

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

In the Matter of)
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)
Ciba-Geigy Limited,)
a corporation,)
)
Ciba-Geigy Corporation,)
a corporation,)
)
Chiron Corporation,)
a corporation,) Docket No. C-
)

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), and Sandoz Ltd., a

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.

1. 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.

1. 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.

1. 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.

1. 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.

1. 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.

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

V. STRUCTURE OF THE MARKETS

Gene Therapy

1. 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.

1. 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.

1. 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.

1. 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.

1. 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.

1. 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

1. 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.

1. Ciba's metholachlor herbicides, sold under the brands Dual

component in premixed herbicide formulations, including Marksma®, Guardsmar® and Bicep®, as well as in pre-emergent and post emergent herbicides sold by competitors of Ciba and Sandoz. well as in pd 4.f

Gene Therapy

1. 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

1. 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.

1. 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;

1. 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

1. 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 ~~com~~ 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

- 1. The merger agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, 15 U.S.C. ▲