likely to use its combined patents to block Regeneron from marketing an IL-1 inhibitor. Furthermore, Amgen and Immunex are the only companies actively engaged in the development of TNF/IL-1 combination therapies, which may prove more efficacious for the treatment of rheumatoid arthritis in many patients than using either drug alone. The proposed merger, therefore, is likely to lead to unilateral anticompetitive effects in the IL-1 inhibitor market by eliminating potential competition between Amgen and Immunex as well as the ongoing research and development competition between the companies.

The proposed Consent Order remedies the merger's anticompetitive effects by requiring that Immunex license certain patents to Regeneron, giving Regeneron the freedom of operation necessary to bring its IL-1 Trap product to the market and compete against Amgen in this market.

The purpose of this analysis is to facilitate public comment on the proposed Consent Order, and it is not intended to constitute an official interpretation of the proposed Consent Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

BIOVAIL CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4060; File No. 0110094
Complaint, October 2, 2002--Decision, October 2, 2002

This consent order addresses practices used by Respondent Biovail Corporation – a Canadian manufacturer of branded and generic pharmaceutical products – with respect to an Abbreviated New Drug Application filed by Andrx Pharmaceuticals, Inc. to make and sell a generic version of Tiazac, a once-a-day diltiazem-based prescription drug used to treat high blood pressure and to reduce the occurrence of chronic chest pain . The order, among other things, requires the respondent to divest to DOV Pharmaceuticals, Inc. the exclusive rights to the ‘463 patent – which the respondent listed in the United States Food and Drug Administration Orange Book as claiming Tiazac – previously acquired from DOV. The order also prohibits the respondent from taking any actions that would result in an additional 30-month stay of final FDA approval for a generic form of Tiazac, and from wrongfully listing any patents in the Orange Book in violation of applicable law. In addition, the order prohibits the respondent from participating in any lawsuits to enforce the ‘463 patent in the Tiazac Field, and requires the respondent to dismiss a pending patent infringement claim against Andrx. The order also requires the respondent to give the Commission prior notice before it acquires an exclusive license to any patent that it plans to list in the Orange Book for a product for which it already has an FDA-approved New Drug Application.

Participants

For the Commission: *Markus H. Meier, Bradley S. Albert, Oscar Voss, George Bellack, David Dudley, Jerod Klein, Mary Connelly-Draper, Daniel Bress, Rendell A. Davis, Jr., Roberta S. Baruch, Abraham Wickelgren, Leslie Farber, and Mary T. Coleman.*

For the Respondent: *Ron Rauchberg, Proskauer Rose LLP, and Ken Cancellara, Biovail.*