

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

In the Matter of)	
)	
)	
AMGEN INC.,)	
a corporation;)	
)	
and)	
)	Docket No. C-4053
IMMUNEX CORPORATION,)	
a corporation.)	
)	
)	

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.

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 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 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 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-1 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 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 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.

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.

Donald S. Clark
Secretary

SEAL: