ANALYSIS OF PROPOSED CONSENT ORDER
TO AID PUBLIC COMMENT

The proposed complaint alleges that the merger violates 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, by lessening competition or tending to create a monopoly in markets involving three general areas: (1) gene therapy research and development; (2) corn herbicides; and (3) flea control products. According to the complaint, the merger will increase the level of concentration and increase barriers to entry in 2) corn he TD 0.36152 Tc 0.0127 568 the the relj T* 0.005 arketrdiposedomerger will 0.0122 arkets and el

of only a very small number of entities capable of commercially developing gene therapy products. They possess the intellectual property, the technological, manufacturing, clinical, and regulatory expertise, and the manufacturing assets to commercially develop gene therapy products.

Gene therapy involves treating diseases or medical conditions by modifying genes and then inserting the modified genes into a patient

many sufferers; in cases of trauma, 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 by providing protection to patients' blood systems and allowing 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.

The complaint alleges that each of the gene therapy markets is highly concentrated and that Ciba/Chiron and Sandoz are two of only a few entities capable of commercially developing a broad

disease. Similarly, these two companies are the most advanced of all companies capable of commercially developing viral vectors using the Factor VIII gene for the treatment of hemophilia A and using the MDR-1 gene and the MRP gene for the treatment of chemoresistance. In each instance, Ciba/Chiron and Sandoz are either in clinical development or near clinical development for the treatment of these diseases, are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how. For example, with respect to the HSV-tk gene therapy products, both Ciba/Chiron and Sandoz control intellectual property portfolios sufficient to make it likely that they could market HSV-tk gene therapy products in competition with one another. The merger would eliminate that competition, and because of the parties' patent portfolios, it is extremely unlikely that any other firm would be able to enter to replace that lost competition.

The complaint alleges that entry into the gene therapy markets requires lengthy FDA

merger, the companies' alternative competing gene therapy technologies will be combined, reducing innovation competition. That combination changes the competitive incentives of the merged entity. It will likely lead to a reduction in development of gene therapy products, as the parties combine their research and development pipelines and eliminate or slow down their parallel development projects.

In addition, Novartis, the merged firm, will have a disincentive to license intellectual property rights to or collaborate with other companies as compared to the pre-merger incentives of the independent competitors, Ciba/Chiron and Sandoz. Although Ciba/Chiron and Sandoz had substantial individual intellectual property portfolios pre-merger, they had the incentive and did act as rival centers from which others could obtain needed intellectual property rights. Ciba/Chiron and Sandoz would grant limited intellectual property rights to other developers and researchers in return for receiving marketing or other valuable rights back from them. Consequently, as the complaint alleges, the merger may heighten barriers to entry by resulting in one entity holding so extensive a portfolio of patents and patent applications, of uncertain breadth and validity, as to diminish its incentives to license, thus impeding the ability of other gene therapy researchers and developers to continue developing their products.

To remedy the alleged competitive harm, the proposed Order provides for a set of patent licenses to allow other companies to replace the competition otherwise lost due to the merger. The Commission believes that licensing, rather than divestiture of assets, is sufficient because access to certain key intellectual property rights held by the merged firm is a crucial component of successful commercialization of many potential gene therapy products. Competitors already have (to varying

degrees) the hard assets, *e.g.*, production facilities, researchers and scientists, needed to compete. Rivals and other scientists confirm that licensing would enable them to develop gene therapy products and replace the competition lost due to the merger. Further, an asset divestiture might create substantial disruption in the parties' research and development efforts. In this case, therefore, a licensing remedy appears to be the preferred approach to restoring the competition lost by the merger.

The proposed Order includes the following remedy provisions. First, in the research, development, manufacture, and sale of gene therapy, the proposed Order would require Sandoz and Chiron to provide to all gene therapy researchers and developers non-exclusive licenses or sublicenses to certain proprietary and patented technologies essential for the competitive development and commercialization of gene therapy products. In the United States, Chiron owns the rights to commercialize cytokine Interleukin 2 ("IL-2"), and Sandoz has exclusive rights to the Anderson *ex vivo* patent, and claims arising there-under, and owns the rights to cytokines Interleukin 3 ("IL-3") and Interleukin 6 ("IL-6"). Within thirty (30) days of the date the Order becomes final, the companies are required to grant to other gene therapy researchers non-exclusive licenses to each of these essential gene therapy technologies. In addition, each licensee must be given access to drug master files, the data filed with the FDA establishing the safety and purity of these cytokines. These licensing arrangements will remedy the reduction in competition in research and development of gene therapy caused by the merger.

As detailed in the Order, the IL-2, IL-3 and IL-6 cytokines and the Anderson *ex vivo* patent licenses include a right to a royalty payment at low rates (based upon net sales with no minimum amount). In the past, the Commission has had concerns with royalty payments in connection with

licenses that are meant to restore competition eliminated by a merger. This is because continuing entanglements between the divesting company and the acquirer might provide opportunities for information exchange between competitors and interfere with their economic incentives to compete vigorously. These risks are relatively slight under the terms of the proposed Order, particularly because of the low royalties and potential number of non-exclusive licenses to the industry required under the proposed Order. In addition, to minimize further the financial relationships and the exchange of competitively sensitive information among Novartis, Chiron and potential competitor-licensees, an independent auditor will be appointed to collect and aggregate the royalty payments. Sandoz, Ciba, Chiron, and Novartis will be prohibited from gaining access to this confidential sales information. Each license will also include a binding arbitration clause to resolve disputes regarding the royalties or any other terms, a provision that further insulates Sandoz, Ciba, Chiron, and Novartis from interactions with the potential licensees.

Second, the proposed Order provides for further remedies regarding the anticompetitive harm alleged with respect to the HSV-tk product markets. Both Sandoz and Ciba/Chiron are developing HSV-tk gene therapies for cancer and graft versus host disease. After the merger, Ciba/Chiron and Sandoz would control dominating intellectual property portfolios for HSV-tk gene therapy. The proposed Order restores the pre-merger incentives for research, development, manufacture and sale of HSV-tk gene therapy products for cancer and graft versus host disease by requiring licensing of the Sandoz' and Chiron's worldwide HSV-tk patent rights, including rights relating to vectors. By September 1, 1997, Sandoz and Chiron each are required to grant a non-exclusive license to Rhône-Poulenc Rorer ("RPR"), with whom Ciba, Sandoz and Chiron have entered into a letter of intent for this purpose. If the agreement between RPR and Ciba, Sandoz, and Chiron were to fall through,

Ciba, Sandoz and Chiron would be required to license these assets to another licensee who has received Commission approval by September 1, 1997. Under the terms of the proposed Order, the license granted to RPR, or an alternative licensee, must include the right to sublicense in fields that are not developed by RPR or the licensee, as well as a technology transfer from Sandoz of necessary

The proposed Order also provides for the appointment of a trustee if Novartis and/or Chiron fail to grant any of these licenses within the appropriate time period. In that event, the trustee is authorized to divest either Sandoz or Chiron's HSV-tk businesses in their entirety.

Corn Herbicides

According to the Commission's proposed complaint, the merger of Ciba and Sandoz into Novartis, absent relief, would have adverse effects on various markets for corn herbicide. United States sales of corn herbicides -- chemical products designed to kill or control weeds that interfere with corn production -- totaled $1.4 billion in 1995. According to the proposed complaint, the markets for corn herbicide are distinguished by the types of weeds -- broadleaf or grass -- against which the herbicide is chemically effective as well as by the stage of growth of the corn crop or weed -- pre-emergent or post-emergent -- at which the herbicide is safe for use on the corn crop and chemically effective against the weeds to be controlled.

The Commission's proposed complaint alleges that Ciba's metolachlor herbicides, sold under the brands Dual® and Bicep®, are the leading corn herbicides for pre-emergent control of grasses. The complaint alleges that Sandoz recently introduced dimethenamid grass herbicides, sold under the brands Frontier® and Guardsman®, are gaining share against Ciba's metolachlor grass herbicides.

The complaint also alleges that Sandoz dicamba herbicides, sold under the brands Banvel®, Marksman®, and Clarity®, are the leading corn herbicides for post-emergent control of broadleaf weeds. According to the complaint, Ciba's recently introduced sulfonyl urea broadleaf herbicide, sold under the brand Exceed®, is rapidly gaining share against Sandoz dicamba broadleaf herbicides, and Ciba and Sandoz recognize that current users of Sandoz dicamba herbicides are the principal

target for expected market share gain by Ciba's Exceed® herbicide. Ciba is also the dominant supplier of atrazine, a broadleaf weed control product that is widely used as a component in premixed herbicide formulations sold by Ciba, Sandoz and their competitors.

According to the complaint, each of the corn herbicide markets is highly concentrated, as measured by the Herfindahl-Hirschman Index ("HHI") and other measures of concentration. Ciba accounts for over 35 percent of corn herbicide sales in the United States and over 40 percent of treated acres, while Sandoz has approximately a 10 percent share by either measure. Further, the complaint alleges that 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.

In the market for pre-emergent treatment of corn acres for grasses, the complaint alleges that Ciba products accounted for over 40 percent and that Sandoz accounted for approximately 3 percent in 1995. The proposed merger would increase concentration in that market, as measured by the HHI, by approximately 300 points to approximately 3400. In addition, in the market for post-emergent treatment of corn acres for broadleaf weeds, the complaint alleges that Sandoz products accounted for over 30 percent and that Ciba's Exceed® brand accounted for approximately 5 percent in 1995. Combining Exceed® and other Ciba products with Sandoz's products, the proposed merger would increase concentration in that market, as measured by the HHI, by approximately 1900 points to over 4000.

The complaint alleges that 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, possible

carcinogenic and mutagenic effects and effects on prenatal deformation; 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. Further, according to the complaint, 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.

Additionally, the complaint alleges that, 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.

Further, according to the complaint, supply agreements, joint product development agreements, and joint marketing agreements among producers of corn herbicide increase coordinated interaction and the recognition of mutual interdependence among competitors in each of the relevant markets for corn herbicide.

The complaint further alleges that the proposed merger of Ciba and Sandoz would 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; eliminate the potential for increased actual, direct and substantial price competition and cause consumers to pay higher prices for corn herbicides; increase barriers to entry; increase the level of concentration in the corn herbicide markets; 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; and increase the likelihood and degree of coordinated interaction between or among competitors in the market for corn herbicide for pre-emergent control of grasses.

The Order accepted for public comment contains provisions that would require Sandoz to divest its corn herbicide business, including Sandoz

alleges that there are no economic substitutes for flea control products for the treatment and prevention of flea infestation in cats and dogs.

The complaint further alleges that the flea control products market is a very highly concentrated market that had sales in the U.S. of approximately $400 million in 1995. Ciba is the leading developer, manufacturer and seller of flea control products, and Ciba's market share is approximately 50 percent. Ciba's Program® brand flea control products have a dominant share of the flea control products market. Sandoz ranks second in flea control products sales from sales of its flea control products, under the Vetkem® and Zodiac® brands, and from sales of the active ingredient, methoprene, used by other companies in flea control products. The complaint also alleges that, prior to the merger, Sandoz and Ciba were both developing additional flea control products, which likely would be in direct and substantial competition with each other's products.

The proposed complaint alleges that 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 qualifit es qualifitbf Tjuritiof Tilithlea coOrdee me 0.0065 T

combining the two closest substitutes in the market. According to the complaint, the proposed

may continue to be manufactured for Sandoz on behalf of the acquirer for two years. To ensure the viability of the flea products acquirer, Novartis is prohibited from re-entering the U.S. market with a methoprene-based flea control product for six years. In addition, Novartis is required under the proposed Order to notify the Commission if it plans to acquire flea control assets in the U.S. during the next ten years.

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