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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Robert Pitofsky, Chairman
Mary L. Azcuenaga
Janet D. Steiger
Roscoe B. Starek, III
Christine A. Varney

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,	)	DECISION AND ORDER
Sandoz Corporation, a corporation, and	)	
Novartis AG, a corporation.	)	

The Federal Trade Commission having initiated an investigation of the proposed merger between respondent Ciba-Geigy Limited, including its wholly-owned subsidiary Ciba-Geigy Corporation, and respondent Sandoz Ltd., including its wholly-owned subsidiary, Sandoz Corporation, into respondent Novartis AG, and respondents having been furnished thereafter with a copy of a draft of complaint that the Bureau of Competition presented to the Commission for its

consideration and which, if issued by the Commission, would charge respondents with violations 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

The respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondents of all the jurisdictional facts set forth in the aforesaid draft of the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its Complaint, makes the following jurisdictional findings and enters the following Order:

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.

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 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. 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. 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. 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. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

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.

F. "Commission" means the Federal Trade Commission.

G. “EPA” means the United States Environmental Protection Agency.

H. “FDA” means the Food and Drug Administration of the United States Department of Health and Human Services.

I. “Respondents” means Ciba, Sandoz, or Novartis, respectively, and in Paragraphs IX.A., IX.B., IX.F., IX.G., X, XIV, XV, XVI, and XVII, Chiron, or any combination thereof.

J. “Agricultural Chemical Active Ingredient” means a chemical that alone or in combination with other chemicals imparts or demonstrates herbicidal, insecticidal, fungicidal, or other pesticidal properties.

K. “Agricultural Chemical Formulation” means a formulation or pre-mix containing one or more Agricultural Chemical Active Ingredients.

L. “Agricultural Chemical Acquirer” means the entity or entities to whom Respondents shall divest either the Sandoz Corn Herbicide Business or the Sandoz Agricultural Chemical Business required to be divested pursuant to this Order.

M. “Agricultural Chemical” means any corn herbicides and other herbicides, insecticides, fungicides, and other pesticides developed, manufactured or sold by Sandoz in the United States or Canada or developed by Sandoz outside the United States and Canada for production or sale in the United States or Canada, other than products manufactured and sold by the Sandoz Animal Health Business.

N. “Base Active Flea Ingredient” means any final or intermediate form of any chemical, that alone or in combination with other chemicals is registered or under development as a Flea Control Product, including, but not limited to, Methoprene.

O. "Core Data Package" means data and information required by regulatory authorities in the United States and Canada to register Flea Control Products, Other Dallas Products, and ingredients for both.

P. “Corn Herbicides” means all Agricultural Chemical Active Ingredients and Agricultural Chemical Formulations used, or suitable for use, on corn crops to control weeds, including, but not limited to, Dimethenamid, Dicamba, and Pyridate.

Q. “Cost” means the manufacturer's average direct per unit cost of manufacturing exclusive of any overhead expenses.

R. “Dicamba” means technical concentrate of dicamba, chemical name 3,6-dichloro-o-anisic acid, and salts of dicamba, e.g., dimethylamine, diglycolamine, potassium, sodium, isopropylamine, DPL, and APM salts of dicamba, and any Agricultural Chemical Formulation containing dicamba.

S. “Dimethenamid” means technical concentrate of dimethenamid, chemical name 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethyl-thien-3-yl)-acetamide or (1RS, aRS)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-acetamide, and any Agricultural Chemical Formulation containing dimethenamid.

T. “FIFRA” means the Federal Insecticide, Fungicide, and Rodenticide Act and all statutory amendments, modifications or replacements thereof.

U. “Flea Control Products" means all products used or intended to be used to treat or prevent ectoparasitic (flea) infestation in connection with canines or felines and all research and development projects to develop products to be used to treat or control ectoparasitic infestation in connection with canines and felines.

V. “Merger” means the Merger of Ciba and Sandoz into Novartis.

W. “Methoprene” means (S)-Methoprene, chemical name Isopropyl (2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate, and (RS)-Methoprene, chemical name Isopropyl (E,E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate.

X. "Other Dallas Products" means products, other than Flea Control Products, that are manufactured or produced at the Sandoz facility located in Dallas, Texas and are sold in the United States or Canada.

Y. “Pyridate” means technical concentrate of pyridate, chemical name O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate, and includes any Agricultural Chemical Formulation containing pyridate.

Z. “Registration Data” means all data relating to the applicable Agricultural Chemical Active Ingredient or Agricultural Chemical Formulation that has been, or will be, submitted to the EPA, under FIFRA, or to any state or foreign regulatory agency for purposes of obtaining or maintaining any registration or authorizations for any product containing such Agricultural Chemical Active Ingredient or Agricultural Chemical Formulation.

AA. “Sandoz Corn Herbicide Business” means all physical assets, properties and business located in the United States or Canada and all goodwill, tangible and intangible assets, used by Sandoz in the research, development, manufacture, formulation, registration, distribution or sale of Corn Herbicides (other than Pyridate) in the United States or Canada, all as specified in the Asset Purchase Agreement dated as of September 26, 1996, between Sandoz and BASF.

BB. “Sandoz Agricultural Chemical Business” means all physical assets, properties and business located in the United States or Canada and all goodwill, tangible and intangible assets, used by Sandoz in the research, development, manufacture, formulation, registration, distribution or sale of Agricultural Chemicals in the United States or Canada, or for production or sale in the

United States or Canada, excluding the Sandoz Animal Health Business, including, without limitation, the following:

1. all owned or leased production facilities used in the manufacture of Agricultural Chemical Active Ingredients or Agricultural Chemical Formulations, including, but not limited to, the following:

a. the Dimethenamid plant and assets at Beaumont, Texas; and

b. the Dicamba plant and assets at Beaumont, Texas;

2. all EPA, state and foreign registrations and approvals relating to the manufacture or sale of Agricultural Chemical Active Ingredients and Agricultural Chemical Formulations in North America, including, but not limited to, EPA registrations 55947-1 (Banvel), 55947-24 (Weedmaster), 55947-28 (Banvel SGF), 55947-39 (Marksman), 55947-46 (Clarity), 55947-47 (dicamba, isopropylamine salt), 55947-140 (Frontier), 55947-141 (dimethenamid 96% technical), 55947-149 (dicamba, potassium salt), 55947-150 (Guardsman), 55947-155 (dicamba WG/70.0% wettable granule), 55947-159 (Frontier 6.0), 55947-160 (sodium dicambate technical 85% wettable granule), 55947-161 (Tough 3.75 EC), Tough 5 EC (56% EC), 55947-162 (Tough 45% WP), 55947-164 (Banvel 10G), 55947-165 (dicamba, diglycolamine salt), and 55947-166 (66% sodium salt of dicamba + 10% metribuzin);

3. all Registration Data, submissions and supporting data and documents, including, without limitation, all labels, label extensions, or planned or pending label extensions for any application;

4. all intellectual property located, generated, obtained, or used in the United States and Canada, including, but not limited to, trade secrets, test data, technology and know-how, and all United States and Canadian patents, patent applications, patent rights and licenses;

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.

CC. "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.

DD. "Sandoz Animal Health Business Acquirer" means the entity or entities to whom Respondents shall divest the Sandoz Animal Health Business required to be divested pursuant to this Order.

EE. "Sandoz Flea Control Products" means all Flea Control Products that as of November 22, 1996, are: (1) being manufactured, distributed and sold by Sandoz in the United States and Canada; and (2) all projects in research and development by Sandoz in the United States and Canada that relate to improving existing, or developing new, Flea Control Products or Base Active Flea Ingredients therefor.

FF. "Strategic Plan" means a detailed plan that sets forth *inter alia* the means by which the Sandoz Animal Health Business Acquirer will begin the manufacture and sale of Methoprene, including dates by which the Sandoz Animal Health Business Acquirer plans to have received necessary governmental approvals to manufacture and sell Methoprene in the United States and Canada.

GG. "Anderson Patent" means US Patent Number 5,399,346 issued March 21, 1995, and any pending divisionals, continuations, continuations in part, extensions or reissues of said original US patent application number 07/365,567.

HH. "Anderson Patent License" means a non-exclusive license obtained by any Person under the Anderson Patent for any gene therapy product or process.

II. "Anderson Patent Licensee" means a Person that obtains an Anderson Patent License.

JJ. "Cytokine License" means, as to each Respondent, a non-exclusive license or sublicense under such Respondent's Cytokine Patent Rights for use in any Cytokine Licensed Product as follows: (a) as to Respondent Chiron, with respect to IL-2, the right to use IL-2 sold by Respondent Chiron in a Cytokine Licensed Product, or if Respondent Chiron ceases offering IL-2 for sale, then the right to manufacture and use IL-2 in a Cytokine Licensed Product; and (b) as to Respondent Novartis with respect to IL-3 and IL-6, the right to manufacture and use IL-3 and/or IL-6 in a Cytokine Licensed Product.

KK. "Cytokine Licensed Product" means any research protocol or commercial product and/or service incorporating or to be used with cells that have been expanded, mobilized or cultured *ex vivo* with IL-2, IL-3 and/or IL-6 proteins.

LL. "Cytokine Licensee" means each and every Person that requests and obtains a Cytokine License.

MM. “Cytokine Patent Rights” means with respect to each Respondent, all worldwide patents and patent applications, issued or pending, which, as of the date this Order becomes final, are owned or controlled by such Respondent or licensed by a third party to such Respondent with the right to sublicense, which, in the case of Respondent Chiron, are directed to the manufacture, use, or sale of IL-2 in Cytokine Licensed Products, and, in the case of Respondent Novartis, are directed to the manufacture, use, or sale of IL-3 and/or IL-6 in Cytokine Licensed Products. Additionally, at the option of the Cytokine Licensee, the Cytokine Patent Rights shall also include a cross-reference right to the licensing Respondent’s respective drug regulatory files at the FDA with respect to IL-2 in the case of Respondent Chiron, and with respect to IL-3 and/or IL-6 in the case of Respondent Novartis.

NN. “Gene Therapy” means a therapeutic intervention in humans based on modification of the genetic material of autologous, allogeneic, or xenogeneic living cells. Cells may be modified *ex vivo* for subsequent administration or altered *in vivo* by gene therapy products given directly to the patient.

OO. "Gene Therapy License" means any and all of the HSV-tk License, Cytokine License, Anderson Patent License, and Hemophilia License.

PP. "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.

QQ. "HSV-tk Gene Therapy” means the introduction of the HSV-tk gene into a patient by *in vivo* and/or *ex vivo* transduction for the treatment of human disease.

RR. "HSV-tk License" means, as to each Respondent, the license or sublicense granted to RPR or the HSV-tk Licensee under such Respondent’s HSV-tk Patent Rights, to make, use, or sell an HSV-tk Licensed Product, including, at the option of RPR or the HSV-tk Licensee, the right to sublicense in fields that are not being developed by RPR or the HSV-tk Licensee.

SS. "HSV-tk Licensee" means a pharmaceutical company, other than RPR, with the demonstrated plan and ability to commercialize the HSV-tk Licensed Product, including vector production facilities and clinical gene therapy experience.

TT. "HSV-tk Licensed Product" means an HSV-tk Gene Therapy product in development or to be developed by RPR or the HSV-tk Licensee.

UU. "HSV-tk Patent Rights" means the following:

1. With respect to Respondent Novartis, all claims in issued U.S. and foreign patents and all claims in the pending patent applications, respectively, to make, have made, use and sell HSV-tk Licensed Products, owned by or under the control of Respondent Novartis as of the date this Order becomes final, including divisionals, continuations, extensions and reissues of such patents or pending patent applications, and including those which Respondent Novartis has licensed from a third party as of said date and has a right to sublicense, all to the extent that such patents or patent applications are directed to the use of the HSV-tk gene in the development of any and all HSV-tk Licensed Products. The HSV-tk Patent Rights owned by or under the control of Respondent Novartis are referenced in Part 1 of non-public Appendix A. Respondent Novartis HSV-tk Patent Rights shall include any and all rights obtained in the future to the patents and patent applications listed in Part 3 of non-public Appendix A under exclusive license with the right to sublicense. Respondent Novartis' HSV-tk Patent Rights may also include, at the option of RPR or the HSV-tk Licensee, all technical information, know-how or materials, owned or controlled by Respondent Novartis as of the date on which this Order becomes 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 Chiron's HSV-tk Patent Rights do not include claims to proprietary manufacturing methods, methods of administration, vector constructs, packaging or producer cells lines, genes, or other compositions, methods or processes that may be useful in making, using, or selling HSV-tk Licensed Products, but which do not dominate the use of the HSV-tk gene in HSV-tk Gene Therapy. Respondent Chiron's HSV-tk Patent Rights also do not include technical information, know-how or materials. Respondent Chiron's HSV-tk Patent Rights shall include any and all rights obtained in the future to the claims in patents and patent applications listed in Part 3 of non-public Appendix A under exclusive license with the right to sublicense, 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.

VV. "HSV-tk Business" means all the assets utilized by Respondent Sandoz in the research and development of HSV-tk Gene Therapy products, or at the option of all Respondents in the event that the requirements of Paragraph IX.A. have not been satisfied, all the assets utilized by Respondent Chiron in the research and development of HSV-tk Gene Therapy products.

WW. "HSV-tk Sublicensee" means any Person that receives a sublicense under the HSV-tk Patent Rights from RPR or the HSV-tk Licensee in fields not being developed by RPR or the HSV-tk Licensee.

XX. "MDR-1" means the multiple drug resistance-1 gene.

YY. "MRP" means the multiple resistance protein gene.

ZZ. "Net Sales Price" means the total amount received from the sale of royalty bearing products and/or services, less transportation charges and insurance, sales taxes, use taxes, excise taxes, value added taxes, customs duties or other imposts, normal and customary quantity and cash discounts, rebates (to the extent actually made) and disallowed reimbursements and allowances and credit on account of rejection or return of royalty bearing products or services. Royalty bearing products or services shall be considered "sold" when billed out or invoiced. The total amount received by Cytokine Licensee from the sale of Cytokine Licensed Products and/or 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 *ex vivo* gene therapy treatment (e.g., physician charges related to the removal and readministration of cells).

AAA. "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.

BBB. “Person” means any natural person, corporate entity, partnership, association, joint venture, non-profit organization, university, government entity, or trust.

CCC. "RPR" means Rhone Poulenc Rorer, Inc., 500 Arcola Road, Collegeville, PA 19426-0107.

DDD. "Subsequent Hemophilia Licensee" means any Person, other than RPR, that may obtain a Hemophilia License from Novartis, or from Genetics Institute, Inc. if Novartis converts its exclusive license from Genetics Institute, Inc. to a non-exclusive license.

II.

IT IS FURTHER ORDERED that:

A. Respondents shall divest, absolutely and in good faith, as an ongoing business, the Sandoz Corn Herbicide Business to BASF pursuant to the agreement between Sandoz and BASF dated as of September 26, 1996, no later than ten (10) days after the date on which this Order becomes final; or, in the event that BASF breaches that agreement, Respondents shall divest, absolutely and in good faith, as an ongoing business, the Sandoz Corn Herbicide Business, at no minimum price, within sixty (60) days of the date on which this Order becomes final, to an Agricultural Chemical Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, and shall also divest such additional ancillary assets and businesses and effect such arrangements as are necessary to assure the marketability and the independence, viability and competitiveness of the Sandoz Corn Herbicide Business.

B. The purpose of the divestiture of the Sandoz Corn Herbicide Business is to ensure the continuation of the Sandoz Corn Herbicide Business as an ongoing, viable enterprise engaged in the research, development, manufacture, distribution and sale of Corn Herbicides independent of Ciba, Sandoz, and Novartis and able to compete with Ciba, Sandoz and Novartis and to remedy the lessening of competition alleged in the Commission's complaint.

C. Pending divestiture of the Sandoz Corn Herbicide Business, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Sandoz Corn Herbicide Business and the Sandoz Agricultural Chemical Business and shall not cause or permit the destruction, removal, wasting, deterioration, or impairment of the Sandoz Corn Herbicide Business or of the Sandoz Agricultural Chemical Business, except in the ordinary course of business and except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

A. Respondents shall divest, absolutely and in good faith, as an ongoing business, within the time periods specified in Paragraph III.B. below, the Sandoz Animal Health Business. Respondents shall also enter into, and fulfill the terms of, a Contract Manufacturing Agreement ("CMA"), as specified in Paragraph V below, and effect such arrangements as are necessary to assure the marketability, independence, viability and competitiveness of the Sandoz Animal Health Business.

B. Respondents shall divest the Sandoz Animal Health Business to Central Garden and Pet Company and/or its affiliates pursuant to the Asset Purchase Agreement dated as of October 11, 1996, among Sandoz Ltd., Central Garden and Pet Company, and Centic Acquisition

Corp., as amended to conform to the terms of this Order in a manner that receives the prior approval of the Commission, within thirty (30) days of the date on which this Order becomes final; or, Respondents shall divest the Sandoz Animal Health Business, at no minimum price, within ninety (90) days of the date on which this Order becomes final, to a Sandoz Animal Health Business Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Sandoz Animal Health Business is to ensure the continued use of the assets of the Sandoz Animal Health Business in the same business in which the assets of the Sandoz Animal Health Business are engaged at the time of the proposed divestiture and to remedy the lessening of competition from the proposed merger of Ciba and Sandoz as alleged in the Commission's complaint.

C. Pending divestiture of the Sandoz Animal Health Business, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Sandoz Animal Health Business and shall not cause or permit the destruction, removal, wasting, deterioration or impairment of the Sandoz Animal Health Business, except in the ordinary course of business and except for ordinary wear and tear. Respondents shall maintain research and development of all current research and development projects at the levels planned by Sandoz for such projects as of June 4, 1996.

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 Respondents' 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 to 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 Respondents and training at either or both the Sandoz Animal Health Business Acquirer's facilities, or those of its designee, and the Respondents' facilities for a period of time sufficient to satisfy the Sandoz Animal Health Business Acquirer's management that its personnel, or those of its designee, are appropriately trained in the manufacture of Methoprene. Respondents shall continue to provide such information, assistance and advice 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. Respondents may charge the Sandoz Animal Health Business Acquirer at a rate no greater than Respondents' direct cost for providing such technical assistance.

F. Respondents shall use best efforts to facilitate the Sandoz Animal Health Business Acquirer's ability to obtain adequate supplies of Methoprene starter material, chemical name S-(3,7-Dimethyl-7-methoxy-1-octanal) from Takasago Iwata.

VI.

IT IS FURTHER ORDERED that for a period of six (6) years from the date on which the Sandoz Animal Health Business is divested, Respondents shall not: (1) manufacture and sell, or cause to be manufactured for sale, in the United States and Canada, Methoprene to any entity other than the Sandoz Animal Health Business Acquirer, or its designee; and (2) sell any products that contain Methoprene in the United States and Canada.

VII.

IT IS FURTHER ORDERED that for a period of six (6) years from the date this Order is placed on the public record for comment, except as required to comply with the terms of this Order, Respondents shall not provide, disclose or otherwise make available to any other Person or 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.

5. The trustee shall have full and complete access to the personnel, books, records and facilities related to the Sandoz Animal Health Business or to any other relevant information, as the trustee may request. Respondents shall develop such financial or other information as such trustee may request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of his or her responsibilities pursuant to this Order.

6. 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 set forth in the trust agreement. 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 expenses incurred. The Commission shall approve the account of the trustee, including fees for his or her services.

7. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

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

9. The Commission 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 assure compliance with the requirements of this Order.

B. The agreement pursuant to which Respondents divest the Sandoz Animal Health Business shall require the Sandoz Animal Health Business Acquirer to submit to the trustee appointed pursuant to this Paragraph, periodic written reports setting forth in detail the efforts of

the Sandoz Animal Health Business Acquirer to obtain all FDA, EPA and other governmental 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. The first report shall be submitted within sixty (60) days after the date on which the Commission approves the Sandoz Animal Health Business Acquirer and every ninety (90) days thereafter until the Sandoz Animal Health Business Acquirer has obtained all FDA, EPA and other governmental 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' obligations to comply with this Order.

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's 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's 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 *ex 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's 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's 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's grant of a Cytokine License includes the right to manufacture, this Subparagraph IX.B.3. shall not apply to reduce the Cytokine Licensee's 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 *ex 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 *ex 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's 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 any 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 Net 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 sublicensee hereunder to license or sublicense its own patents or patent applications to other third parties. Nothing in this Order requires any Respondent to guarantee freedom of operation under any third party patents not included within such Respondent's HSV-tk Patent Rights, Cytokine Patent Rights, Anderson Patent Rights or the patent rights subject to the Hemophilia License.

X.

IT IS FURTHER ORDERED that:

A. If Respondent Novartis has not divested, absolutely and in good faith and with the Commission's prior approval, the Sandoz Corn Herbicide Business within the time required by Paragraph II of this Order, the Commission may appoint a trustee, or direct the trustee appointed pursuant to Paragraph VIII of this Order, to divest the Sandoz Agricultural Chemical Business.

B. If Respondent Novartis has not divested, absolutely and in good faith and with the Commission's prior approval, the Sandoz Animal Health Business within the time required by Paragraph III of this Order, the Commission may appoint a trustee, or direct the trustee appointed pursuant to Paragraph VIII of this Order, to divest the Sandoz Animal Health Business.

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 HSV-tk Business, 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. The trustee shall be a person with experience and expertise in acquisitions and divestitures. 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. If a trustee is directed under Subparagraph A. of this Paragraph to divest the Sandoz Agricultural Chemical Business, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting the Sandoz Agricultural Chemical Business.

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 Business. If a trustee is directed under Subparagraph C. of this Paragraph to convert Respondent Novartis' exclusive rights to the beta-domain deleted Factor VIII gene from Genetics Institute to a non-exclusive license, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include converting Respondent Novartis' exclusive rights to the beta-domain deleted Factor VIII gene from Genetics Institute to a non-exclusive license.

5. Subject to the prior approval of the Commission and consistent with Paragraphs II through IX, the trustee shall have the exclusive power and authority to divest the assets identified in the Commission's appointment or extension of the trustee's authority and responsibilities.

6. Within ten (10) days after the appointment of the trustee or the extension of the trustee's authority and responsibilities, Respondents shall execute a trust agreement, or shall amend the existing trust agreement in a manner that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this Order.

7. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement or the amended trust agreement, described in Subparagraph E. of this Paragraph, to accomplish the divestiture or divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the applicable twelve-month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, such divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend each divestiture period only two (2) times.

8. The trustee shall have full and complete access to the personnel, books, records and facilities related to the Sandoz Agricultural Chemical Business, the Sandoz Animal Health Business, the HSV-tk Business, the license to hemophilia patents and/or patent applications granted to Respondent Novartis by Genetics Institute, or to any other relevant information, as the trustee may request. Respondents shall develop such financial or other information as such trustee may request and shall cooperate with the trustee. 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 trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the Sandoz Agricultural Chemical Business, the Sandoz Animal Health Business, or the HSV-tk Business, as applicable.

11. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

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 that, Respondents shall comply with all terms of the Agreement to Hold Separate attached to this Order and made a part hereof as Appendix I. The Agreement to Hold Separate shall continue in effect until (a) with respect to the Sandoz Corn Herbicide Business, such time as Respondents have divested the Sandoz Corn Herbicide Business and (b) with respect to the Sandoz Animal Health Business, such time as Respondents have divested the Sandoz Animal Health Business pursuant to Paragraphs II and III of this Order; or, if a trustee is appointed or the trustee’s authorities and responsibilities have been extended pursuant to Paragraph X of this Order, the Agreement to Hold Separate shall continue in effect until such time as Respondents or the trustee have divested all of the Sandoz Animal Health Business and, as applicable, the Sandoz Corn Herbicide Business or the Sandoz Agricultural Chemical Business pursuant to this Order.

XII.

IT IS FURTHER ORDERED that, for a period of ten (10) years after the date the Order becomes final, Respondents shall not, without prior notice to the Commission, directly or indirectly, through subsidiaries, partnerships, or otherwise:

A. Acquire more than 5% of any stock, share capital, equity, or other interest in any concern, corporate or non-corporate, engaged in at the time of such acquisition, or within the two years preceding such acquisition, the research, development, manufacture, distribution or sale of Flea Control Products or other products containing Methoprene in the United States; or

B. Acquire any assets currently used, or used in the previous two years (and still suitable for use for) for the research, development, manufacture, distribution or sale of Flea Control Products or other products containing Methoprene in the United States. Provided, however, that this Paragraph XII shall not apply to the acquisition of equipment, machinery, supplies or facilities constructed, manufactured or developed by or for Respondents.

The prior notifications required by this Paragraph 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 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. § 18a.

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 Reports") 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 the next nine (9) 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 on March 24, 2007.

By the Commission.

Donald S. Clark
Secretary

ISSUED: March 24, 1997

[Electronic copy of Agreement to Hold Separate not enclosed here.]

SEPARATE STATEMENT OF CHAIRMAN ROBERT PITOFSKY, AND COMMISSIONERS JANET D. STEIGER, ROSCOE B. STAREK, III, AND CHRISTINE A. VARNEY in Ciba-Geigy, Ltd., C-3725

We write to respond to Commissioner Azcuenaga's suggestion that the Commission erred by requiring licensing rather than divestiture in order to remedy competitive problems in the gene therapy markets.

The Commission's Complaint in this matter alleges that the merger of Ciba-Geigy Ltd. ("Ciba") and Sandoz Ltd. ("Sandoz") may substantially lessen competition or tend to create a monopoly in several gene therapy markets, including "gene therapy technologies" and "research and development of gene therapies" as well as specific gene therapy product markets.[1] No gene therapy product is currently marketed or even approved by the Food and Drug Administration, and none is expected to obtain regulatory approval until the year 2000. The Complaint notes, however, that sales of gene therapy products are projected to reach $45 billion by 2010.[2] The Complaint emphasizes that patent rights to proprietary inputs sufficient to provide a firm in this industry with reasonable assurances of freedom to operate are necessary for the firm to reach advanced stages of development.[3] Moreover, the Complaint alleges not only that Ciba and Sandoz "are two of only a few" entities capable of commercially developing gene therapy products, but also that they "control the substantial proprietary rights necessary to commercialize gene therapy products" and "control critical gene therapy proprietary portfolios, including patents, patent applications, and know-how."[4] We are left with a post-merger picture of potentially life-saving therapies whose competitive development could be hindered by the merged firm's control of substantially all of the proprietary rights necessary to commercialize gene therapy products. Preserving long-run innovation in these circumstances is critical.

Commissioner Azcuenaga argues that the Commission should have required the divestiture of Ciba's or Sandoz's gene therapy businesses, rather than licensing, in order to "preserve the competition that existed before the merger."[5] Of course, an injunction or divestiture is often the remedy chosen to resolve competition problems arising from mergers and acquisitions. In this case, however, patent licensing not only alleviated the competitive problems but also avoided divestiture's potentially disruptive effects on the parties' ongoing research.

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1 Complaint ¶ 9.

2 *Id.* ¶ 10.

3 *Id.* ¶ 26.

4 *Id.* ¶¶ 14, 15; see also *id.* ¶¶ 16-19.

5 See Statement of Commissioner Azcuenaga at 1.

As the Commission explained in the Analysis to Aid Public Comment that accompanied acceptance of the proposed consent agreement in this case, licensing was as effective in preserving competition as the traditional remedy of divestiture:

> 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.[6]

Licensing was preferable to divestiture in this case because an asset divestiture "might create substantial disruption in the parties' research and development efforts."[7] Not a single comment was submitted during the public comment period questioning this analysis, despite the invitation in the statement that Commissioner Azcuenaga issued when the Commission accepted the proposed Order for public comment.

Commissioner Azcuenaga asks why the Commission could not have ordered a divestiture of Sandoz's wholly-owned Gene Therapy, Inc. ("GTI") subsidiary or Ciba's partially-owned Chiron Corporation subsidiary. It may be appealing to call for divestiture of businesses acquired only two or three years ago -- as both GTI and Chiron were -- particularly when one such business is only partially owned. Ciba and Chiron, however, have numerous joint efforts that would have to be unraveled to separate the two companies. And GTI's U.S. clinical development is being closely coordinated with trials that Sandoz is conducting in Europe. Divestiture in this case would not be simple. To divest a business that would have such extensive continuing entanglements with the merged firm -- its principal competitor -- not only could hamper efficiency but also could be less effective in restoring competition if it led to coordinated interaction or left the divested business at the mercy of the merged firm.[8]

Instead of divestiture, the Order requires the merged firm to license gene therapy technology and patent rights to Rhône-Poulenc Rorer Inc. ("RPR"), so as to put RPR in a position to compete against the combined firm. In this way, RPR will be able to continue its research to develop HSV-tk gene therapy products for cancer and graft versus host disease. Commissioner Azcuenaga suggests that this relief only creates a potential "clone" that "may

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[6] Analysis to Aid Public Comment at 7.

[7] Id.

[8] Divestiture of the type that Commissioner Azcuenaga favors also might have disrupted or even ended the merging firms' ongoing collaborations with academic researchers.

follow identical [research] tracks."[9] We can not agree. This licensing package will give RPR the intellectual property that it likely could have obtained but for this merger's effect in reducing Novartis' incentive to license, so that RPR may continue to research and develop products on its own. Given RPR's ongoing research efforts, there is no basis for the assertion that this licensing package will turn RPR's efforts into a "clone" of the merging firms'.

In addition, the Order mandates that the merged firm license specific patents of Ciba and Sandoz to any interested person at a reasonable royalty. The dissent seems to suggest that such relief is ill-advised because it is based on some notion of the "essential facilities" doctrine, it usurps the role of the Patent and Trademark Office, and the setting of a royalty rate puts the Commission in the position of a price regulator.

First, it is not accurate to suggest that this remedy flows from the essential facilities doctrine. The Commission is not saying that Sandoz's *ex vivo* patent and associated cytokine patents are so important that they "ought" to be shared with everyone. Instead, the remedy is a response to a *merger* in which the merging parties possessed competing technologies. Before the merger, if developers of potential gene therapies were unable to reach agreement with Sandoz to license the *ex vivo* and associated patents, in many instances they could have worked with Ciba and used other technologies that did not infringe the *ex vivo* patent.[10] The merger has eliminated that option. Granting the right to sublicense was necessary to restore access to the critical patents for other developers of many gene therapies.

Second, although the Commission alleges in its Complaint that both Ciba and Sandoz control portfolios of issued patents and patent applications "of uncertain breadth and validity,"[11] the Commission does so not as a patent tribunal but as a body charged with evaluating how market reality -- including firms' perceptions of their own and others' positions -- affects competitive behavior. Ciba and Sandoz each controlled a variety of patents and patent applications, and their merger combined alternative technologies and approaches to research and development. Whereas before the merger third parties might have had the option of licensing one party's patents or challenging the validity of the other's, the Commission was concerned that the merger created a "killer" patent portfolio so broad as to eliminate that option. As a result, the

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[9] Statement of Commissioner Azcuenaga at 3.

[10] Analysis to Aid Public Comment at 6 ("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.").

[11] Complaint ¶ 31 f.

merger created a disincentive for Novartis to license third parties.[12] Broad licensing of the *ex vivo* patent and the cytokines resolves these concerns. Simply stated, licensing of these patents preserves the innovation competition that would otherwise be lost as a result of the merger.[13]

Third, the Commission must always think long and hard before it enters an order which sets a price. But that cautionary rule should not be turned into an absolute. The Commission believes that a compulsory license was a more focused and effective remedy than divestiture. If there is to be a compulsory license, there must be a price, and that price cannot be too high.[14] In this case the price was set at a level that would not interfere with the restoration of competition, and was commensurate with similar kinds of licenses negotiated in similar situations in the free market.

In short, requiring Novartis to license the key gene therapy patent rights is the best way to maintain competition and preserve the efficiencies gained in this transaction.

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[12] Complaint ¶¶ 15, 31 f, g. See W. Tom and J. Newberg, "U.S. Enforcement Approaches to the Antitrust/Intellectual Property Interface," in Competition Policy, Intellectual Property Rights, and International Economic Integration.

[13] The dissent appears to suggest the that licensing remedy called into question the decision of NIH to license the *ex vivo* patent to Sandoz on an exclusive basis. Statement of Commissioner Azcuenaga at 5. That criticism is inapt since NIH's license grants Sandoz the full authority to sublicense the patent.

[14] In previous cases the Commission has had concerns with royalty payments in licenses meant to restore competition eliminated by merger. There are two reasons for such a concern: (1) royalties can lead to information exchanges facilitating collusion, and (2) royalties can interfere with firms' incentives to compete vigorously. The Order issued today minimizes the exchange of competitively sensitive information through use of an independent auditor to collect and aggregate royalty payments. Moreover, the relatively low royalty rate is unlikely to affect development of potential "blockbuster" drugs. See Analysis to Aid Public Comment at 8.

STATEMENT OF COMMISSIONER MARY L. AZCUENAGA,
CONCURRING IN PART AND DISSENTING IN PART,
in Ciba-Geigy Limited , Docket C-3725

The order in this matter seeks to remedy the alleged anticompetitive effects of the merger of Ciba-Geigy Limited and Sandoz Ltd. in several product markets, corn herbicides, flea control products, and various gene therapy markets. I concur in the requirements of the order that the merged firm, Novartis, divest the corn herbicide business and the flea control product business that belonged to Sandoz. I do not concur with the order in the gene therapy markets, in which the Commission has bypassed the obvious, simple and effective remedy of divestiture in favor of a complex regulatory concoction that promises to be less effective and more costly.

Given the allegations of the complaint, the obvious remedy in the gene therapy markets is to require the divestiture of the gene therapy business of either Ciba-Geigy or Sandoz. A divestiture of GTI [1] or of Ciba-Geigy's interest in Chiron [2] would eliminate the alleged anticompetitive overlaps in the gene therapy markets [3] and preserve the competition that existed before the merger. It is a remedy that would be simple, complete, and easily reviewable. Normally, divestiture would be the remedy of choice, and no persuasive reason for a different remedy has been presented in this case.

The order of the Commission instead imposes licensing requirements that do not necessarily preserve the competition that existed before the merger. The only explanation offered for preferring licensing over an asset divestiture is the assertion in the Analysis To Aid Public Comment that a divestiture "might create a substantial disruption in the parties' research and

[1] Sandoz participated in the gene therapy market through its wholly-owned subsidiary Gene Therapy, Inc. (GTI), a corporation headquartered in Maryland that Sandoz acquired in 1995.

[2] Ciba-Geigy participated in the gene therapy market through Chiron Corporation, a company headquartered in California, in which Ciba-Geigy acquired a 46.5% interest in 1994. Chiron acquired Viagene, Inc., a U.S. gene therapy firm, in 1995.

[3] See Complaint ¶¶ 31.d through g.

development efforts." [4] What this means is not clear. Any divestiture is likely to involve substantial disruption, and if concerns about "disruption" were sufficient to avert a divestiture, that remedy would never be used. No doubt the parties prefer the negotiated licensing arrangement, but the preferences of the parties should not define the remedy.

The implication that divestiture in this case somehow would be counterproductive does not ring quite true. This is an industry in which cooperative research and development often is undertaken and in which innovative companies frequently change hands. Indeed, Ciba-Geigy and Sandoz only recently acquired their interests in the gene therapy field. [5] The gene therapy products at issue require years of research, and the FDA approval process also takes years. If the respective acquisitions by Ciba-Geigy and Sandoz in 1994 and 1995 of gene therapy companies did not hamper ongoing and future R&D projects, one must wonder why a divestiture in 1997 of one of those companies would be problematic.

Also, the licensing requirements imposed by the order are somewhat different from what we previously have seen. In the HSV-tk gene therapy markets, the complaint on which the order is based alleges that Ciba-Geigy and Sandoz, after the merger, could "combine alternative technologies, and reduce innovation competition" [6] and that "[o]nly two companies [presumably Ciba and Sandoz] are capable of commercially developing" [7] the HSV-tk gene therapies at issue. [8] The order permits Ciba-Geigy and Sandoz to combine their research and development projects in the HSV-tk gene therapy markets and requires them to license their combined intellectual property to an entity approved by the Commission. Instead of preserving the premerger competition between Ciba-Geigy and Sandoz, the order allows the allegedly anticompetitive combination to stand, as long as it clones its intellectual property. [9] Novartis remains free to "combine alternative

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[4] Analysis To Aid Public Comment at 7. The Analysis, published with the proposed consent order, states that its "purpose . . . 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." Id. at 17.

[5] See notes 1 & 2 supra.

[6] Complaint ¶ 31.d.

[7] Complaint ¶¶ 16 & 17.

[8] The complaint alleges HSV-tk gene therapy markets for the treatment of cancer and for the treatment of graft versus host disease.

[9] In addition, at the option of the licensee of the intellectual property, Novartis (but not Chiron, see note 2 supra) is required to provide "technical information, know-how or materials . . . necessary to enable" the licensee to research and

technologies," as alleged in the complaint. The diversity of research projects is an element of the pre-merger competition between Sandoz and Ciba-Geigy that is worth preserving, [10] but the order does not ensure that it is preserved.

The remedy in the market for Factor VIII gene therapy for the treatment of hemophiliacs offers two alternatives for licensing. [11] It is not clear how these alternatives will eventually work out, but neither of them necessarily preserves the competition that existed before the merger. A divestiture of either GTI or of Ciba-Geigy's interest in Chiron would have preserved the diversity of competition that existed before the merger.

The complaint also alleges a market for "the research and development of gene therapy," in which Ciba-Geigy and Sandoz are "two of only a few entities capable of commercially developing gene therapy products" and in which they control "critical gene therapy proprietary portfolios." [12] In this overall market for the research and development of gene therapy, the merger allegedly would "heighten barriers to entry by combining portfolios of patents and patent applications of uncertain breadth and validity" and "create a disincentive in the merged firm to license intellectual property rights" [13] to others. The remedy for the alleged violation is to require the licensing of intellectual property rights at a "low" [14] royalty rate stipulated in the order. [15]

Remedies that require the Commission to police prices generally are disfavored as highly regulatory, difficult to enforce and likely to distort the normal functioning of the market. They should be particularly disfavored in cases such as this in which a clean, simple divestiture of a gene therapy business is readily available and would not impede consummation of the remainder of the transaction, which is neutral or procompetitive. This agency often has been in the forefront in

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develop HSV-tk products. Order ¶ IX.A.2.

[10] See FTC & DOJ, Antitrust Guidelines for the Licensing of Intellectual Property ¶ 3.2.3 (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132.

[11] Order ¶ IX.D requires Sandoz to convert its exclusive license to the partial Factor VIII hemophilia gene to a nonexclusive one or to license certain of its relevant intellectual property ("Hemophilia License," defined in Order ¶ I.PP).

[12] Complaint ¶¶ 14 & 15.

[13] Complaint ¶¶ 31.f & g.

[14] Analysis To Aid Public Comment, supra note 4, at 8.

[15] Order ¶¶ IX.B & C.

opposing government price controls, which makes this part of the order particularly mystifying.

The compulsory licensing requirement applies to the so-called ex vivo or Anderson patent. [16] The ex vivo patent, issued in 1995, is owned by the National Institutes of Health (NIH) and licensed by NIH exclusively to Sandoz. To commercialize a gene therapy product, a researcher would need either a license from Sandoz under the ex vivo patent or a different mode of transduction. [17]

The requirement to license the ex vivo patent does not follow, as in the usual case, from ownership by the merger partner of competing technology. There is no substitute for the ex vivo patent, and Sandoz is the exclusive licensee under the patent. The question, then, is what links the compulsory licensing requirement to the violation alleged in the complaint. One possibility is that the compulsory licensing requirement reflects a judgment that the ex vivo patent is excessively broad. The complaint alleges that the merger will "combin[e] portfolios of patents and patent applications of uncertain breadth and validity." This is a curious allegation for a complaint under Section 7 of the Clayton Act and one that is not explained. Antitrust can provide the basis for challenging the use or combination of patents in some circumstances, but patent law, not antitrust law, customarily applies to assess the breadth and validity of patents. As far as I am aware, we have neither standards nor evidence by which we might conclude that the breadth or validity of the ex vivo patent provides a basis for liability under Section 7 of the Clayton Act.

One authority has identified the ex vivo patent as a "broad" patent that "cover[s] enormous areas of technology" and suggested that compulsory licensing would encourage follow-on invention in the field. [18] Others maintain that broad patent protection for inventions is necessary to encourage groundbreaking research and disclosure and that compulsory licensing would harm those incentives. These are important public policy issues, but they

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[16] Order ¶ IX.C. As I understand it, the two modes of delivery (called "transduction") for gene therapies are ex vivo and in vivo. Ex vivo delivery involves removing, modifying and replacing the patient's cells and has been used in the majority of gene therapy trials. In vivo delivery involves delivery of genetic material directly into the patient.

[17] The need to invent around existing patents can be a significant incentive for invention. To the extent that the compulsory licensing required by the order may reduce this incentive, it may reduce the research and development of alternative means of transduction for gene therapy.

[18] John Barton, Global Hearings Tr. 3409 (Nov. 29, 1995) (suggesting at Tr. 3415 that compulsory licensing for follow-on investors is "an anathema in the United States"); see FTC Staff Report, "Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace," Ch. 8, at 13-14 (May 1996).

are not elements of a violation under Section 7 of the Clayton Act.

Even if some might think the ex vivo patent is too broad, it was granted to NIH by the U.S. Patent and Trademark Office, also an agency of the U.S. government, and licensed by NIH to Sandoz. It would seem curious for this agency, charged with enforcing Section 7 of the Clayton Act and Section 5 of the FTC Act, to call into question the breadth and validity of a patent granted by the Patent Office to another federal agency. It also would seem curious to call into question the decision of NIH to license the patent on an exclusive basis. To the extent that such a decision entails evaluation of the potential for advancing scientific research in aid of human health, the National Institutes of Health would appear to have qualifications superior to the FTC. The fact that the respondents agreed to this remedy tells us nothing about its competitive implications. We must look elsewhere for an explanation of the requirement to license the ex vivo patent.

A theme running through the complaint is that the ex vivo patent is "essential" to commercializing a gene therapy product.[19] But the courts and the Commission consistently have held that a patent holder has no obligation to deal and is free to refuse to grant licenses,[20] even if some believe that the patent is "essential" to follow-on inventors. There being no apparent basis for the compulsory licensing of the ex vivo patent under Section 7 of the Clayton Act, perhaps the majority selected this remedy in the belief that it serves the public good. The patent was developed with tax dollars, it is owned by a government agency, and access to the patent could be useful to follow-on inventors. Put another way, the majority may believe it is protecting the public health or even saving lives. These are powerful arguments, but Congress heard them and decided instead to encourage the patenting of inventions resulting from government-sponsored research and the licensing of the patents to

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[19] The "essential facilities" doctrine ordinarily is triggered by a refusal to deal by a monopolist and is not part of an analysis under Section 7 of the Clayton Act.

[20] See Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 426-30 (1908); see also Hartford-Empire Co. v. United States, 323 U.S. 386, 432-33, clarified, 324 U.S. 570 (1945); SCM Corp. v. Xerox Corp., 645 F.2d 1195 (2d Cir. 1981), cert. denied, 455 U.S. 1016 (1982); United States v. Westinghouse Elec. Corp., 648 F.2d 642, 647 (9th Cir. 1981); E.I. duPont de Nemours & Co., 96 F.T.C. 705, 748 & n.40 (1980). See also FTC & DOJ, Antitrust Guidelines for the Licensing of Intellectual Property ¶ 2.2 (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132 ("The Agencies will not presume that a patent . . . necessarily confers market power upon its owner. . . . If a patent . . . does confer market power, that market power does not by itself offend the antitrust laws. . . . Nor does such market power impose on the intellectual property owner an obligation to license the use of that property to others.").

private industry as an incentive for industry to make the significant investments to bring a product to market. [21]

A divestiture of the gene therapy business of either Ciba-Geigy or Sandoz would resolve the alleged anticompetitive overlap in all the gene therapy markets. It would preserve the competition in research and development that existed before the merger, without compulsory licensing under order, without the mandating by the Commission of "reasonable" fees, and without creating possible disincentives for innovative research.

I dissent from the order in the gene therapy markets.

[21] 35 U.S.C. §§ 200-211; 15 U.S.C. §§ 3701-3714. See Eisenberg, "Symposium: A Technology Policy Perspective on the NIH Gene Patenting Controversy," 55 U. Pitt. L. Rev. 633 (1994).