

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

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In the Matter of	)	
	)	
Ciba-Geigy Limited,	)	
a corporation,	)	
	)	
Ciba-Geigy Corporation,	)	
a corporation,	)	
	)	
Chiron Corporation,	)	
a corporation,	)	File No. 961-0055
	)	
Sandoz Ltd.,	)	
a corporation,	)	
	)	
Sandoz Corporation,	)	
a corporation, and	)	
	)	
Novartis AG,	)	
a corporation.	)	

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AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed merger ("Merger") between Ciba-Geigy Limited, including its wholly-owned subsidiary Ciba-Geigy Corporation (collectively, "Ciba"), and Sandoz Ltd., including its wholly-owned subsidiary, Sandoz Corporation (collectively, "Sandoz"), into Novartis AG ("Novartis"), and it now appearing that Ciba, Sandoz, Novartis, and Chiron Corporation ("Chiron") in whom Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder, holding as of September 30, 1996, not solely as an investment, approximately 46.5% of the Chiron capital stock, hereinafter sometimes collectively referred to as "Proposed Respondents," are willing to enter into an agreement containing an Order to divest certain assets and businesses and to provide for other relief:

IT IS HEREBY AGREED by and between Proposed Respondents, by their duly authorized officers and attorneys, and counsel for the Commission that:

1. Proposed 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.
2. Proposed 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. Proposed Respondent Chiron Corporation, in whom Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder, holding as of September 30, 1996, not solely as an investment, approximately 46.5% of the Chiron capital stock, 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.
4. Proposed 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.
5. Proposed 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.
6. Proposed 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.
7. Proposed Respondents admit all the jurisdictional facts set forth in the draft of complaint here attached.
8. Proposed Respondents waive:
  - a. any further procedural steps;
  - b. the requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
  - c. all rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this agreement; and

d. any claim under the Equal Access to Justice Act.

9. Each Proposed Respondent shall submit within thirty (30) days of the date this agreement is signed by Proposed Respondents, a verified written report, pursuant to Section 2.33 of the Commission's Rules, signed by the Proposed Respondents setting forth in detail the manner in which the Proposed Respondents will comply with Paragraphs II through XII of this Order

required to file one or more compliance reports showing how they are complying or that they have fully complied with the Order. Proposed Respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

## ORDER

### I.

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

A. "Ciba" means Ciba-Geigy Limited, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Ciba-Geigy Limited, including, but not limited to, Ciba-Geigy Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Chiron" means Chiron Corporation, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Chiron, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

C. "Sandoz" means Sandoz Ltd., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Sandoz Ltd., including, but not limited to, Genetic Therapy, Inc. and Sandoz Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

D. "Novartis" means Novartis AG, a company jointly formed by Ciba and Sandoz to effectuate the merger of Ciba and Sandoz through the acquisition of Ciba and Sandoz by Novartis. Novartis includes Ciba and Sandoz; all of Novartis's directors, officers, employees, agents and representatives, predecessors, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Novartis AG; and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

E. "BASF" means BASF Aktiengesellschaft, a company organized under the laws of Germany with its principal office and principal place of business located at Ludwigshafen, Germany.







5. a paid-up, non-exclusive right to develop, manufacture and sell any Agricultural Chemical Active Ingredient or Agricultural Chemical Formulation anywhere in the world under all foreign patents, patent applications, licenses, registrations, submissions and approvals and to use all other intellectual property located, generated, obtained, or used outside the United States and Canada, including a copy of all trade secrets, test data, technology and know-how;
6. all trademarks and trade names for Agricultural Chemical Active Ingredients and Agricultural Chemical Formulations, including, without limitation, exclusive world rights to the trademarks or trade names Frontier, Guardsman, Century, Banvel, Clarity, Marksman, Dycleer, Vanquish, Weedmaster, Tough, Lentagran and Phoenix;
7. all contracts and agreements relating to formulating and packaging, including, without limitation, all toll supply agreements;
8. all owned or leased facilities, equipment, real property and other assets used in research, development, technical support, testing, or product registration in the United States and Canada, including, but not limited to, the Gilroy Research Center, the Palo Alto Research Center, the Greenville Field Station, and facilities at Des Plaines, Illinois;
9. all tangible and intangible assets associated with research and development projects, process improvement projects, production projects, and label extension projects; and all registrations, submissions and approvals, Registration Data, supporting data and documents, patents, patent applications, and other intellectual property relating to each such project;
10. all owned or leased offices, distribution facilities, real property and other assets used in sales or technical service of Sandoz Agricultural Chemicals, including, but not limited to, offices and facilities located in Englewood, Colorado, Des Plaines, Illinois and Palo Alto, California;
11. all books, records and files, customer lists, customer records and files, vendor lists, catalogs, sales promotion literature, advertising materials, research materials, technical information, management information systems, software, inventions, specifications, designs, drawings, processes and quality control data;
12. all interest in and to contracts and agreements with customers, joint venturers, suppliers, sales representatives, distributors, agents, personal property lessors,



personal property lessees, licensors, licensees, consignors and consignees, and rights under warranties and guarantees, express or implied; and

13. rights to make or sell Pyridate in the United States and Canada and to make or sell, or license others to make or sell, in the United States and Canada, Agricultural Chemical Formulations containing Pyridate.

CCO "Sandoz Animal Health Business" means the business units of Sandoz that are engaged in the research, development, manufacture and production of Flea Control Products and Other Dallas Products at the Sandoz facility in Dallas, Texas which products are distributed and sold in the United States and Canada, excluding the Sandoz Agricultural Chemical Business, and all assets, properties, business and goodwill, tangible and intangible, trademarks and trade names used, in whole or in part, in the research, development, manufacture, and production of Flea Control Products and Other Dallas Products at the Sandoz facility located in Dallas, Texas which products are distributed and sold in the United States and Canada, including, but not limited to, the following:

1. all machinery, fixtures, equipment, vehicles, transportation facilities, furniture, tools and other tangible personal property;
2. all customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, research materials, technical information, management information systems, software, inventions, trade secrets, intellectual property, patents, technology, know-how, specifications, designs, drawings, processes and quality control data;
3. inventory and storage capacity;
4. all rights, titles and interests in and to owned or leased real property at the Sandoz facility located at 12200 Denton Drive, Dallas, Texas, together with appurtenances, licenses and permits;
5. all rights, titles and interests in and to the contracts entered into in the ordinary course of business with customers (together with associated bid and performance bonds), suppliers, sales representatives, distributors, agents, personal property lessors, personal property lessees, licensors, licensees, consignors and consignees;
6. all rights, titles and interests in and to development projects;
7. all rights under warranties and guarantees, express or implied;
8. all books, records, and files;

9. all rights, titles and interests in registrations or other governmental approvals for manufacture and sale of any Flea Control Products and Other Dallas Products or research and development efforts for Flea Control Products and Other Dallas Products; provided, however, Respondents shall retain rights of referral to the Core Data Package for uses outside the United States and Canada;

10. a non-exclusive license to develop, manufacture and sell any Flea Control Products and Other Dallas Products, including research and development efforts for Flea Control Products and Other Dallas Products, anywhere in the world under all foreign patents, patent applications, and licenses, and to use all other intellectual property (exclusive of any trademarks and trade names) located, generated, obtained, or used anywhere in the world, including all trade secrets, test data, technology and know-how; and

11. all items of prepaid expense.

Notwithstanding the foregoing, Sandoz Animal Health Business shall exclude the production facility located at Muttenz, Switzerland, operated by Sandoz to produce Methoprene and other materials, Flea Control Products and Other Dallas Products that are sold outside of the United States and Canada, and assets that were part of Ciba prior to the Merger.

DD0 "Sandoz Animal Health Business Acquiree" means the entity or entities to whom  
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PP0 "Hemophilia License" means one (1) non-exclusive license under patents and/or patent applications to which Sandoz held rights, as of October 1, 1996, to develop a gene therapy product using the beta-domain deleted Factor VIII gene for the treatment of hemophilia, including, at the option of RPR or the Subsequent Hemophilia Licensee, all technical information, know-how or materials owned or controlled by Sandoz, as of the date on which this Order becomes final, necessary for the development and manufacture of such product, including, but not limited to, hemophilia gene therapy vectors.

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final, necessary to enable RPR or the HSV-tk Licensee to adequately and fully research and develop any and all HSV-tk Licensed Products; and

2. With respect to Respondent Chiron, all claims in the issued U.S. and foreign patents which are issued from patent applications corresponding to, derived from or equivalent to those United States patent applications listed in Part 2 of non-public Appendix A, and divisionals, continuations, extensions and reissues thereof, which claims are directed specifically to the use of the HSV-tk gene in HSV-tk Gene Therapy, or would otherwise dominate such use of the HSV-tk gene. Respondent's HSV-tk Patent Rights do not include claims to proprietary manufacturing methods, methods of

by Anderson Patent Licensee from the sale of gene therapy products covered by the Anderson Patent Rights may or may not incorporate hospital and/or physician costs relating to the gene therapy treatment (e.g., physician charges related to the removal and readministration of cells).

AAA0 "Other Cytokines" means all cytokines, other than IL-2, IL-3, and IL-6, including but not limited to, stem cell factors, interferons, colony stimulating factors, tumor necrosis factors and erythropoetins.

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D. The contract of divestiture shall provide that, at the option of Respondent Novartis, the Sandoz Animal Health Business Acquirer shall enter into a transitional toll manufacturing agreement of up to two year's duration to produce for Respondents products currently produced at Dallas, but not subject to the divestiture pursuant to this Paragraph, for sale by Respondents outside the United States and Canada, all at a price equal to the Sandoz Animal Health Business Acquirer's Cost plus twenty percent (20%) mark-up.

IV.

IT IS FURTHER ORDERED that:

Upon reasonable notice and request to Respondents from the Sandoz Animal Health Business Acquirer, Respondents shall provide information, assistance and advice with respect to the Sandoz Animal Health Business divested pursuant to this Order such that the Sandoz Animal Health Business Acquirer or its designee will be capable of:

(1) manufacturing all products currently produced by the Sandoz Animal Health Business divested pursuant to this Order; and

(2) manufacturing and/or obtaining all necessary ingredients, other than Methoprene, for products of the Sandoz Animal Health Business divested pursuant to this Order,

in substantially the same manner and quality employed, achieved or planned by the Respondents prior to divestiture. Such information, assistance and advice shall include reasonable consultation with knowledgeable employees of Respondents for a period of time sufficient to satisfy the Sandoz Animal Health Business Acquirer's management that its personnel are appropriately trained in the research, development, manufacture, distribution and sale of the products and research and development projects of the Sandoz Animal Health Business divested pursuant to this Order. Respondents shall convey all know-how necessary to manufacture or have manufactured, distribute, sell and obtain all necessary governmental approvals, including EPA approvals, and licenses to research, develop, manufacture or have manufactured, distribute and sell in the United States and Canada the products of the Sandoz Animal Health Business divested pursuant to this Order. Respondents shall provide such information, assistance and advice for one (1) year from the date Respondents divest the Sandoz Animal Health Business divested pursuant to this Order. Respondents may charge the Sandoz Animal Health Business Acquirer at a rate no greater than Respondent's cost for providing such technical assistance.

V.



IT IS FURTHER ORDERED that:

Respondents shall enter into a Contract Manufacturing Agreement ("CMA") with the Sandoz Animal Health Business Acquirer to contract manufacture and deliver to the Sandoz Animal Health Business Acquirer, in a timely manner, Methoprene in the volumes requested by the Sandoz Animal Health Business Acquirer. The CMA shall be effective for the shorter of six (6) years from the date Respondents divest the Sandoz Animal Health Business or three (3) months after the Sandoz Animal Health Business Acquirer or its designee obtains all EPA or FDA approvals necessary to manufacture all Methoprene required for products of the Sandoz Animal Health Business. The CMA shall contain the following provisions:

A. Respondents shall make representations and warranties to the Sandoz Animal Health Business Acquirer that the Methoprene manufactured pursuant to the CMA meets all applicable EPA, FDA and other governmental requirements for the United States and Canada, and Respondents shall agree to indemnify, defend and hold the Sandoz Animal Health Business Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of Methoprene manufactured pursuant to the CMA to meet such governmental specifications. This obligation shall be contingent upon the Sandoz Animal Health Business Acquirer giving Respondents prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting Respondents to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel. This obligation shall not require Respondents to be liable for any negligent act or omission of the Sandoz Animal Health Business Acquirer or for any representations and warranties, express or implied, made by the Sandoz Animal Health Business Acquirer that exceed the representations and warranties made by Respondents to the Sandoz Animal Health Business Acquirer.

B. Respondents shall agree to package and deliver the Methoprene manufactured pursuant to the CMA in a manner and form and according to a schedule reasonably requested by the Sandoz Animal Health Business Acquirer.

C. The CMA shall require that, for the first three years during which the CMA is effective, the Sandoz Animal Health Business Acquirer shall compensate Respondents for all Methoprene supplied pursuant to the CMA at a rate not to exceed Respondents' cost of producing such Methoprene during the period from July 1, 1995, through June 30, 1996, which Cost may be adjusted for demonstrated input expenditure increases as determined by the trustee appointed pursuant to Paragraph VIII of this Order.

D. The contract of divestiture shall be submitted and approved by the Commission prior to the divestiture of the Sandoz Animal Health Business required by this Order. Respondents' application for approval of the divestiture pursuant to this Order shall include: (1) a certification attesting to the good faith intention of the Sandoz Animal Health Business Acquirer

to obtain, or to cause its designee to obtain, in an expeditious manner all FDA, EPA and other governmental approvals required in the United States and Canada to manufacture and sell Methoprene; (2) a Strategic Plan to obtain all FDA, EPA and other governmental approvals required in the United States and Canada to manufacture or have manufactured, and sell Methoprene; and (3) a CMA pursuant to this Paragraph.

E. Respondents shall provide information, assistance, and advice to the Sandoz Animal Health Business Acquirer, or its designee, to enable the Sandoz Animal Health Business Acquirer, or its designee, to manufacture and sell Methoprene in the United States or Canada. Respondents shall convey all know-how required to manufacture, sell and obtain all necessary EPA, FDA and other government approvals to manufacture and sell Methoprene in the United States or Canada. Such information, assistance and advice shall include reasonable consultation with knowledgeable employees of in the Unit221u.nclude reasonable coTj 36 -28.3u0100.0282 Tc -0

to any employee of Novartis, any non-public information relating to any research and development project ongoing as of March 1, 1996, at Sandoz to develop or improve any Base Active Flea Ingredient or any Sandoz Flea Control Product, if said Person or employee did not have knowledge of such non-public information as of March 1, 1996.

VIII.

IT IS FURTHER ORDERED that:

A. The Commission may appoint a trustee to ensure that Respondents and the Sandoz Animal Health Business Acquirer expeditiously perform their responsibilities required under this Order with respect to the Sandoz Animal Health Business. The trustee shall also ensure that the provisions of the Agreement to Hold Separate between Respondents and the Commission, dated November 26, 1996, are carried out in good faith. Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

1 The Commission shall select the trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee.

2 The trustee shall have the power and authority to assure Respondents compliance with the terms of this Order.

3 Within ten (10) days after appointment of the trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the trustee all rights and powers necessary to permit the trustee to assure Respondents compliance with the terms of this Order relating to the Sandoz Animal Health Business. As part of the trust agreement, the trustee shall execute confidentiality agreement(s) with Respondents.

4 The trustee shall serve until the ninetieth (90th) day following the date on which the Sandoz Animal Health Business Acquirer or its designee obtains EPA approval to manufacture and sell Methoprene. If the responsibilities of the trustee are extended pursuant to the provisions of Paragraph X, the trustee shall serve until such date as required by that Paragraph.



approvals required in the United States and Canada to continue the research, development, manufacture and sale of the products and projects of the Sandoz Animal Health Business.

C. Respondents shall comply with all reasonable directives of the trustee regarding Respondents

IX.

IT IS FURTHER ORDERED that:

A.

1. On or before September 1, 1997, each Respondent shall (i) grant a non-exclusive license to RPR to make, use and sell HSV-tk Licensed Products under such Respondent's HSV-tk Patent Rights, in a manner that has received prior Commission approval and, except as provided in this Order, is consistent with the Letter of Intent dated November 20, 1996 between RPR and Sandoz Ltd., which contains licensing terms concerning Sandoz and Chiron HSV-tk Patent Rights, hemophilia gene rights, and the Anderson Patent; or (ii) grant a non-exclusive license to make, use and sell HSV-tk Licensed Products under such Respondent's HSV-tk Patent Rights to an HSV-tk Licensee that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, in perpetuity and in good faith, at no minimum price. In consideration for the HSV-tk License, each Respondent may request from the HSV-tk Licensee compensation in the form of royalties and/or an equivalent cross-license.

2. At the option of RPR or the HSV-tk Licensee, Novartis shall, in good faith, within one (1) year of execution of said HSV-tk License, or within one (1) year of the execution of any sublicense to the HSV-tk Patent Rights by RPR or the HSV-tk Licensee, provide to RPR or the HSV-tk Licensee, or the HSV-tk Sublicensee(s), technical information, know-how or material owned or controlled by Novartis as of the date on which this Order become final, as is necessary to develop the HSV-tk Licensed Products. Such technical assistance may include reasonable consultation with knowledgeable employees of Novartis and training at RPR or the HSV-tk Licensee facilities, or the HSV-tk Sublicensee's facilities, or at such other place as is mutually satisfactory to Novartis and RPR or the HSV-tk Licensee or the HSV-tk Sublicensee(s), such consultation to be for a period of time within the one-year period reasonably sufficient to satisfy RPR or the HSV-tk Licensee or the HSV-tk Sublicensee(s).

3. RPR or the HSV-tk Licensee may sublicense, to any HSV-tk Sublicensee, fields that are not being developed by RPR or said HSV-tk Licensee.

4. The purpose for the HSV-tk License is to ensure the continuation of HSV-tk gene therapy research and development for an HSV-tk Gene Therapy product 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 complaint.

5. Pending licensing of the HSV-tk Patent Rights, each Respondent shall take such action as is necessary to maintain the viability and marketability of the HSV-tk Patent

Rights and the HSV-tk Licensed Products, including, but not limited to, maintaining in the ordinary course the research and development of HSV-tk products.

B. For the purpose of ensuring continuation of *in vivo* gene therapy research and development, and to ensure the availability of cytokines for Gene Therapy, and to remedy the lessening of competition and research and development of Gene Therapy resulting from the Merger as alleged in the Commission complaint, commencing within thirty (30) days of the date this Order becomes final, Respondents shall perform the following obligations:

1. Respondent Novartis shall grant to each Person who so requests a Cytokine License, in perpetuity and in good faith. In payment for such license, Respondent Novartis shall receive a royalty, or its equivalent, of no greater than three percent (3%) of the Net Sales Price of Cytokine Licensed Products, paid from the date of first commercial sale of royalty bearing products or services until a time no later than the expiration of the last to expire patent. Respondent Novartis may also request certain non-exclusive rights to obtain and use safety and efficacy data generated by said Cytokine Licensee to support its own regulatory filings.

2. Respondent Chiron shall grant to each Person who so requests a Cytokine License, in perpetuity and in good faith. In payment for such license, Respondent Chiron shall receive a royalty, or its equivalent, of no greater than three percent (3%) of the Net Sales Price of Cytokine Licensed Products, paid from the date of first commercial sale of royalty bearing products or services until a time no later than the expiration of the last to expire patent; provided, however, that if Respondent Chiron grant of a Cytokine License includes the right to manufacture, then Respondent Chiron shall receive a royalty of no greater than one percent (1%) above the royalty due from Respondent Chiron to all third party IL-2 licensors of Respondent Chiron. Respondent Chiron may also request certain non-exclusive rights to obtain and use safety and efficacy data generated by said Cytokine Licensee to support its own regulatory filings.

3. In the event that royalties are to be paid by any such Cytokine Licensee under a Cytokine License described in Subparagraphs 1 or 2 to a party who is not an affiliate of such Cytokine Licensee for royalty bearing products or services, then the royalties to be paid to Respondents shall be reduced by up to one-half of the negotiated royalty rate of said Cytokine License, but in no event shall any royalties under Subparagraphs 1 and/or 2 be reduced by more than fifty percent (50%). These stacking provisions shall also apply if at any time in the future it becomes scientifically advantageous to combine IL-2, IL-3, and IL-6, or any combination thereof, into a single Cytokine Licensed Product so that the royalty payable to all Respondents shall be no more than three percent (3%). However, if Respondent Chiron grant of a Cytokine License includes the right to manufacture, this Subparagraph IX.B.3. shall not apply to reduce the

Cytokine Licenses obligations to pay royalties owed to third party IL-2 licensors of Chiron.

4. If a Person seeking a Cytokine License has patent rights and/or drug regulatory files on Other Cytokines for use *in vivo* cell expansion, the licensing Respondent may require equivalent cross licenses for such Other Cytokines from such Person.

C. For the purpose of ensuring continuation of *in vivo* gene therapy research and development, and to ensure the availability of Anderson Patent Licenses, and to remedy the lessening of competition in research and development of Gene Therapy resulting from the Merger as alleged in the Commission complaint, commencing within thirty (30) days of the date this Order becomes final, Respondent Novartis shall grant to each Person who requests an Anderson Patent License a non-exclusive license or sub-license under any and all Anderson Patent Rights, in perpetuity and in good faith, in the United States. In payment for such license, Respondent Novartis shall be entitled to receive: (i) a one-time payment of Ten Thousand Dollars (\$10,000) and (ii) a royalty based on the Net Sales Price of gene therapy product covered by the Anderson Patent Rights of no greater than one percent (1%) above the royalty due from Respondent Novartis to the United States National Institutes of Health. Such royalty shall be paid from the date of first commercial sale of royalty bearing products or services in the United States, provided that the Anderson Patent is valid and enforceable, until the expiration of the last to expire patent.

D. Respondent Novartis shall by no later than September 1, 1997, either (i) convert its exclusive rights to the beta-domain deleted Factor VIII hemophilia gene from Genetics Institute to a non-exclusive license; or (ii) grant a Hemophilia License to RPR in a manner that has received prior Commission approval and in a manner consistent with the Letter of Intent dated November 20, 1996 between RPR and Sandoz Ltd.; or (iii) grant a Hemophilia License to a Subsequent Hemophilia Licensee that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, at no minimum amount. In consideration for the Hemophilia License, Respondent Novartis may request from RPR or the Subsequent Hemophilia Licensee compensation in the form of royalties and/or an equivalent cross-license. At the option of RPR or the Subsequent Hemophilia Licensee, Respondent Novartis shall, in good faith, within one (1) year of the execution of the Hemophilia License provide to RPR or the Subsequent Hemophilia Licensee, such technical information, know-how or materials, owned or controlled by Genetic Therapy, Inc. as of the date on which this Order become final, necessary for the development of a gene therapy product using the beta-domain deleted Factor VIII gene for the treatment of hemophilia.



E. Respondent Novartis shall not acquire from Ingenex, Inc. or the United States National Institutes of Health exclusive rights in intellectual property related to the gene sequence for MDR-1 or MRP.

F. Respondents shall include in each license granted pursuant to this Paragraph a provision that ensures Respondents have no access to any Licensee's Sales Price information. Respondents shall, in each license granted pursuant to this Paragraph, provide for:

1. The appointment of an independent auditor agreed upon among the respective parties who shall: (a) enter into appropriate confidentiality agreements; (b) have full and complete access to the pertinent personnel, books, records, technological information, or any other information as to which the auditor may reasonably require; and (c) be authorized to collect, audit, aggregate and distribute the respective aggregated royalties on an annual basis. Respondents shall notify the Commission of the appointment of any independent auditor.

2. A binding arbitration clause to resolve any and all disputes regarding the royalties or any other License terms. Respondents shall notify the Commission of the institution of any arbitration.

G. There will be no limitations upon the rights of any Respondent or any licensee or

C. If Respondents have not complied with the requirements of Paragraph IX.A. of this Order within the time required by Paragraph IX.A. of this Order, the Commission may appoint a trustee or direct the trustee appointed pursuant to Paragraph VIII of this Order to divest the HSV-tk Business to a buyer that receives the prior approval of the Commission, and in a manner that receives the prior approval of the Commission, at no minimum price. If Respondent Novartis has not complied with the requirements of Paragraph IX.D. of this Order within the time required by Paragraph IX.D. of this Order, the Commission may appoint a trustee or direct the trustee appointed pursuant to Paragraph VIII of this Order to convert Respondent Novartis exclusive rights to the beta-domain deleted Factor VIII gene from Genetics Institute to a non-exclusive license.

D. 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 trustee in such action. Neither the appointment or extension of responsibilities of a trustee nor a decision not to appoint or extend the responsibilities of a 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 trustee, pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.

E. If a trustee is appointed or directed by the Commission or a court pursuant to Subparagraph A. of this Paragraph to divest the Sandoz Agricultural Chemical Business, or pursuant to Subparagraph B. of this Paragraph to divest the Sandoz Animal Health Business, or pursuant to Subparagraph C. of this Paragraph to divest the HSHd 0 Tw c leshsha, 19 3.103ssi61.2

3. If a trustee is directed under Subparagraph B. of this Paragraph to divest the Sandoz Animal Health Business, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting the Sandoz Animal Health Business.

4. If a trustee is directed under Subparagraph C. of this Paragraph to divest the HSV-tk Business, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting the HSV-tk

Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestitures. 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 trustee, by the court.

9. The trustee shall make every reasonable effort to negotiate the most favorable price and terms available in each contract submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made in the manner and to the Agricultural Chemical Acquirer as set out in Paragraph II of this Order, or to the Animal Health Business Acquirer as set out in Paragraph III of this Order, or to the acquirer of the HSV-tk Business as set out in Paragraph X.C. of this Order, as applicable; provided, however, if the trustee receives bona fide offers from more than one acquiring entity for the Sandoz Agricultural Chemicals Business, or for the Sandoz Animal Health Business, or for the HSV-tk Business, and if the Commission determines to approve more than one such acquiring entity, the trustee shall divest to the acquiring entity or entities selected by Respondents from among those approved by the Commission.

10. The 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 Commission or a court may set. The 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 trustee's duties and responsibilities. The 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 trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the trustee's power shall be terminated. The

12. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph VIII or this Paragraph of this Order.

13. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional Orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

14. In the event that the trustee determines that he or she is unable to divest the Sandoz Agricultural Chemical Business, if directed to divest pursuant to Subparagraph A. of this Paragraph, in a manner consistent with the Commission's purpose as described in Paragraph II of this Order; or in the event that the trustee determines that he or she is unable to divest the Sandoz Animal Health Business, if directed to divest pursuant to Subparagraph B. of this Paragraph, in a manner consistent with the Commission's purpose as described in Paragraph III of this Order; or in the event that the trustee determines that he or she is unable to divest the HSV-tk Business, if directed to divest pursuant to Subparagraph C. of this Paragraph, in a manner consistent with the Commission's purpose as described in Paragraph IX.A.2. of this Order, the trustee may divest additional assets ancillary to the Sandoz Agricultural Chemical Business, ancillary to the Sandoz Animal Health Business, or as applicable, ancillary to the HSV-tk Business, and effect such arrangements as are necessary to satisfy the requirements of this Order.

15. The trustee shall have no obligation or authority to operate or maintain the Sandoz Agricultural Chemical Business, the Sandoz Animal Health Business, or the HSV-tk Business.

16. The trustee shall report in writing to Respondents and the Commission every sixty (60) days concerning the trustee's efforts to accomplish divestiture.

XI.

IT IS FURTHER ORDERED

Respondents and not of any other party to the transaction. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (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, Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request for additional information. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Notwithstanding, 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.

### XIII.

IT IS FURTHER ORDERED that, Respondent Ciba and/or Respondent Novartis shall not, without prior notice to the Commission, directly or indirectly, through subsidiaries, partnerships, or otherwise acquire common stock of Chiron such as to increase by more than one percent (1%) or more the percentage of Chiron stock that Ciba owns as of the date this Order becomes final, until the receipt by the Commission of a certification by RPR, the trustee, or Respondents, that Respondents have complied with the requirements of Paragraphs IX.A. and IX.D. of this Order; provided, however, in no event shall this provision apply later than five (5) years from the date this Order becomes final.

The prior notifications required by this Paragraph XIII 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 Respondent Novartis and not of any other party to the transaction. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (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, Respondent Novartis shall not consummate the transaction until twenty (20) days after substantially complying with such request for additional information. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Notwithstanding, 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.

XIV.

IT IS FURTHER ORDERED that:

A. Within sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until Respondents have fully complied with the provisions of Paragraphs II, III, and IX.A. and IX.D. of this Order requiring, respectively, divestiture of the Sandoz Corn Herbicide Business, divestiture of the Sandoz Animal Health Business, and granting of the HSV-tk License, Respondent Novartis shall submit to the Commission verified written report(s) ("Compliance Report") setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with Paragraphs II through IX of this Order. After completing the divestitures required under Paragraphs II, III., the licensing required under Paragraph IX.A, and the requirements of Paragraph IX.D. of this Order, and until the termination of the CMA required under Paragraph V of this Order, Respondent Novartis shall submit such Compliance Reports every one hundred eighty (180) days beginning on the date of the divestiture of the Sandoz Animal Health Business. Following termination of the CMA required under Paragraph V of this Order, Respondent Novartis shall submit to the Commission annual Compliance Reports on the anniversary of the date this Order became final, until and including the tenth anniversary date of this Order. Respondents shall include in their Compliance Reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs II through IX of the Order, including a description of all substantive contacts or negotiations for the divestiture or relating to the Gene Therapy License obligations. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

B. One year (1) from the date this Order becomes final, annually for ~~three (3)~~ years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondent Novartis 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 Paragraphs XII and XIII of this Order.



XV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents 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.

XVI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, upon written request, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents relating to any matters contained in this Order; and
- B. Upon five days' notice to Respondents and without restraint or interference from them, to interview officers, directors, or employees of Respondents.

XVII.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date this Order becomes final.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 1996.

FOR THE BUREAU OF COMPETITION  
FEDERAL TRADE COMMISSION

\_\_\_\_\_  
Morris A. Bloom  
Attorney

\_\_\_\_\_  
Elizabeth A. Jex  
Attorney

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Claudia R. Higgins  
Attorney

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Rhett R. Krulla  
Senior Litigator

FOR CIBA-GEIGY LIMITED

\_\_\_\_\_  
A. Krauer

\_\_\_\_\_  
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FOR CIBA-GEIGY CORPORATION

\_\_\_\_\_  
Jeff Benjamin

FOR CHIRON CORPORATION

\_\_\_\_\_  
Dr. William J. Rutter  
Chairman

FOR SANDOZ LTD.

APPROVED:

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H. J. Rudloff

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William J. Baer  
Director

FOR NOVARTIS AG

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Dr. Daniel Vasella

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