

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

| | | |
|--------------------------------|---|-------------------|
| _____ |) | |
| In the Matter of |) | |
| |) | |
| Ciba-Geigy Limited, |) | |
| a corporation, |) | |
| |) | |
| Ciba-Geigy Corporation, |) | |
| a corporation, |) | |
| |) | |
| Chiron Corporation, |) | |
| a corporation, |) | Docket No. C-3725 |
| |) | |
| Sandoz Ltd., |) | |
| a corporation, |) | |
| |) | |
| Sandoz Corporation, |) | |
| a corporation, and |) | |
| |) | |
| Novartis AG, |) | |
| a corporation. |) | |
| _____ |) | |

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and of the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (the "Commission"), having reason to believe that respondents Ciba-Geigy Ltd., a corporation including its wholly-owned subsidiary, Ciba-Geigy Corporation, (collectively, "Ciba"), and Sandoz Ltd., a corporation, including its wholly-owned subsidiary, Sandoz Corporation, (collectively, "Sandoz"), corporations subject to the jurisdiction of the Commission, have agreed to merge into Novartis Ltd. ("Novartis"), a corporation, 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. RESPONDENTS

1. Respondent Ciba-Geigy Limited is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland, with its office and principal place of business located at Klybeckstrasse 141, CH-4002 Basel, Switzerland. Ciba operates in the United States through its wholly-owned subsidiary, Ciba-Geigy Corporation, and is engaged in the discovery, development, manufacture and sale of agricultural crop protection chemicals, proprietary and generic pharmaceutical products, and animal health products. Ciba participates in the field of gene therapy in the United States through the Chiron Corporation.

2. Respondent Ciba-Geigy Corporation, a wholly-owned subsidiary of Ciba-Geigy Limited, is a corporation organized, existing, and doing business under and by virtue of the laws of New York with its office and principal place of business located at 520 White Plains Road, Tarrytown, New York 10591.

3. Respondent Sandoz Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland, with its office and principal place of business located at Lichtstrasse 35, CH-4002 Basel, Switzerland. Sandoz operates in the United States through its wholly-owned subsidiary, Sandoz Corporation, and is engaged in the discovery, development, manufacture and sale of agricultural crop protection chemicals, proprietary and generic pharmaceutical products, and animal health products. Sandoz participates in the field of gene therapy in the United States through its wholly-owned subsidiary, Sandoz Pharmaceuticals Corporation, headquartered in New Jersey, and through its wholly-owned subsidiary, Genetic Therapy, Inc., headquartered in Maryland.

4. Respondent Sandoz Corporation, a wholly-owned subsidiary of Sandoz Ltd., is a corporation organized, existing, and doing business under and by virtue of the laws of New York with its office and principal place of business located at 608 Fifth Avenue, New York, New York 10020.

5. Respondent Chiron Corporation ("Chiron") is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware with its office and principal place of business located at 4560 Horton Street, Emeryville, California 94608. Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder of Chiron, holding, not solely for investment, approximately 46.5% of the Chiron capital stock as of September 30, 1996. Chiron is engaged in the discovery, development, manufacture and sale of proprietary and generic pharmaceutical products, including gene therapy products. Ciba has agreed to fund research at

Chiron and guarantee its debt, and has the right to appoint members of its board of directors and to veto specified actions of the company.

6. Respondent Novartis AG, is a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland with its office and principal place of business located at Centralbahnstrasse 7, CH-4010 Basel, Switzerland.

II. JURISDICTION

7. Ciba, Sandoz, Chiron, and Novartis 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 businesses are in or affect 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

8. On or about March 6, 1996, Ciba and Sandoz signed a merger agreement providing that both companies will merge with Novartis Ltd., a Swiss company jointly formed by Ciba and Sandoz to effectuate the merger of their businesses. The total value of the stock involved in the transaction is in excess of \$63 billion. The merged entity, Novartis, will control worldwide assets valued at approximately \$80 billion.

IV. THE RELEVANT MARKETS

9. One relevant line of commerce in which to analyze the effects of the proposed merger is gene therapy technology and research and development of gene therapies, including *ex vivo* and *in vivo* gene therapy. Specific gene therapy product markets, in which the effects of the proposed merger may be analyzed include the research, development, manufacture and sale of :

- (a) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer;
- (b) HSV-tk gene therapy for the treatment of graft versus host disease;
- (c) gene therapy for the treatment of hemophilia; and
- (d) chemoresistance gene therapy.

Gene therapy is a therapeutic intervention in humans based on modification of the genetic material of living cells. Cells may be modified *ex vivo* for subsequent administration or altered *in vivo* by gene therapy products given directly to the patient.

10. While no gene therapy product has yet been approved by the FDA, gene therapy treatments now in clinical trials offer patients the prospect of significant medical improvements or cures for diseases, particularly in oncology, transplantation and central nervous system diseases. The first regulatory approvals for commercial sales of gene therapy products, expected by the year 2000, will most likely be in the area of oncology. These oncology gene therapy products are anticipated to have sales exceeding \$600 million by 2002 and will likely use the HSV-tk gene with viral vectors, the means of delivering the gene. Sales of all gene therapy products are projected to reach \$45 billion by 2010, resulting from approvals for additional gene therapies using the HSV-tk gene and other gene therapies. HSV-tk gene therapy is expected to be used, inter alia, to treat graft versus host disease, an acute, chronic and sometimes fatal complication occurring in approximately 70 percent of all bone marrow transplantations. Gene therapy treatments for hemophilia are likely to be used prophylactically, other than in cases of trauma in which instance gene therapy products would likely be used in combination with recombinant and purified Factor VIII proteins. Cancer patients could benefit significantly from gene therapy for chemoresistance that could provide protection to patients' blood systems and allow higher, more effective doses of cancer chemotherapy to be administered. If chemoresistance gene therapy research is successful, sales are projected to exceed \$1 billion by 2004. There are no economic substitutes for gene therapy products.

11. Another relevant line of commerce in which to analyze the effects of the proposed merger is the research, development, manufacture and sale of corn herbicide. Corn herbicides are chemical products designed to kill or control weeds that interfere with corn production. Separate markets for corn herbicides are distinguished by the types of weeds, *i.e.*, broadleaf or grass, against which the herbicide is economically effective and the stage of growth of the corn crop or weed, *i.e.*, pre-emergent or post emergent, at which the herbicide is both safe for use on the corn crop and economically effective against the weeds to be controlled. Corn herbicides are essential to economic production of corn. There are no economic substitutes for corn herbicide for pre-emergent control of grasses or for corn herbicides for post emergent control of broadleaf weeds.

12. Another relevant line of commerce in which to analyze the effects of the proposed merger is the research, development, manufacture and sale of flea control products. Flea control products are chemical products designed to treat and prevent flea infestation in cats and dogs. Flea control products are sold in various forms including pills, collars, shampoos, sprays, and foggers, and are sold through various channels of distribution including veterinarians, pet specialty stores, lawn and garden centers, mass merchandisers, and grocery stores. There are no economic substitutes for flea control products for the treatment and prevention of flea infestation in cats and dogs.

13. The United States is a relevant geographic area in which to analyze the effects of the merger. U.S. Environmental Protection Agency (“EPA”) and Food and Drug Administration (“FDA”) regulations impose substantial barriers on the introduction of products which do not meet those agencies’ regulations.

V. STRUCTURE OF THE MARKETS

Gene Therapy

14. The market for the research and development of gene therapy is highly concentrated. Ciba and Chiron together, and Sandoz, are two of only a few entities capable of commercially developing gene therapy products. Only Ciba together with Chiron, and Sandoz control the substantial proprietary rights necessary to commercialize gene therapy products and possess the technological, manufacturing, clinical, regulatory expertise and manufacturing capability to commercially develop gene therapy products. Each is either in clinical development or near clinical development for the treatment of human diseases for which there are large unmet medical needs.

15. Ciba and Chiron together, and Sandoz are the two leading commercial developers of gene therapy technologies and control critical gene therapy proprietary portfolios, including patents, patent applications, and know-how.

16. The market for the research and development of HSV-tk gene therapy for the treatment of cancer is highly concentrated. Only two companies are capable of commercially developing HSV-tk gene therapy products with viral vectors and are either in clinical development or near clinical development to treat cancer. Sandoz and Chiron are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

17. The market for the research and development of HSV-tk gene therapy for the treatment of graft versus host disease is also highly concentrated. Only two companies are capable of commercially developing HSV-tk gene therapy products with viral vectors, and are either in clinical development or near clinical development to treat graft versus host disease. Chiron and Sandoz are the leading commercial developers of these gene therapy technologies and/or control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

18. The market for the research and development of gene therapy for the treatment of hemophilia is highly concentrated. Only two companies are capable of commercially developing gene therapy products for the treatment of hemophilia using the Factor VIII gene with viral vectors. Chiron and Sandoz are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

19. The market for the research and development of chemoresistance gene therapy is highly concentrated. Only three companies are capable of commercially developing gene therapy products for the treatment of chemoresistance using the MDR-1 gene and only two companies are capable of commercially developing gene therapy products for the treatment of chemoresistance using the MRP gene. Chiron and Sandoz are the leading commercial developers of these gene therapy technologies and/or control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

Corn Herbicides

20. The market for corn herbicide, and the relevant markets included therein, herbicide for pre-emergent control of grasses and herbicide for post-emergent control of broadleaf weeds, are each highly concentrated, as measured by the Herfindahl-Hirschman Index ("HHI") and other measures of concentration. Ciba is the leading developer, manufacturer and seller of corn herbicide in the United States with a share of over 35 percent of sales and over 40 percent of treated acres. Sandoz has approximately a 10 percent share by either measure. United States sales of corn herbicide totaled \$1.4 billion in 1995. The proposed merger would increase concentration, as measured by the HHI, by approximately 700 points for dollar sales, and by approximately 1000 points for treated acres, to approximately 3000 for sales and approximately 3300 for treated acres.

21. Ciba's metholachlor herbicides, sold under the brands Dual® and Bicep®, are the leading corn herbicides for pre-emergent control of grasses in the United States. Ciba products accounted for over 40 percent of pre-emergent treatment of corn acres for grasses in 1995. In 1996, Sandoz doubled its sales of its recently introduced dimethenamid herbicides, sold under the brands Frontier® and Guardsman®, which accounted for approximately 3 percent of pre-emergent treatment of corn acres for grasses in 1995. Based on 1995 treated acres, the proposed merger would increase concentration, as measured by the HHI, by approximately 300 points to approximately 3400.

22. Sandoz's dicamba herbicides, sold under the brands Banvel®, Marksman®, and Clarity®, are the leading corn herbicides for post-emergent control of broadleaf weeds in the United States. Sandoz products accounted for over 30 percent of post emergent treatment of corn acres for broadleaf weeds in 1995. In 1996, Ciba tripled its sales of its recently introduced sulfonyl urea herbicide, sold under the brand Exceed®, which accounted for approximately 5 percent of post emergent treatment of corn acres for broadleaf weeds in 1995. Based on 1995 post emergent broadleaf treated acres, the proposed merger would increase concentration, as measured by the HHI, by approximately 1900 points to over 4000. Moreover, Ciba and Sandoz recognize that current users of Sandoz's dicamba herbicides are the principal target for expected market share gain by Ciba's Exceed® herbicide.

23. Prior to the merger described in Paragraph 8, Ciba and Sandoz each cooperated and coordinated with other producers of corn herbicide through supply agreements for corn herbicide active ingredients and through joint development and promotion of corn herbicide formulations. Ciba is the dominant supplier of atrazine, a broadleaf weed control product that is widely used as a component in premixed herbicide formulations, including Marksman®, Guardsman® and Bicep®, as well as in pre-emergent and post emergent herbicides sold by competitors of Ciba and Sandoz. Supply agreements, joint product development agreements, and joint marketing agreements among producers of corn herbicides increase coordinated interaction and the recognition of mutual interdependence among competitors in each of the relevant markets for corn herbicide.

Flea Control Products

24. The flea control products market is very highly concentrated as measured by the HHI and other measures of concentration. Sales of flea control products in the U.S. amounted to approximately \$400 million in 1995. Ciba is the leading developer, manufacturer and seller of flea control products with a share of approximately 50 percent. Ciba's Program® has a dominant share of the flea control products market. Sandoz ranks second in flea control products sales from sales of Vetkem® and Zodiac® flea control products and sales of base active methoprene. The proposed merger would increase concentration as measured by the HHI by approximately 3050 points to a level of approximately 6600. Moreover, prior to the merger described in Paragraph 8, Sandoz and Ciba were developing additional flea control products, which likely would be direct and substantial competitors.

VI. ENTRY CONDITIONS

25. Entry into the relevant markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract anticompetitive effects of the merger. Regulations by the Food and Drug Administration ("FDA") covering gene therapy products and systemic flea control products and by the Environmental Protection Agency ("EPA") covering corn herbicides and externally applied flea control 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.

Gene Therapy

26. Entry into the gene therapy markets requires lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the FDA. Entry into each gene therapy market can extend up to and beyond 10 to 12 years. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. The FDA must approve all phases of gene therapy development, including extensive preclinical and clinical work. No company may reach advanced stages of development

in the relevant gene therapy markets without: (1) clinical gene therapy expertise; (2) scientific research that requires years to complete; (3) patent rights to all the necessary proprietary inputs into the gene therapy product sufficient to provide the company with reasonable assurances of freedom to operate; and (4) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs include genes, vectors and vector manufacturing technology, and cytokines, proteins necessary for many gene therapy applications.

Corn Herbicides

27. Despite the expiration of United States patents on dicamba and metolachlor, post-patent strategies pursued by Ciba and Sandoz, including product reformulation, distribution agreements, purchase and supply contracts with manufacturers, and joint product development agreements, have limited entry of generic competition to Ciba's leading pre-emergent grass herbicides and Sandoz's leading post emergent broadleaf herbicides.

28. Entry into the corn herbicide markets requires over a decade for chemical synthesis; laboratory and greenhouse testing; formulation; process development; pilot production; pilot trials; field trials; testing for acute, subchronic and chronic toxicity, carcinogenic and genetic effects, and incidence of birth defects that may be associated with the product; environmental toxicology testing; measurement of plant, animal, soil, water and air residues and testing of degradation of plant, animal, soil, and water environment; data collection; product registration and EPA review; construction of production facilities; and use optimization. Once a product is introduced to the market, several years are often required to gain customer acceptance through demonstrated safety, performance and reliability, over a variety of weather conditions.

Flea Control Products

29. Entry into the flea control products market requires over a decade for chemical synthesis, lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years as well as qualified manufacturing facilities in order to achieve the required EPA or FDA approvals for commercial sale of these products. Once a product is introduced to the market, extensive sunk costs must be incurred for advertising and promotion to gain significant customer and pet owner acceptance.

30. Despite the expiration of United States patents on methoprene, the base active ingredient used in Sandoz's second generation flea control products, the EPA registrations and proprietary technology involved in the production of methoprene, have prevented entry of generic competition to Sandoz' flea control products.

VII. EFFECTS OF THE PROPOSED MERGER

31. The effects of the merger, if consummated, may be substantially to lessen competition or 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. Specifically the merger will:

- a. eliminate Ciba and Sandoz as substantial, independent competitors; eliminate actual, direct, and substantial competition between Ciba and Sandoz, including the reduction in, delay of or redirection of research and development projects; and increase the level of concentration in the relevant markets;
- b. eliminate actual potential and perceived potential competition in the relevant markets;
- c. increase barriers to entry into the relevant markets;

Gene Therapy

- d. combine alternative technologies, and reduce innovation competition among researchers and developers of gene therapy products, including reduction in, delay of or redirection of research and development tracks;
- e. increase the merged firm's ability to exercise market power, either unilaterally or through coordinated interaction with Chiron, in the gene therapy markets, because the merged firm will have both complete ownership of the Sandoz gene therapy research and development and a 46.5% stock ownership interest in Chiron, the only other firm in a position to commercialize work in gene therapy;
- f. heighten barriers to entry by combining portfolios of patents and patent applications of uncertain breadth and validity, requiring potential entrants to invent around or declare invalid a greater array of patents;
- g. create a disincentive in the merged firm to license intellectual property rights to or collaborate with other companies as compared to premerger incentives;

Corn herbicides

- h. eliminate the potential for increased actual, direct and substantial price competition and cause consumers to pay higher prices for corn herbicides;

- i. increase the merged firm's ability unilaterally to exercise market power in the market for corn herbicide for post-emergent control of broadleaf weeds, by combining the two closest substitutes in the market;
- j. increase the likelihood and degree of coordinated interaction between or among competitors in the market for corn herbicide for pre-emergent control of grasses;

Flea Control Products

- k. increase the merged firm's ability unilaterally to exercise market power in the flea control products market by combining the two closest substitutes in the market;
- l. increase the likelihood and degree of coordinated interaction between or among competitors in the flea control products market; and
- m. eliminate the potential for actual, direct and substantial price competition and cause consumers to pay higher prices for flea control products, as well as reduce innovation competition among producers of flea control products by eliminating, delaying or redirecting the introduction of new products under development.

VIII. VIOLATIONS CHARGED

32. The merger agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

33. The merger, if consummated, would constitute a violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. § 18.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this Complaint to be signed by the Secretary and its official seal to be affixed, at Washington, D.C. this twenty-fourth day of March, 1997.

By the Commission.

SEAL

Donald S. Clark
Secretary