APPENDIX I

INTERIM AGREEMENT

This Interim Agreement is by and between The Boeing Company ("Boeing"), a corporation organized and existing under the laws of the State of Delaware, and the Federal Trade Commission ("Commission"), an independent agency of the United States Government, established under the Federal Trade Commission Act of 1914, 15 U.S.C. 41, *et seq.*

PREMISES

Whereas, Boeing has proposed to acquire Rockwell International Corporation's Aerospace and Defense business; and

Whereas, the Commission is now investigating the proposed Acquisition to determine if it would violate any of the statutes the Commission enforces; and

Whereas, if the Commission accepts the Agreement Containing Consent Order ("Consent Agreement"), the Commission will place it on the public record for a period of at least sixty (60) days and subsequently may either withdraw such acceptance or issue and serve its complaint and decision in disposition of the proceeding pursuant to the provisions of Section 2.34 of the Commission's Rules; and

Whereas, the Commission is concerned that if an understanding is not reached preserving competition during the period prior to the final issuance of the Consent Agreement by the Commission (after the 60-day public notice period), there may be interim competitive harm and divestiture or other relief resulting from a proceeding challenging the legality of the proposed Acquisition might not be possible, or might be less than an effective remedy; and

Whereas, Boeing entering into this Interim Agreement shall in no way be construed as an admission by Boeing that the proposed Acquisition constitutes a violation of any statute; and

Whereas, Boeing understands that no act or transaction contemplated by this Interim Agreement shall be deemed immune or exempt from the provisions of the antitrust laws or the Federal Trade Commission Act by reason of anything contained in this Interim Agreement,

Now, therefore, Boeing agrees, upon the understanding that the Commission has not yet determined whether the proposed

Acquisition will be challenged, and in consideration of the Commission's agreement that, at the time it accepts the Consent Agreement for public comment, it will grant early termination of the Hart-Scott-Rodino waiting period, as follows:

1. Boeing agrees to execute and be bound by the terms of the order contained in the Consent Agreement, as if it were final, from the date Boeing signs the Consent Agreement.

2. Boeing agrees to deliver, within three (3) days of the date the Consent Agreement is accepted for public comment by the Commission, a copy of the Consent Agreement and a copy of this Interim Agreement to the United States Department of Defense, Teledyne Ryan Aeronautical, McDonnell Douglas Corporation and Lockheed Martin Corporation.

3. Boeing agrees to submit, within thirty (30) days of the date the Consent Agreement is signed by Boeing, an initial report, pursuant to Section 2.33 of the Commission's Rules, signed by Boeing setting forth in detail the manner in which Boeing will comply with paragraphs II through X of the Consent Agreement. Boeing agrees to include in such report a detailed description and explanation of the procedures it has implemented or will implement to comply with paragraphs II through X of the order.

4. Boeing agrees that, from the date Boeing signs the Consent Agreement until the first of the dates listed in subparagraphs 4.a and 4.b, it will comply with the provisions of this Interim Agreement:

a. Ten (10) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Section 2.34 of the Commission's Rules; or

b. The date the Commission finally issues its complaint and its Decision and Order.

5. Boeing waives all rights to contest the validity of this Interim Agreement.

6. For the purpose of determining or securing compliance with this Interim Agreement, subject to any legally recognized privilege and applicable United States Government national security requirements, upon written request, and on reasonable notice, to Boeing made to its principal office, Boeing shall permit any duly authorized representative or representatives 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 Boeing relating to compliance with this Interim Agreement; and

b. Upon five (5) days' notice to Boeing and without restraint or interference from it, to interview officers, directors, or employees of Boeing, who may have counsel present, regarding such matters.

7. This Interim Agreement shall not be binding until accepted by the Commission.

IN THE MATTER OF

PROGRESSIVE MORTGAGE CORPORATION, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE TRUTH IN LENDING ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3724. Complaint, March 10, 1997--Decision, March 10, 1997

This consent order prohibits, among other things, the Ohio-based mortgage corporation and its president from misrepresenting any terms or conditions of financing, such as, the annual percentage rate and finance charges of consumer loans; the number, amount and timing of mortgage payments; and the total number of payments to repay consumer loans.

Appearances

For the Commission: *John Mendenhall* and *Brenda Doubrava*.
For the respondents: *Leonard Wolkov*, Russell, OH.

COMPLAINT

The Federal Trade Commission, having reason to believe that Progressive Mortgage Corporation, a corporation, has violated the provisions of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 45-58, as amended, and the Truth in Lending Act ("TILA"), 15 U.S.C. 1601-1667, as amended, and its implementing Regulation Z, 12 CFR 226, and that Sanford Cramer, individually and as an officer of Progressive Mortgage Corporation, has violated the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, issues this complaint and alleges as follows:

PARAGRAPH 1. Respondent Progressive Mortgage Corporation is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Ohio, with its principal place of business at 5400 Transportation Boulevard, Cleveland, Ohio.

Respondent Sanford Cramer is the President of Progressive Mortgage Corporation. He formulates, directs and controls the acts and practices of the corporate respondent, including the acts and practices alleged in this complaint. His principal place of business is the same as that of the corporate respondent.

PAR. 2. Respondent Progressive Mortgage Corporation has been and is now engaged in the business of offering "consumer credit" to the public and is a "creditor," as those terms are defined in the TILA and Regulation Z.

PAR. 3. The acts and practices of respondents alleged in this complaint have been and are in or affecting commerce, as "commerce" is defined in the FTC Act, 15 U.S.C. 44.

PAR. 4. Respondent Progressive Mortgage Corporation, in the course and conduct of its business, on certain occasions, has failed to include the premiums for mortgage insurance, for so long as such insurance is required, in determining the finance charge and annual percentage rate for consumer credit transactions, and, thus, has understated the annual percentage rate and finance charge in its TILA disclosures.

PAR. 5. The aforesaid practice of respondent Progressive Mortgage Corporation violates Sections 106, 107 and 128 of the TILA, 15 U.S.C. 1605, 1606 and 1638, respectively, and Sections 226.4(b)(5); 226.22; and 226.18(d) and (e) of Regulation Z, 12 CFR 226.4(b)(5); 226.22; and 226.18(d) and (e), respectively, and constitutes an unfair and deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

PAR. 6. Respondent Progressive Mortgage Corporation, in the course and conduct of its business, on certain occasions, has failed to disclose accurately the number, amount, and timing of payments scheduled to repay the obligation in its TILA disclosures.

PAR. 7. The aforesaid practice of respondent Progressive Mortgage Corporation violates Section 128 of the TILA, 15 U.S.C. 1638, and Section 226.18(g) of Regulation Z, 12 CFR 226.18(g), and constitutes an unfair and deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

PAR. 8. Respondent Progressive Mortgage Corporation, in the course and conduct of its business, on certain occasions, has failed to disclose accurately the total of payments scheduled to repay the obligation in its TILA disclosures.

PAR. 9. The aforesaid practice of respondent Progressive Mortgage Corporation violates Section 128 of the TILA, 15 U.S.C. 1638, and Section 226.18(h) of Regulation Z, 12 CFR 226.18(h), and constitutes an unfair and deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

PAR. 10. Respondent Sanford Cramer, in the course and conduct of his business, has provided written disclosures to customers and potential customers of Progressive Mortgage Corporation relating to the TILA that state, for mortgage loans, the annual percentage rate, the finance charge, the monthly payment amount, and the total of payments scheduled to repay the obligation.

PAR. 11. Through the use of these written disclosures, respondent Sanford Cramer has represented, directly or by implication, that the figures and amounts stated therein truthfully represent the annual percentage rate, the finance charge, the monthly payment amount, and the total of payments scheduled to repay the obligation.

PAR. 12. In truth and fact, on certain occasions, the figures and amounts contained in these written disclosures were less than the actual annual percentage rate, finance charge, monthly payment amount, and total of payments scheduled to repay the obligation. Therefore, the representations set forth in paragraph eleven were, and are, false and misleading.

PAR. 13. The aforesaid acts and practices of respondent Sanford Cramer constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of respondents, Progressive Mortgage Corporation and Sanford Cramer, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Cleveland Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Truth in Lending Act ("TILA") and its implementing Regulation Z, and Section 5 of The Federal Trade Commission Act ("FTC Act"); and

The respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of 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 the 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 Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Progressive Mortgage Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio with its principal office and place of business located at 5400 Transportation Boulevard, Cleveland, Ohio.

Respondent Sanford Cramer is president of said corporation. He formulates, directs and controls the policies, acts and practices of said corporation, and his principal office and place of business is located at the above address.

2. The 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 respondent, Progressive Mortgage Corporation, a corporation, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, division, subsidiary or any other device, in connection with any extension of consumer credit in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Failing to include premiums for mortgage insurance, for so long as such insurance is required, in determining the finance charge and annual percentage rate as required by Sections 106 and 107 of the TILA, 15 U.S.C. 1605 and 1606, and Sections 226.4(b)(5) and 226.22 of Regulation Z, 12 CFR 226.4(b)(5) and 226.22.

B. Failing to disclose accurately, where mortgage insurance is required, the finance charge and the annual percentage rate as

required by Sections 106, 107 and 128 of the TILA, 15 U.S.C. 1605, 1606, and 1638, and Section 226.4, 226.22, and 226.18(d) and (e) of Regulation Z, 12 CFR 226.4, 226.22, and 226.18(d) and (e).

C. Failing to disclose accurately, where mortgage insurance is required, the number, amount, and timing of payments scheduled to repay the obligation, as required by Section 128 of the TILA, 15 U.S.C. 1638, and Section 226.18(g) of Regulation Z, 12 CFR 226.18(g).

D. Failing to disclose accurately, where mortgage insurance is required, the total of payments scheduled to repay the obligation, as required by Section 128 of the TILA, 15 U.S.C. 1638, and Section 226.18(h) of Regulation Z, 12 CFR 226.18(h).

E. Failing to make all disclosures determined in accordance with Sections 106 and 107 of the TILA, 15 U.S.C. 1605 and 1606, and Sections 226.4 and 226.22 of Regulation Z, 12 CFR 226.4 and 226.22, in the manner, form and amount required by Sections 226.17, 226.18, 226.19, and 226.20 of Regulation Z, 12 CFR 226.17, 226.18, 226.19, and 226.20.

F. Misrepresenting any term or condition of financing for any consumer credit transaction.

II.

It is further ordered, That respondent Sanford Cramer, individually and as an officer of respondent Progressive Mortgage Corporation, and his agents, representatives and employees, directly or through any corporation, division, subsidiary or any other device in connection with any extension of consumer credit in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Misrepresenting the annual percentage rate and the finance charge in written disclosures provided to consumers relating to the TILA.

B. Misrepresenting the number, amount, and timing of payments scheduled to repay the obligation in written disclosures provided to consumers relating to the TILA.

C. Misrepresenting the total of payments scheduled to repay the obligation in written disclosures provided to consumers relating to the TILA.

D. Misrepresenting any term or condition of financing for any consumer credit transaction.

III.

It is further ordered, That for six (6) years after the date of service of this order, respondent Progressive Mortgage Corporation, its successors or assigns, and respondent Sanford Cramer, individually and as an officer of Progressive Mortgage Corporation, shall maintain and upon request make available to the Commission and its employees all records that will demonstrate compliance with the requirements of this order.

IV.

It is further ordered, That respondent Progressive Mortgage Corporation, and its successors and assigns, and respondent Sanford Cramer, shall deliver a copy of this order to all current and future principals, officers, directors and managers, and to all current and future employees, agents and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

It is further ordered, That respondent Progressive Mortgage Corporation and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take

place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C.

VI.

It is further ordered, That respondent Sanford Cramer shall promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. In addition, for a period of five (5) years from the date of service of this order, he shall promptly notify the Commission of each affiliation with a new business or employment. Each such notice shall include his business address and a statement of the nature of the business or employment in which the respondent is newly engaged, as well as a description of his duties and responsibilities in connection with the business or employment.

VII.

It is further ordered, That respondent Progressive Mortgage Corporation, its successors and assigns, and respondent Sanford Cramer shall, within sixty (60) days of the date of service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order. The report shall be forwarded to the Federal Trade Commission, Enforcement Division, Washington, D.C.

VIII.

It is further ordered, That this order shall terminate on March 10, 2017, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

IN THE MATTER

TRANS UNION CORPORATION

Docket 9255. Interlocutory Order, March 12, 1997

ORDER DIRECTING GENERAL COUNSEL TO ENFORCE THIRD-PARTY SUBPOENA

In early November 1996, respondent Trans Union Corporation ("Trans Union") served a non-party, Experian Information Solutions Inc. ("Experian"), with a *subpoena duces tecum.* On January 24, 1997, Experian, which competes with Trans Union in providing services at issue in this case, filed a motion to quash this subpoena, which the Administrative Law Judge denied by order of February 19, 1997. On March 5, 1997, Trans Union filed a Motion for Enforcement of a Subpoena Duces Tecum Issued to Experian Information Solutions, Inc. On March 6, 1997, the Administrative Law Judge certified Trans Union's motion for enforcement of the subpoena to the Commission with a recommendation that the Commission seek enforcement.

The subpoena to Experian seeks documents falling into two categories: those relating to the source and makeup of Experian's target-marketing lists, and those relating to consent orders entered in 1991 and 1993 against Experian's predecessor, TRW. Trans Union and Experian have agreed, in a document signed on December 13, 1996, to limit the scope of the subpoena. The limitations agreed to reflect the objections and concerns later raised in Experian's Motion To Quash. After this agreement was reached, Experian produced certain documents in response to the subpoena.

The current dispute does not concern documents. The issue is whether, in further response to the subpoena, Experian will produce a representative for an oral deposition who can "authenticate any documents Experian produced in response to the Subpoena and . . . explain general background information that [is] either not contained in the documents or [is] not self-evident from the documents." Trans Union's Response to Motion To Quash at 7. Experian acknowledges that "negotiations ha[ve] broken down due to an impass on [the] single issue . . . whether Experian voluntarily would produce a witness to testify regarding the documents requested in the Subpoena." Motion To Quash at 2.

The motion to quash takes the position that "an unrestrained oral deposition would endanger Experian's confidential business strategies and proprietary trade secrets. . . ." Motion To Quash at 2-3. For the most part, however, Experian's motion appears to be an effort to argue to the Administrative Law Judge issues that were largely resolved in negotiations with Trans Union over the scope of the subpoena. Although Trans Union has offered to meet with the deponent and Experian's counsel before conducting the deposition to discuss the scope of questioning, Experian has declined, arguing that unless Trans Union is willing to accept alternative discovery in the form of a sworn declaration or an oral deposition on written questions, it will not produce the requested representative in response to the subpoena.

The Administrative Law Judge refused to quash the subpoena, ruling that "Trans Union's refusal to accept the alternative discovery offered by Experian is not unreasonable, and its offer of a meeting before a deposition is conducted is acceptable." Order at 3. He also observed that "[s]ince Experian and Trans Union have agreed on the information which will be produced pursuant to the subpoena, there is no need to consider any arguments raised by Experian except that involving the proposed deposition." *Id.*

The Commission agrees with the ruling of the Administrative Law Judge on the motion to quash. In addition, the Commission has a strong interest in ensuring the integrity of its adjudicative process. In his certification, the Administrative Law Judge concludes that "[t]he information sought by Trans Union is relevant and Experian's refusal to comply with my order justifies Trans Union's request for court enforcement of the subpoena." *Id.* at 1. The Commissionn agrees that enforcement of the subpoena is warranted. The Commission notes, however, that by producing its representative in response to the subpoena, Experian, of course, would not waive its right to limit the information provided in response to questions proffered on grounds of privilege, or to request the Administrative Law Judge to issue an appropriate protective order limiting access to the information provided. Accordingly,

It is ordered, That the General Counsel be, and he hereby is directed promptly to take appropriate action to enforce Trans Union's subpoena to Experian.

IN THE MATTER OF

CIBA-GEIGY LIMITED, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3725. Complaint, March 24, 1997--Decision, March 24, 1997

This consent order requires, among other things, the licensing of specified gene therapy technology and patent rights to Rhone-Poulene Rorer, Inc., to put Rhone-Poulene in a position to compete against the combined firm. The consent order also requires divestiture of the Sandoz U.S. and Canadian corn herbicide assets to BASF and its flea control business to Central Garden & Pet Company or another Commission-approved buyer.

Appearances

For the Commission: *William Baer, Howard Morse* and *Morris Bloom.*

For the respondents: *Kenneth Prince, Shearman & Sterling,* New York, N.Y. and *Michael Malina, Kaye, Scholer, Fierman, Hays & Handler,* New York, N.Y.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and of the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (the "Commission"), having reason to believe that respondents Ciba-Geigy Ltd., a corporation including its wholly-owned subsidiary, Ciba-Geigy Corporation, (collectively, "Ciba"), and Sandoz Ltd., a corporation, including its wholly-owned subsidiary, Sandoz Corporation, (collectively, "Sandoz"), corporations subject to the jurisdiction of the Commission, have agreed to merge into Novartis Ltd. ("Novartis"), a corporation, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. RESPONDENTS

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

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

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

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

5. Respondent Chiron Corporation ("Chiron") is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware with its office and principal place of business located at 4560 Horton Street, Emeryville, California. Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder of Chiron, holding, not solely for investment, approximately 46.5% of the Chiron capital stock as of September 30, 1996. Chiron is engaged

in the discovery, development, manufacture and sale of proprietary and generic pharmaceutical products, including gene therapy products. Ciba has agreed to fund research at Chiron and guarantee its debt, and has the right to appoint members of its board of directors and to veto specified actions of the company.

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

II. JURISDICTION

7. Ciba, Sandoz, Chiron, and Novartis are, and at all times relevant herein have been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and are corporations whose businesses are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

III. THE PROPOSED MERGER

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

IV. THE RELEVANT MARKETS

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

(a) Herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer;

(b) HSV-tk gene therapy for the treatment of graft versus host disease;

(c) Gene therapy for the treatment of hemophilia; and
(d) Chemoresistance gene therapy.

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

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

11. Another relevant line of commerce in which to analyze the effects of the proposed merger is the research, development, manufacture and sale of corn herbicide. Corn herbicides are chemical products designed to kill or control weeds that interfere with corn production. Separate markets for corn herbicides are distinguished by the types of weeds, *i.e.*, broadleaf or grass, against which the herbicide is economically effective and the stage of growth of the corn crop or weed, *i.e.*, pre-emergent or post emergent, at which the

herbicide is both safe for use on the corn crop and economically effective against the weeds to be controlled. Corn herbicides are essential to economic production of corn. There are no economic substitutes for corn herbicide for pre-emergent control of grasses or for corn herbicides for post emergent control of broadleaf weeds.

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

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

V. STRUCTURE OF THE MARKETS

Gene Therapy

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

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

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

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

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

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

Corn Herbicides

20. The market for corn herbicide, and the relevant markets included therein, herbicide for pre-emergent control of grasses and herbicide for post-emergent control of broadleaf weeds, are each

highly concentrated, as measured by the Herfindahl-Hirschmann Index ("HHI") and other measures of concentration. Ciba is the leading developer, manufacturer and seller of corn herbicide in the United States with a share of over 35 percent of sales and over 40 percent of treated acres. Sandoz has approximately a 10 percent share by either measure. United States sales of corn herbicide totaled $1.4 billion in 1995. The proposed merger would increase concentration, as measured by the HHI, by approximately 700 points for dollar sales, and by approximately 1000 points for treated acres, to approximately 3000 for sales and approximately 3300 for treated acres.

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

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

23. Prior to the merger described in paragraph eight, Ciba and Sandoz each cooperated and coordinated with other producers of corn herbicide through supply agreements for corn herbicide active ingredients and through joint development and promotion of corn herbicide formulations. Ciba is the dominant supplier of atrazine, a

broadleaf weed control product that is widely used as a component in premixed herbicide formulations, including Marksman®, Guardsman® and Bicep®, as well as in pre-emergent and post-emergent herbicides sold by competitors of Ciba and Sandoz. Supply agreements, joint product development agreements, and joint marketing agreements among producers of corn herbicides increase coordinated interaction and the recognition of mutual interdependence among competitors in each of the relevant markets for corn herbicide.

Flea Control Products

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

VI. ENTRY CONDITIONS

25. Entry into the relevant markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract anticompetitive effects of the merger. Regulations by the Food and Drug Administration ("FDA") covering gene therapy products and systemic flea control products and by the Environmental Protection Agency ("EPA") covering corn herbicides and externally applied flea control products create long lead times for the introduction of new products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry.

Gene Therapy

26. Entry into the gene therapy markets requires lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the FDA. Entry into each gene therapy market can extend up to and beyond 10 to 12 years. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. The FDA must approve all phases of gene therapy development, including extensive preclinical and clinical work. No company may reach advanced stages of development in the relevant gene therapy markets without: (1) clinical gene therapy expertise; (2) scientific research that requires years to complete; (3) patent rights to all the necessary proprietary inputs into the gene therapy product sufficient to provide the company with reasonable assurances of freedom to operate; and (4) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs include genes, vectors and vector manufacturing technology, and cytokines, proteins necessary for many gene therapy applications.

Corn Herbicides

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

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

customer acceptance through demonstrated safety, performance and reliability, over a variety of weather conditions.

Flea Control Products

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

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

VII. EFFECTS OF THE PROPOSED MERGER

31. The effects of the merger, if consummated, may be substantially to lessen competition or tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45. Specifically the merger will:

a. Eliminate Ciba and Sandoz as substantial, independent competitors; eliminate actual, direct, and substantial competition between Ciba and Sandoz, including the reduction in, delay of or redirection of research and development projects; and increase the level of concentration in the relevant markets;

b. Eliminate actual potential and perceived potential competition in the relevant markets;

c. Increase barriers to entry into the relevant markets;

Gene Therapy

d. Combine alternative technologies, and reduce innovation competition among researchers and developers of gene therapy products, including reduction in, delay of or redirection of research and development tracks;

e. Increase the merged firm's ability to exercise market power, either unilaterally or through coordinated interaction with Chiron, in the gene therapy markets, because the merged firm will have both complete ownership of the Sandoz gene therapy research and development and a 46.5% stock ownership interest in Chiron, the only other firm in a position to commercialize work in gene therapy;

f. Heighten barriers to entry by combining portfolios of patents and patent applications of uncertain breadth and validity, requiring potential entrants to invent around or declare invalid a greater array of patents;

g. Create a disincentive in the merged firm to license intellectual property rights to or collaborate with other companies as compared to premerger incentives;

Corn Herbicides

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

i. Increase the merged firm's ability unilaterally to exercise market power in the market for corn herbicide for post-emergent control of broadleaf weeds, by combining the two closest substitutes in the market;

j. Increase the likelihood and degree of coordinated interaction between or among competitors in the market for corn herbicide for pre-emergent control of grasses;

Flea Control Products

k. Increase the merged firm's ability unilaterally to exercise market power in the flea control products market by combining the two closest substitutes in the market;

l. Increase the likelihood and degree of coordinated interaction between or among competitors in the flea control products market; and

m. Eliminate the potential for actual, direct and substantial price competition and cause consumers to pay higher prices for flea control products, as well as reduce innovation competition among producers of flea control products by eliminating, delaying or redirecting the introduction of new products under development.

VIII. VIOLATIONS CHARGED

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

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

DECISION AND ORDER

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 Section 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.

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.

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.

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.

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 Section 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 Section 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.

APPENDIX I

AGREEMENT TO HOLD SEPARATE

This Agreement to Hold Separate ("Hold Separate") is by and between Sandoz Ltd. ("Sandoz"), a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland, with its office and principal place of business at Lichtstrasse 35, Basel, Switzerland, 4002; Ciba-Geigy Limited ("Ciba"), a corporation, organized, existing, and doing business under and by virtue of the laws of Switzerland with its principal place of business located at Klybeckstrasse 141, Basel, Switzerland 4002; and the

Federal Trade Commission (the "Commission"), an independent agency of the United States Government, established under the Federal Trade Commission Act of 1914, 15 U.S.C. 41, *et seq.* (collectively, the "Parties").

PREMISES

Whereas, on March 6, 1996, Ciba and Sandoz entered into an Agreement providing for the merger (hereinafter the "Merger") of Ciba and Sandoz into Novartis AG ("Novartis"); and

Whereas, Sandoz, through its subsidiary Sandoz Agro, Inc., operates, *inter alia,* (a) an agricultural chemical business as defined in an Agreement Containing Consent Order ("the "consent order"); and (b) an animal health business as defined in the consent order; and

Whereas, Ciba, through its subsidiary Ciba-Geigy Corporation, operates *inter alia,* (a) an agricultural chemical business, and (b) an animal health business; and

Whereas, the Commission is now investigating the Merger to determine whether it would violate any of the statutes enforced by the Commission; and

Whereas, if the Commission accepts the consent order, which would require the divestiture of certain assets, the Commission must place the consent order on the public record for a period of at least sixty (60) days and may subsequently withdraw such acceptance pursuant to the provisions of Section 2.34 of the Commission's Rules; and

Whereas, the Commission is concerned that if an understanding is not reached, preserving the *status quo ante* of the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business as defined in paragraph I of the consent order during the period prior to the final acceptance and issuance of the consent order by the Commission (after the 60-day public comment period), divestiture resulting from any proceeding challenging the legality of the Merger might not be possible, or might be less than an effective remedy; and

Whereas, the Commission is concerned that if the Merger is consummated, it will be necessary to preserve the Commission's ability to require the divestiture of the Sandoz Agricultural Chemical Business, as described in paragraph I.BB of the consent order, and the Sandoz Animal Health Business, as described in paragraph I.CC of the consent order, and the Commission's right to have the Sandoz

Agricultural Chemical Business and the Sandoz Animal Health Business continue as viable competitors independent of Ciba, Sandoz and Novartis; and

Whereas, even if the Commission determines to finally accept the consent order, it is necessary to hold separate the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business to protect interim competition pending divestiture or other relief; and

Whereas, the purpose of the Hold Separate and the consent order is:

1. To preserve the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business as viable and competitive, independent businesses pending the divestitures required by the consent order;

2. To remedy any anticompetitive effects of the Merger; and

3. To preserve the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business as ongoing and competitive entities engaged in the same businesses in which they are presently employed until divestiture is achieved; and

Whereas, Sandoz and Ciba's entering into this Hold Separate shall in no way be construed as an admission by Sandoz or Ciba that the Merger is illegal; and

Whereas, Sandoz and Ciba understand that no act or transaction contemplated by this Hold Separate shall be deemed immune or exempt from the provisions of the antitrust laws or the Federal Trade Commission Act by reason of anything contained in this Hold Separate.

Now, therefore, the respondents, upon understanding that the Commission has not yet determined whether the Merger will be challenged, and in consideration of the Commission's agreement at the time it accepts the consent order for public comment that, unless the Commission determines to reject the consent order, the Commission will not seek a temporary restraining order, preliminary injunction, or permanent injunction to prevent consummation of the Merger, and will grant early termination of the Hart-Scott-Rodino waiting period, the Parties agree as follows:

1. Ciba and Sandoz agree that from the date this Hold Separate is signed by Sandoz and Ciba until the earliest of the dates listed in

paragraphs 1.a or 1.b they each will comply with the provisions of this Hold Separate:

a. Twenty (20) days after the Commission withdraws its acceptance of the consent order pursuant to the provisions of Section 2.34 of the Commission's Rules; or

b. The day after each of the divestitures required by the consent order has been completed.

2. Ciba and Sandoz agree to execute and be bound by the attached consent order and to comply, from the date this Hold Separate is accepted, with the provisions of the consent order as if it were final.

3. The terms capitalized herein shall have the same definitions as in the consent order.

4. To ensure the complete independence and viability of the properties to be divested and to ensure that no competitive information is exchanged between the properties to be divested and Sandoz, Ciba or Novartis, Sandoz and Novartis shall hold the properties to be divested as they are presently constituted separate and apart on the following conditions:

a. The held separate businesses shall be held separate and apart and shall be operated independently of Ciba, Sandoz and Novartis (meaning here and hereinafter, Ciba, Sandoz and Novartis excluding the properties to be divested and excluding all personnel connected with the properties to be divested as of the date this Hold Separate was signed) except to the extent that Ciba, Sandoz or Novartis must exercise direction and control over the held separate businesses to assure compliance with this Hold Separate or the consent order.

b. The properties to be divested shall be staffed with sufficient employees to maintain the viability and competitiveness of the properties to be divested. Neither Sandoz, Ciba nor Novartis shall employ, or make offers of employment to, any person employed by Sandoz in connection with the properties to be divested or whose principal duties, during the year prior to the date of the signing of this Hold Separate, related to the management, operation, research, development, regulatory registration, sales or marketing activities of the properties to be divested. Sandoz, Ciba and Novartis shall encourage and facilitate employment by the properties to be divested of Sandoz employees who had line responsibility with respect to the properties to be divested in the year prior to the signing of this Hold

Separate; shall not offer any incentive to such employees to decline employment with the properties to be divested or accept other employment in Sandoz, Ciba or Novartis; and shall remove any impediments that may deter such employees from accepting employment with the properties to be divested, including but not limited to, the payment, or transfer for the account of the employee, of all accrued bonuses, pensions and other accrued benefits to which such employees would otherwise have been entitled had they remained in the employment of Sandoz.

c. Ciba, Sandoz or Novartis personnel connected with the properties to be divested or providing support services to the properties to be divested as of the date of this Hold Separate was signed, may continue, as employees of Sandoz or Novartis, to provide such services as they are currently providing to the held separate businesses. Such Sandoz or Novartis personnel must retain and maintain all material confidential information relating to the held separate businesses on a confidential basis and, except as is permitted by this Hold Separate, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any Sandoz or Novartis business.

d. Sandoz, Ciba and Novartis shall not exercise direction or control over, or influence directly or indirectly, the properties to be divested, the Management Committee (as defined in subparagraph 4.f), or any of its operations or businesses; provided, however, that Ciba, Sandoz and Novartis may exercise only such direction and control over the properties to be divested as is necessary to assure compliance with this Hold Separate or with the consent order.

e. Ciba, Sandoz and Novartis shall maintain the marketability, viability and competitiveness of the properties to be divested and shall not take any action that may cause or permit the destruction, removal, wasting, deterioration or impairment of the properties to be divested, except for ordinary wear and tear, and shall not sell, transfer, encumber (other than in the normal course of business), or otherwise impair the marketability, viability or competitiveness of the properties to be divested. Sandoz shall provide the properties to be divested with sufficient working capital to operate at current rates of operation, including but not limited to, current levels of research and development activities, to perform all necessary routine maintenance to, and replacement of, plant and equipment of the properties to be

divested, and to maintain the viability and competitiveness of the properties to be divested.

f. Sandoz shall appoint a three-person Management Committee for the properties to be divested (the "Management Committee"), one of whom shall be named chairman of the Management Committee. The Management Committee shall consist of persons who are, and shall remain, independent of Sandoz, Ciba and Novartis and competent to assure the continued viability and competitiveness of the properties to be divested. Sandoz shall not permit any director, officer, employee or agent of Ciba, Sandoz or Novartis also to be a director, officer, employee or agent of the properties to be divested. Each Management Committee member shall enter into a confidentiality agreement agreeing to be bound by the terms and conditions of this Hold Separate.

g. Except as required by law and except to the extent that necessary information is exchanged in the course of evaluating and consummating the Merger, defending investigations or litigation, obtaining legal advice, or complying with this Hold Separate or the consent order (including accomplishing the divestitures), neither Sandoz, Ciba nor Novartis shall receive or have access to, or the use of, any material confidential information of the properties to be divested or the activities of the Management Committee, not in the public domain. Sandoz may receive on a regular basis from the properties to be divested aggregate financial reports, tax returns and personnel reports. Any such information that is obtained pursuant to this subparagraph shall only be used for the purposes set out in this subparagraph. ("Material confidential information," as used in this Hold Separate, means competitively sensitive or proprietary information not independently known to Ciba, Sandoz or Novartis from sources other than the properties to be divested or the Management Committee, as applicable, and includes but is not limited to customer lists, customers, price lists, prices, individual transactions, marketing methods, patents, technologies, processes, or other trade secrets).

h. All material transactions, out of the ordinary course of business and not precluded by paragraph four hereof, shall be subject to a majority vote of the Management Committee (as defined in paragraph 4.f hereof).

i. Sandoz shall not change the composition of the Management Committee unless it is necessary to do so in order to assure

compliance with this Hold Separate or with the consent order. The Chairman of the Management Committee shall have the power to remove members of the Management Committee for cause and to appoint replacement members of the Management Committee. Sandoz shall not change the composition of the management of the properties to be divested except that the Management Committee shall have the power to remove management employees for cause. If the Chairman ceases to act or fails to act diligently, a substitute Chairman shall be appointed in the same manner as provided in paragraph 4.f. The Management Committee shall circulate to the management employees of the properties to be divested and appropriately display a notice of this Hold Separate and the consent order at a conspicuous place at all offices and facilities of the properties to be divested.

j. All earnings and profits of the properties to be divested shall be retained separately in the properties to be divested.

k. Subject to the direction of the Management Committee, Sandoz and Novartis shall cause the properties to be divested to continue to expend funds for the advertising and trade promotion of such businesses at levels not lower than those budgeted for 1995 and 1996, and shall increase such spending as deemed reasonably necessary in light of competitive conditions. If necessary, Sandoz and Novartis shall provide the held separate businesses with funds necessary to accomplish the foregoing. Sandoz and Novartis shall continue to provide to the properties to be divested such support services as is reasonably necessary and was provided prior to the merger by Sandoz.

5. Should the Federal Trade Commission seek in any proceeding to compel dissolution of Novartis, to compel Sandoz or Novartis to divest any assets or businesses of Ciba that they may hold, to compel Ciba or Novartis to divest any assets of businesses of Sandoz that they may hold, or to seek any other injunctive or equitable relief, neither Sandoz nor Ciba shall raise any objection based upon the expiration of the applicable Hart-Scott-Rodino Antitrust Improvements Act waiting period or the fact that the Commission has permitted the Merger. Sandoz and Ciba also waive all rights to contest the validity of this Hold Separate.

6. Within twenty-one (21) days after the date this Hold Separate is signed by respondents and every thirty (30) days thereafter,

respondents shall each submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Hold Separate and the consent 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 the terms of the consent order, including a description of all contacts and negotiations for the divestirure and the identity of all parties contacted. 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 the divestitures.

7. For the purpose of determining or securing compliance with this Hold Separate, subject to any legally recognized privilege, and upon written request and five day's notice, Sandoz and Ciba shall permit any duly authorized representative(s) of the Commission:

a. Access during the office hours of Sandoz or Ciba 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 Sandoz, Ciba or Sandoz Agro relating to compliance with this Hold Separate;

b. Without restraint or interference from respondents, to interview Sandoz or Ciba officers, directors or employees, or employees of the properties to be divested, who may have counsel present, regarding any such matters.

8. This Hold Separate shall not be binding until approved by the Commission.

ATTACHMENT A

NOTICE OF DIVESTITURE AND
REQUIREMENT FOR CONFIDENTIALITY

Ciba-Geigy Limited ("Ciba") and Sandoz Ltd. ("Sandoz") have entered into a Agreement Containing Consent Order and Agreement to Hold Separate with the Federal Trade Commission ("Commission") relating to the divestiture of certain Sandoz businesses. Until after the Commission's order becomes final and those businesses are divested, the Sandoz Agricultural Chemical

Business and the Sandoz Animal Health Business must be managed and maintained as separate, ongoing businesses, independent of all other Ciba, Sandoz and Novartis businesses. All competitive information relating to the held separate businesses, must be retained and maintained by the persons involved in these businesses on a confidential basis and such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any other Ciba, Sandoz or Novartis business. Similarly, all such persons involved in the Ciba, Sandoz or Novartis business. Similarly, all such persons involved in the Ciba, Sandoz or Novartis Agricultural Chemical and Animal Health Business shall be prohibited from providing, discussing, exchanging, circulating or otherwise furnishing competitive information about such business to or with any person whose employment involves the held separate businesses.

Any violation of the Consent Order or the Agreement to Hold Separate, incorporated by reference as part of the Consent Order, may subject Ciba, Sandoz and Novartis to civil penalties and other relief as provided by law.

SEPARATE STATEMENT OF CHAIRMAN ROBERT PITOFSKY AND COMMISSIONERS JANET D. STEIGER, ROSCOE B. STAREK, III AND CHRISTINE A. VARNEY

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

[1] Complaint ¶ 9.

[2] *Id.* ¶ 10.

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.

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]

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[3] *Id.* ¶ 26.

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

[5] *See* Statement of Commissioner Azcuenaga at 1.

[6] Analysis to Aid Public Comment at 7.

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 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.

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[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.

[9] Statement of Commissioner Azcuenaga at 3.

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 merger created a disincentive for Novartis to license

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[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.

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.

STATEMENT OF COMMISSIONER MARY L. AZCUENAGA, CONCURRING IN PART AND DISSENTING IN PART

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.

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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 that the 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.

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 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

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[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.

[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.*

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 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

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[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 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).

"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 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

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[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.

[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.

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 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.

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[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).

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 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.

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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 FTC 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.").

[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).

IN THE MATTER OF

BAXTER INTERNATIONAL INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3726. Complaint, March 24, 1997--Decision, March 24, 1997

This consent order requires, among other things, Baxter International ("Baxter"), an Illinois-based corporation, to divest its Autoplex product to a Commission-approved buyer, and to license Immuno International AG's ("Immuno") product in development to a Commission-approved licensee within four months of the date Baxter signs the consent. This would resolve antitrust concerns raised by the $463 million acquisition of Immuno by Baxter, which both manufacture a wide variety of biologic products derived from human blood plasma.

Appearances

For the Commission: *Pamela Taylor* and *George Cary*.

For the respondent: *Michael Sennett, Bell, Boyd & Lloyd,* Chicago, IL.

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondent, Baxter International Inc. ("Baxter"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire the majority of the outstanding voting stock of Immuno International AG ("Immuno"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. 45, and that such an acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18 and Section 5 of the FTC Act, as amended, 15 U.S.C. 45; and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent Baxter is a corporation organized, existing, and doing business under and by virtue of the laws of the state of

Delaware, with its principal place of business located at One Baxter Parkway, Deerfield, Illinois.

2. Respondent is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

II. THE ACQUIRED COMPANY

3. Immuno is a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland, with its principal place of business located at Zollikerstrasse 60, CH-8702, Zollikon, Switzerland.

4. Immuno is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

III. THE ACQUISITION

5. On or about August 28, 1996, Baxter entered into a Stock Purchase Agreement with Pharminvest Ltd., Albenga Holding en Handelmaatschappij V.V. and Bio-Products and Bio-Engineering SA to purchase the majority of the voting stock of Immuno for approximately $462.8 million ("Acquisition").

IV. THE RELEVANT MARKETS

6. For purposes of this complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are:

a. The research, development, manufacture and sale of Factor VIII Inhibitor Treatments approved by the United States Food and Drug Administration ("FDA") for sale in the United States; and

b. The research, development, manufacture and sale of Fibrin Sealant to be approved by the FDA for sale in the United States.

7. For purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

V. STRUCTURE OF THE MARKET

8. The market for the research, development, manufacture and sale of Factor VIII Inhibitor Treatments is highly concentrated as measured by the Herfindahl-Hirschmann Index ("HHI"). Baxter and Immuno are the only two suppliers of Factor VIII Inhibitor Treatments in the United States.

9. Baxter and Immuno are actual competitors in the relevant market for the research, development, manufacture and sale of Factor VIII Inhibitor Treatments.

10. The market for the research, development, manufacture and sale of Fibrin Sealant is highly concentrated as measured by the HHI. Baxter and Immuno are two of only a small number of companies seeking FDA approval to market Fibrin Sealant in the United States.

11. Baxter and Immuno are actual competitors in the relevant market for the research, development, manufacture and sale of Fibrin Sealant in the United States.

VI. BARRIERS TO ENTRY

12. Entry into the research, development, manufacture and sale of Factor VIII Inhibitor Treatments is difficult and time consuming, requiring the expenditure of significant resources over a period of many years with no assurance that a viable commercial product will result. The existence of broad patents governing the formulations and the manufacture of such products make new entry both difficult and unlikely.

13. Entry into the research, development, manufacture and sale of Fibrin Sealant is difficult and time consuming, requiring the expenditure of significant resources over a period of many years with no assurance that a viable commercial Fibrin Sealant will result. The existence of broad patents governing the formulations and the manufacture of such products make new entry both difficult and unlikely.

VII. EFFECTS OF THE ACQUISITION

14. The effects of the Acquisition may be substantially to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C.

18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45, in the following ways, among others:

a. By eliminating direct actual competition between Baxter and Immuno in the relevant markets;

b. By increasing the likelihood that Baxter will unilaterally exercise market power in the relevant markets; and

c. By creating a dominant firm in the relevant markets.

VIII. VIOLATIONS CHARGED

15. The Acquisition described in paragraph five constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

16. The Acquisition described in paragraph five, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

Commissioner Starek recused.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of the proposed acquisition by respondent of Immuno International AG, and the respondent 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 respondent 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true 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 the respondent has violated the said Acts, and that a complaint should issue stating