

IN THE MATTER OF

ROCHE HOLDING LTD., 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-3315. Complaint, Nov. 28, 1990—Decision, Nov. 28, 1990

This consent order requires, among other things, Roche Holding, Ltd., a Swiss pharmaceutical company, and related American corporations to divest either Genentech's interest in GLC Associates, a partnership between Genentech and Lubrizol, Inc., or GLC's vitamin C assets. Roche also is required to divest its human growth hormone releasing factor business. Both divestitures are to be effected to Commission-approved acquirers within one year after the effective date of the order; otherwise the Commission may appoint a trustee to make the divestitures.

Appearances

For the Commission: *M. Howard Morse* and *Steven A. Newborn*.

For the respondents: *Bertram M. Kantor, Wachtell, Lipton, Rosen & Katz*, New York, N.Y. and *Arthur F. Golden, Davis Polk & Wardwell*, New York, N.Y.

COMPLAINT

The Federal Trade Commission, having reason to believe that respondents, Roche Holding Ltd., Roche Holdings, Inc., and Hoffman-La Roche Inc. (collectively "Roche"), all subject to the jurisdiction of the Federal Trade Commission, propose to acquire voting securities of Genentech, Inc. ("Genentech"), also subject to the jurisdiction of the Federal Trade Commission, 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 ("FTC Act"), as amended, 15 U.S.C. 45; and it appearing that a proceeding in respect thereof would be in the public interest, the Commission hereby issues its complaint, pursuant to Section 11 of the Clayton Act, 15 U.S.C. 21, and Section (5b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), stating its charges as follows:

I. RESPONDENTS

1. Respondent Roche Holding Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland with its principal executive offices located at Grenzacherstrasse 124, Basle, Switzerland 4002.

2. Respondent Roche Holdings, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of Delaware with its principal executive offices located at 345 Route 17 South, Upper Saddle River, New Jersey.

3. Respondent Hoffman-La Roche Inc. is a corporation organized, existing and doing business under and by virtue of the laws of New Jersey with its principal executive offices located at 340 Kingsland Street, Nutley, New Jersey.

4. Respondent Genentech, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its principal executive offices located at 460 Point San Bruno Boulevard, South San Francisco, California.

II. JURISDICTION

5. Respondents at all times herein have been and now are 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 business or practices are in or affecting commerce as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. 44.

III. THE PROPOSED ACQUISITION

6. On or about February 2, 1990, Roche entered into an Agreement and Plan of Merger with Genentech which contemplates the acquisition by Roche of a controlling interest in Genentech.

IV. THE RELEVANT MARKETS

7. The relevant product markets in which to analyze the proposed acquisition of Genentech are the research, development, production and marketing of: (1) vitamin C, (2) therapeutics for treatment of human growth hormone deficiency or other short stature deficiency, including human growth hormone and human growth hormone releasing factor, and (3) CD4-based therapeutics for the treatment of AIDS and HIV infection.

8. The relevant geographic market is the United States for all

products, except for vitamin C, for which the relevant geographic market is the world.

V. THE MARKET STRUCTURE

9. The vitamin C market, in both the United States and worldwide, is highly concentrated as measured by the Herfindahl-Hirschmann Index ("HHI") or by the four-firm and eight-firm concentration ratios. Roche is the market leader with a dominant market share. Genentech has developed a new patented process for producing vitamin C using recombinant DNA technology.

10. The production and marketing of therapeutics for treatment of human growth hormone deficiency or other short stature deficiency in the United States is highly concentrated as measured by the HHI or concentration ratios. Genentech has a near-monopoly share of the market, is protected by the Orphan Drug Act, and has sued its only human growth hormone competitor for patent infringement. Roche has conducted advanced clinical trials with a product which would compete with human growth hormone, human growth hormone releasing factor, and has developed and patented human growth hormone releasing factor analogs.

11. Genentech is the most advanced of a limited number of companies developing CD4-based therapeutics for use in the treatment of AIDS/HIV infection. Roche has also engaged in research and development of CD4-based therapeutics and has patent applications pending on its products.

VI. BARRIERS TO ENTRY

12. Entry into each of the relevant markets is difficult and time consuming. FDA regulations create long lead times for the introduction of new drugs; patents create large and often insurmountable barriers to entry.

VII. EFFECTS

13. The effect of the proposed acquisition may be to substantially lessen competition in the relevant markets described above in violation of Section 7 of the Clayton Act, 15 U.S.C. 18, and Section 5 of the FTC Act, 15 U.S.C. 45, by, among other things:

- a. Eliminating actual competition in the relevant markets;
- b. Eliminating potential competition in the relevant markets;

- c. Enhancing the likelihood of collusion or interdependent coordination between or among the firms in the relevant market;
- d. Eliminating respondents as potential entrants and thus preventing a decrease in concentration in the relevant markets; and
- e. Enhancing dominant firm patent protection and raising rivals' costs.

VIII. VIOLATIONS CHARGED

14. The acquisition as set forth in paragraph 6 herein, if consummated, violates Section 7 of the Clayton Act, as amended, 15 U.S.C. 18 and Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

15. The Agreement and Plan of Merger described in paragraph 6 herein violates Section 7 of the Clayton Act, as amended, 15 U.S.C. 18 and Section 5 of the FTC Act, as amended, 15 U.S.C. 45

Commissioner Owen dissenting. Commissioner Starek did not participate.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission would charge respondents with violation of Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission 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 a 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 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 Genentech, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its principal executive offices located at 460 Point San Bruno Boulevard, South San Francisco, CA.

2. Respondent Roche Holding Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland with its principal executive offices located at Grenzacherstrasse 124, Basle, Switzerland 4002.

3. Respondent Roche Holdings, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware with its principal executive offices located at 345 Route 17 South, Upper Saddle River, New Jersey.

4. Respondent Hoffmann-La Roche Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the state of New Jersey with its principal executive offices located at 340 Kingsland Street, Nutley, New Jersey.

5. 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. DEFINITIONS

As used in this order, the following definitions shall apply:

a. "*Genentech*" means Genentech, Inc., a Delaware corporation, its directors, officers, employees, agents and representatives, its predecessors, successors, subsidiaries, divisions, groups and any other corporations, partnerships, joint ventures, companies, and affiliates that Genentech controls, directly or indirectly, and their respective directors, officers, employees, agents and representatives, and their respective successors and assigns.

b. "*Roche*" means Roche Holding Ltd., a Swiss corporation, Roche Holdings, Inc., a Delaware corporation, and Hoffman-La Roche Inc., a New Jersey corporation, their directors, officers, employees, agents and representatives, their predecessors, successors, subsidiaries,

divisions, groups and any other corporations, partnerships, joint ventures, companies, and affiliates that Roche controls, directly or indirectly, and their respective directors, officers, employees, agents and representatives, and their respective successors and assigns, but not including Genentech.

c. "*Respondents*" means Genentech and Roche.

d. "*Acquisition*" means Roche's acquisition of any or all voting securities of Genentech pursuant to the Agreement and Plan of Merger between Roche and Genentech dated February 2, 1990.

e. "*Commission*" means the Federal Trade Commission.

f. "*Patents*" means some, all or any portion of all unexpired patents (including inventor's certificates) and patents issued in the future based upon patent applications filed as of the date this order becomes final, and all substitutions, continuations, continuations-in-part, divisions, renewals, reissues and extensions based on said patents, the applications therefor, or said patent applications.

g. "*Corresponding foreign patents*" means patents in a country other than the United States, entitled to the same priority date (or entitled to the same priority date if it had been timely filed) and based upon the same conception and reduction to practice.

h. "*Process patent*" means a patent whose claims are directed to the methods or manipulative steps used for the manufacture of a particular compound, composition of matter or article of manufacture.

i. "*Product patent*" means a patent which claims a particular compound, composition of matter or article of manufacture.

j. "*Products subject to order*" means Vitamin C, Human Growth Factor, and CD4-Based Therapeutics.

k. "*Vitamin C*" means ascorbic acid, however produced, and products produced as intermediates in the production of ascorbic acid, including but not limited to 2-keto-L-gulonic acid (2-KLG), ketogulonic acid (KGA) and L-ascorbic acid.

l. "*GLC*" means GLC Associates, a partnership between Genentech and the Enterprise Genetics, Inc., a Nevada corporation and wholly-owned indirect subsidiary of the Lubrizol Corporation.

m. "*GLC Vitamin C assets*" means all of GLC's assets relating to Vitamin C, wherever located, including all assets, title, properties, interests, rights and privileges, of whatever nature, tangible and intangible, including without limitation, all patents, trade secrets, technology, and know-how, and chemical and biological substances, and all contractual rights, and including, insofar as they relate to

Vitamin C, books and records, including but not limited to scientific reports, manuals, drawings, specifications, and supplier lists, and the rights, insofar as they related to Vitamin C, to any patents or know-how used by Genentech or GLC in conjunction with the research or development of Vitamin C.

n. "*Human Growth Factor*" means any protein, peptide, or analog thereof, whether produced by recombinant DNA technology, chemical synthesis, purification, or other method, used as a therapeutic for treatment of human growth hormone deficiency, or other short stature deficiency, including but not limited to Human Growth Hormone and Human Growth Hormone Releasing Factor.

o. "*Human Growth Hormone*" means the protein produced by the human pituitary gland or synthetic versions thereof (including versions with an extra methionine amino acid), which stimulates growth and metabolism, used as a therapeutic for treatment of human growth hormone deficiency or other short stature deficiency, whether produced by recombinant DNA technology, chemical synthesis, purification, or other method.

p. "*Human Growth Hormone Releasing Factor*" means growth hormone releasing factor, a polypeptide hormone which stimulates the human pituitary gland to release human growth hormone, or an analog thereof, used as a therapeutic for treatment of human growth hormone deficiency or other short stature deficiency, whether produced by recombinant DNA technology, chemical synthesis, purification, or other method.

q. "*Roche's Human Growth Hormone Releasing Factor Business*" means all of Roche's assets, title, properties, interests, rights and privileges, of whatever nature, tangible and intangible, including without limitation all patents, trade secrets, technology, and know-how, and chemical and biological substances, and all contractual rights (including all rights under the September 15, 1983 Licensing Agreement between Roche and the Salk Institute relating to Human Growth Hormone Releasing Factor), and including, insofar as they relate to Human Growth Hormone Releasing Factor, books and records, including but not limited to the results of research and development efforts by Roche, filings with the U.S. Food and Drug Administration, scientific and clinical reports, manuals, drawings, specifications, and supplier lists, and the exclusive rights, insofar as they relate to Human Growth Hormone Releasing Factor, to any patents or know-how used by Roche in conjunction with the research

or development of Human Growth Hormone Releasing Factor or delivery systems for Human Growth Hormone Releasing Factor, and including Roche's Human Growth Hormone Releasing Factor inventory wherever located; provided that, tangible assets used both in the research, development or production of Human Growth Hormone Releasing Factor as well as in the research, development or production of other compounds shall not be considered part of Roche's Human Growth Hormone Releasing Factor Business.

r. "*Roche's Human Growth Hormone Releasing Factor Patent Portfolio*" means all Roche United States Patents and Corresponding Foreign Patents, and all United States Patents and Corresponding Foreign Patents of other persons licensed to Roche for which Roche has the right to grant licenses or sublicenses, which may be infringed by the manufacture, use or sale of Human Growth Hormone Releasing Factor, including but not limited to the patents listed in Exhibit A to this order.

s. "CD4-Based Therapeutic" means a product containing CD4, soluble CD4, truncated soluble CD4, a CD4 fragment, or a CD4 conjugate, CD4 adhesion variant, CD4 hybrid, or CD4 fusion protein, used for the treatment of HIV-infected patients, whether asymptomatic or with ARC or AIDS, including but not limited to soluble CD4, CD4-IgG, CD4-IgG₃, CD4-IgM, CD4-Mu, and CD4-PE.

t. "*Roche's CD4-Based Therapeutics Patent Portfolio*" means all Roche United States Patents, and all United States Patents of other persons licensed to Roche for which Roche has the right to grant licenses or sublicenses, which may be infringed by the manufacture, use or sale of CD4-Based Therapeutics, including but not limited to the patent application listed in Exhibit B to this order.

II. GLC DIVESTITURE

It is ordered, That:

A. Respondents shall, within twelve (12) months after the date this order becomes final, divest, absolutely and in good faith, either Genentech's interest in GLC or the GLC Vitamin C Assets.

B. Respondents shall divest Genentech's interest in GLC or the GLC Vitamin C Assets only to an acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission. The purpose of this divestiture is to ensure the continuation of GLC or the GLC Vitamin C Assets as an ongoing enterprise engaged in the same business in which GLC is

presently employed and to remedy the lessening of competition resulting from the Acquisition alleged in the Commission's complaint.

C. Respondents shall take such action as is necessary to maintain the viability and marketability of GLC, and to prevent the destruction, removal or impairment of any assets subject to divestiture pursuant to this paragraph II except in the ordinary course of business and except for ordinary wear and tear.

D. Within thirty (30) days after the consummation of the divestiture required by this paragraph II, Genentech will commence teaching a reasonable number of persons designated by the acquirer how to produce Vitamin C using the GLC technology, if requested by the acquirer. Training sessions shall be conducted at the acquirer's facilities or at such other place as is mutually satisfactory to Genentech and the acquirer and shall continue for a period of time sufficient to satisfy the management of the acquirer that its personnel are well enough trained to produce Vitamin C as well as Genentech, *provided however*, that in no event shall Genentech be required to continue the training program for a period of more than one year. The acquirer will pay Genentech its expenses incurred in conducting such training sessions including salaries of its employees and travel and lodging costs.

III. GRF DIVESTITURE

It is ordered, That:

A. Roche shall, within twelve (12) months after the date this order becomes final, divest, absolutely and in good faith, Roche's Human Growth Hormone Releasing Factor Business.

B. The divestiture required by this order shall be made only to an acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission. The purpose of this divestiture is to ensure the continuation of Roche's Human Growth Hormone Releasing Factor Business as an ongoing enterprise engaged in the same business in which it is presently employed and to remedy the lessening of competition resulting from the Acquisition alleged in the Commission's complaint.

C. Roche shall take such action as is necessary to maintain the viability and marketability of Roche's Human Growth Hormone Releasing Factor Business, and to prevent the destruction, removal or impairment of any assets subject to divestiture pursuant to this paragraph III except in the ordinary course of business and except for

ordinary wear and tear. Pending the divestiture pursuant to this paragraph III, Roche shall not divulge to Genentech or use for Genentech's benefit any "material confidential information" relating to Roche's Human Growth Hormone Releasing Factor Business not in the public domain, except as such information would be available to Genentech in the normal course of business if the Acquisition had not taken place. ("*Material confidential information*," as used herein, means competitively sensitive or proprietary information not independently known to Genentech from sources other than Roche, and includes but is not limited to patents, technologies, processes, or other trade secrets).

D. Within thirty (30) days after the consummation of the divestiture required by this paragraph III, Roche will commence teaching a reasonable number of persons designated by the acquirer how to produce Human Growth Hormone Releasing Factor, if requested by the acquirer. Training sessions shall be conducted at the acquirer's facilities or at such other place as is mutually satisfactory to Roche and the acquirer and shall continue for a period of time sufficient to satisfy the management of the acquirer that its personnel are well enough trained to produce Human Growth Hormone Releasing Factor as well as Roche, *provided however*, that in no event shall Roche be required to continue the training program for a period of more than one year. The acquirer will pay Roche its expenses incurred in conducting such training sessions including salaries of its employees and travel and lodging costs.

IV. TRUSTEE DIVESTITURE

It is further ordered, That:

A. If respondents have not divested, absolutely and in good faith and with the Commission's approval, Genentech's interest in GLC or the GLC Vitamin C Assets as required by paragraph II within the twelve-month period provided for in paragraph II, respondents shall consent to the appointment of a trustee by the Commission to divest Genentech's interest in GLC or the GLC Vitamin C Assets. If respondents have not divested, absolutely and in good faith and with the Commission's approval, Roche's Human Growth Hormone Releasing Factor Business as required by paragraph III within the twelve-month period provided for in paragraph III, respondents shall consent to the appointment of a trustee by the Commission to divest Roche's Human Growth Hormone Releasing Factor Business. 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, for any violation of this order, respondents shall consent to the appointment of one or more trustees in such action. Neither the appointment of a trustee nor a decision not to appoint 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, or any other statute enforced by the Commission, for any failure by respondents to comply with this order.

B. If a trustee is appointed by the Commission or a court pursuant to paragraph IV of this order, the following terms and conditions shall apply:

(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.

(2) The trustee shall have the exclusive power and authority, subject to the prior approval of the Commission, to accomplish the divestitures required by paragraph II and paragraph III of this order. The trustee shall have twelve (12) months from the date of appointment to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of such twelve-month period the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or by the court for a court-appointed trustee; *provided, however*, that the Commission or court may only extend the divestiture period two (2) times.

(3) The trustee shall have full and complete access to the personnel, books, records, and facilities relating to Genentech's interest in GLC, and GLC Vitamin C Assets, Roche's Human Growth Hormone Releasing Factor Business, and any other relevant information as the trustee may reasonably request. Respondents shall develop such financial or other information as the trustee may reasonably request and shall cooperate with any reasonable request of 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 the respondents shall extend the time for divestiture under

this paragraph IV in an amount equal to the delay, as determined by the Commission, or the court for a court-appointed trustee.

(4) The trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to respondents' absolute and unconditional obligation to divest at no minimum price and the purpose of the divestitures as stated in paragraphs II and III of this order and subject to the prior approval of the Commission. If the trustee receives bona fide offers from more than one prospective acquirer, and if the Commission approves more than one such acquirer, the trustee shall divest to the acquirer selected by respondents from among those approved by the Commission.

(5) 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 authority to employ, at the cost and expense of respondents, such consultants, accountants, attorneys or other persons reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and for all expenses incurred. After approval by the Commission and, in the case of a court-approved 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 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 accomplishing the divestiture of Genentech's interest in GLC or the GLC Vitamin C Assets or Roche's Human Growth Hormone Releasing Factor Business.

(6) Within sixty (60) days after appointment of the trustee, and subject to the prior approval of the Commission, and, in the case of a court-appointed trustee, of the court, the respondents shall, consistent with the provisions of this order, execute a trust agreement that transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this order.

(7) Except for cases of misfeasance, negligence, willful or wanton acts, or bad faith by the trustee, the trustee shall not be liable to respondents for any action taken or not taken in the performance of the trusteeship. 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, 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, claims, or expenses result from misfeasance, negligence, willful or wanton acts, or bad faith by the trustee.

(8) If the trustee ceases to act or fails to act diligently, one or more substitute trustees shall be appointed in the same manner as provided in paragraph IV of this order.

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

(10) The trustee shall have no obligation or authority to operate or maintain the GLC Vitamin C Assets or Roche's Human Growth Hormone Releasing Factor Business.

V. LICENSING ALTERNATIVE

It is further ordered, That:

A. If respondents have not divested Roche's Human Growth Hormone Releasing Factor Business as required by paragraph III within the twelve-month period provided for in paragraph III, the Commission, rather than appointing a trustee pursuant to paragraph IV, in its sole discretion, may require that Roche, upon written application made within ten (10) years of the date this order becomes final, grant non-exclusive licenses to produce and sell Human Growth Hormone Releasing Factor under Roche's Human Growth Hormone Releasing Factor Patent Portfolio for the life of all patents in the portfolio, at a royalty not in excess of 1% of net sales (if only Process Patents are licensed) or 3% of net sales (if any Product Patents are licensed) and reasonable and customary terms and conditions, to any and all sole proprietorships, partnerships, corporations or other business entities which state an intention to produce or sell a Human Growth Hormone Releasing Factor in the United States, or research and develop a Human Growth Hormone Releasing Factor for purposes of later producing or selling a Human Growth Hormone Releasing Factor in the United States.

B. Neither the Commission's invocation of its option under this paragraph V, nor its decision not to invoke its option under this paragraph V shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it for any failure by respondents to comply with this order.

VI. CD4 MANDATORY LICENSING

It is further ordered, That Roche shall, upon written application made within ten (10) years of the date this order becomes final, grant non-exclusive licenses to produce and sell CD4-Based Therapeutics under Roche's CD4-Based Therapeutic Patent Portfolio for the life of all patents in the portfolio, at a royalty not in excess of 1% of net sales (if only Process Patents are licensed) or 3% of net sales (if any Product Patents are licensed) and reasonable and customary terms and conditions, to any and all sole proprietorships, partnerships, corporations or other business entities which state an intention to produce or sell a CD4-Based Therapeutic in the United States, or research and develop a CD4-Based Therapeutic for purposes of later producing or selling a CD4-Based Therapeutic in the United States.

VII. DISPOSITION OF PATENTS

It is further ordered, That respondents shall not dispose or permit the disposition of any patents or rights thereunder so as to deprive them of the power to grant or cause to be granted the licenses required by this order; *provided that,* if, after the expiration of three (3) years from the date this order becomes final for any patent which has issued prior to the date this order becomes final, or three (3) years from the date of issuance of any patent which has not issued as of the date this order becomes final, if no license has been requested under such patent, respondents may abandon and dedicate to the public such patent.

VIII. PATENT VALIDITY

It is further ordered, That nothing herein shall be deemed to prevent any person from attacking in any proceeding or controversy the validity, scope or enforceability of any present or future patent, nor shall this order be construed as imputing any validity, enforceability, or value to any such patent.

IX. PUBLICATION OF PATENT AVAILABILITY

It is further ordered, That within sixty (60) days after the date this order becomes final and annually thereafter for nine (9) years, respondents shall publish in the Official Gazette of the United States Patent Office a notice (1) identifying by number, title, date of issue, and subject matter, or by other appropriate means, all United States Patents which are available for license pursuant to the terms of this

order; (2) stating that respondents will grant licenses pursuant to the terms of this order; and (3) stating that a copy of this order and a copy of all Patents subject to licensing under the order are available from respondents upon written request. Respondents shall provide a copy of this order and the most recent edition of such notice to all persons who inquire as to the availability of a license for any Patent subject to licensing under this order, and shall provide copies, for a reasonable copying fee, of any Patents subject to licensing under this order, upon request by any person.

X. HOLD SEPARATE AGREEMENT

It is further ordered, That the respondents shall comply with all terms of the Agreement to Hold Separate, attached hereto and made a part hereof as Appendix I. Said Agreement shall continue in effect until respondents' divestiture obligations with respect to GLC under paragraphs II and IV of the order are satisfied, or until such other time as the Agreement to Hold Separate provides.

XI. PRIOR APPROVAL

It is further ordered, That, for a period of ten (10) years from the date this order becomes final, each respondent shall cease and desist from acquiring, without the prior approval of the Commission, directly or indirectly, through subsidiaries or otherwise, except in the ordinary course of business, assets used in, or more than 1% of the stock or share capital of or any interest in any company engaged in, clinical development or the manufacture or sale in the United States of any Products Subject to order, or any exclusive rights whether by license or otherwise to any United States Patents for use in the clinical development or the manufacture or sale of any Products Subject to order. This paragraph XI shall not apply to any acquisition of a nonexclusive license to any United States Patents with respect to any Products Subject to order and shall not apply to the acquisition of any United States Patents or any exclusive license to any United States Patents, with respect to any Products Subject to order, for a present value of less than one million dollars (\$1,000,000) including initial payments and expected future royalties.

XII. COMPLIANCE REPORTS

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 satisfied the divestiture obligations of this order, respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intended to comply, are complying, and have complied with the order. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of all contacts or negotiations with prospective acquirers for the divestitures required by this order, including the identity of all parties contacted. Respondents also shall include in their compliance reports copies of all written communications to and from such parties, and all internal memoranda, reports, and recommendations concerning the required divestitures.

B. One year from the date this order becomes final and annually thereafter for nine (9) years, respondents shall file with the Commission a verified written report of their compliance with paragraphs V (if invoked by the Commission), VI, VII, IX and XI of this order.

XIII. INVESTIGATION

It is further ordered, That for the purposes of determining or securing compliance with this order, and subject to any legally recognized privilege, upon written request and on reasonable notice to respondents made to their principal offices, respondents shall make available to any duly authorized representatives of the Commission:

A. All books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession of under the control of respondents relating to any matters contained in this order, for inspection and copying during office hours and in the presence of counsel; and

B. Upon five (5) days' notice to respondents, and without restraint or interference from respondents, for interview, officers or employees of respondents, who may have counsel present, regarding such matters. Officers and employees of respondents whose place of employment is outside the United States will be made available on reasonable notice.

Information or documents obtained by the Commission pursuant to this paragraph XIII shall be accorded such confidential treatment as is available under Sections 6(f) and 21 of the Federal Trade Commission Act, 15 U.S.C. 46(f) and 57b-2.

XIV. CORPORATE CHANGES

It is further ordered, That respondents shall notify the Commission at least thirty (30) days prior to any proposed change in any respondent, such as dissolution, assignment or sale resulting in the emergence of a successor, or the creation or dissolution, or sale of subsidiaries or any other change that may affect compliance obligations arising out of this order.

Commissioner Owen dissenting. Commissioner Starek did not participate.

EXHIBIT A

U.S. Patent No. 4,622,312 issued Nov. 11, 1986; Arthur M. Felix, Edgar P. Heimer, Thomas F. Mowels; Growth hormone releasing factor analogs; Appl. No. 653,163; Filed Sept. 24, 1984

U.S. Patent No. 4,649,131 issued March 10, 1987; Arthur M. Felix, Edgar P. Heimer, Thomas F. Mowels; Growth hormone releasing factor analogs; Appl. No. 762,891; Filed Aug. 6, 1985

U.S. Patent No. 4,728,609 issued March 1, 1988; Ram S. Bhatt, Kenneth J. Collier, Robert M. Crowl, Mohindar S. Poonian; Recombinant growth hormone releasing factor; Appl. No. 778-779; Filed Sept. 24, 1985

U.S. Patent No. 4,732,972 issued March 22, 1988; Arthur M. Felix, Edgar P. Heimer, Polypeptides having growth hormone releasing activity; Appl. No. 789,922; Filed Oct. 21, 1985

U.S. Patent No. 4,734,399 issued March 29, 1988; Arthur M. Felix, Edgar P. Heimer, Thomas F. Mowels; Growth hormone releasing factor analogs; Appl. No. 922,572; Filed Oct. 23, 1986

EXHIBIT B

U.S. Patent Pending; Klaus Karjalainen, Andre Traunecker; Chimeric CD4-immunoglobulin polypeptides; Appl. No. 510,773; Filed April 18, 1990

APPENDIX I

AGREEMENT TO HOLD SEPARATE

This Agreement to Hold Separate (the "Agreement") is by and among Genentech, Inc. ("Genentech"), a corporation organized and

existing under the laws of the State of Delaware, with its principal executive offices located at 460 Point San Bruno Boulevard, South San Francisco, Ca. Roche Holding Ltd., a corporation organized and existing under the laws of Switzerland, with its principal executive offices located at Grenzacherstrasse 124, Basle, Switzerland 4002; Roche Holdings, Inc., a corporation organized and existing under the laws of the state of Delaware, with its principal executive offices located at 345 Route 17 South, Upper Saddle River, New Jersey; and Hoffmann-La Roche Inc., a corporation organized and existing under the laws of the state of New Jersey, with its principal executive offices located at 340 Kingsland Street, Nutley, New Jersey (collectively "Roche"); 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 February 2, 1990, Genentech and Roche entered into an Agreement and Plan of Merger which contemplates the acquisition by Roche of a controlling interest in Genentech (hereinafter the "Acquisition"); and

Whereas, the Commission is now investigating the Acquisition to determine if the Acquisition would violate any of the statutes enforced by the Commission; and

Whereas, if the Commission accepts the attached Agreement Containing Consent Order (the "Consent Order"), the Commission must place it 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* and holding separate GLC (as defined in the Consent Order) during the period prior to the divestiture of GLC's Vitamin C Assets (as defined in the Consent Order) or the divestiture of Genentech's interest in GLC pursuant to paragraph II or IV of the Consent Order, divestiture might be less than an effective remedy; and

Whereas, the purpose of this Agreement and the Consent Order is to:

- (i) Preserve the viability and marketability of GLC as an indepen-

dent business pending the divestiture of the GLC Vitamin C Assets or Genentech's interest in GLC, and

(ii) Preserve GLC as an ongoing business engaged in the same business in which it is presently employed in the event that divestiture is not achieved; and

(iii) Remedy any possible anticompetitive effects of the Acquisition, and

Whereas, Genentech and Roche (collectively "respondents") entering into this Agreement shall in no way be construed as an admission that the Acquisition is unlawful; and

Whereas, respondents understand that no act or transaction contemplated by this 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 Agreement.

Now, therefore, the Parties agree, upon understanding that the Commission has not yet determined whether the Acquisition would be challenged, and in consideration of the Commission's agreement that, unless the Commission determines to reject the Consent Order, it will not seek further relief from respondents with respect to the Acquisition, except that the Commission may take action at some later date with respect to the effect, if any, of the acquisition on competition with respect to alpha interferon, and may exercise any and all rights to enforce this Agreement and the Consent Order to which it is annexed and made a part thereof, and in the event the required divestiture is not accomplished, to seek divestiture of such assets as are held separate pursuant to this Agreement, as follows:

1. Respondents agree to execute and be bound by the attached Consent Order and agree that terms defined in the Consent Order shall have the same meanings when used therein.

2. Respondents agree that from the date this Agreement is accepted until the earliest of the dates listed in subparagraphs 2.a - 2.c, they will comply with the provisions of paragraph 3 of this Agreement:

a. Three business days after the Commission withdraws its acceptance of the Consent Order pursuant to the provisions of Section 2.34 of the Commission's Rules;

b. One hundred twenty (120) days after publication in the Federal Register of the Consent Order unless by that date the Commission has finally approved and issued the Consent Order, if respondents, at their option, have chosen to terminate this Agreement to Hold Separate,

which they may do by delivering written notice of termination to the Commission, which termination shall be effective ten (10) days after the Commission's receipt of such notice if the Commission does not finally approve and issue the Consent Order before the end of that ten (10) day period;

c. If the Commission issues the Consent Order, the GLC divestiture required by the Consent Order has been completed.

3. Respondents will hold GLC, including all its assets associated with the research and development of vitamin C, as it is presently constituted, separate and apart on the following terms and conditions:

a. GLC, as it is presently constituted, shall be held separate and apart and shall be operated independently of Roche; *provided, however*, that Roche may exercise only such direction and control over GLC as is necessary to assure compliance with this Agreement.

b. Roche shall not exercise direction or control over, or influence directly or indirectly, GLC or any of its operations or businesses; *provided, however*, that Roche may exercise only such direction and control over GLC as is necessary to assure compliance with this Agreement.

c. Respondents shall maintain the viability and marketability of GLC and shall not sell, dispose of, or transfer any assets, property or business of GLC (other than in the ordinary course of business), or encumber or otherwise impair its marketability or viability. Respondents shall refrain from taking any actions which may cause any material adverse change in the business or financial condition of GLC.

d. Respondents shall continue to promote and maintain GLC, including without limitation the levels of research and development efforts presently associated with said business, and shall maintain and preserve all of the intangible rights and other assets of said business so that said business can be divested in accordance with the requirements of the Consent Order.

e. Except as required by law, and except to the extent necessary to defend against investigations or litigation, or to negotiate an agreement to divest GLC in compliance with the Consent Order, Roche shall not receive or have access to, or the use of, any "material confidential information" of GLC not in the public domain, except as such information would be available to Roche in the ordinary course of business if the Acquisition had not taken place. 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 herein, means competitively sensitive or proprietary information not independently known to Roche from sources other than GLC, and includes but is not limited to patents, technologies, processes, production costs, or other trade secrets).

f. Except as permitted by this Agreement, Roche shall not participate in any matter, or attempt to influence GLC with respect to matters that would involve a conflict of interest if Roche and GLC were separate and independent entities. Meetings of the Board or Management Committee of GLC during the term of this Agreement shall be stenographically transcribed and the transcripts retained for two (2) years after the termination of this Agreement.

g. All earnings and profits of GLC shall be retained separately in GLC. If necessary, Roche and Genentech shall provide GLC with sufficient working capital to operate at GLC's current rate of operation.

h. Respondents shall maintain separate financial and operating records and shall prepare separate financial statements for GLC and shall provide the Commission's Bureau of Competition with quarterly and annual financial statements within ten days of their availability.

i. Should the Federal Trade Commission seek in any proceeding to compel respondents to divest Genentech or GLC or any assets of GLC that they may hold, or to seek any other injunctive or equitable relief, respondents shall not 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 Acquisition to be consummated. Respondents also waive all rights to contest the validity of this Agreement.

4. For the purpose of determining or securing compliance with this Agreement, subject to any legally recognized privilege, and upon written request with reasonable notice to respondents, respondents 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 respondents relating to compliance with this Agreement;

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

matters. Officers and employees of respondents whose place of employment is outside the United States will be made available on reasonable notice.

5. Any information or documents obtained by the Commission pursuant to paragraph 4 shall be accorded such confidential treatment as is available under Sections 6(f) and 21 of the Federal Trade Commission Act, 15 U.S.C. 46(f) and 57b-2.

6. This agreement shall not be binding until approved by the Commission.

SEPARATE STATEMENT OF COMMISSIONER ANDREW J. STRENIO, JR.

Although I preferred securing relief in additional markets, I concur with the majority in finding sufficient grounds to accept the consent agreement.

DISSENTING STATEMENT OF COMMISSIONER DEBORAH K. OWEN

In the matter of the acquisition of Genentech, Inc. by Roche Holdings Ltd., and its United States subsidiaries, Roche Holdings, Inc. and Hoffman-La Roche Inc., the Federal Trade Commission has today accepted a consent agreement and issued a final order based on the doctrine of actual potential competition. In finding reason to believe that this acquisition would violate Section 7 of the Sherman Act and Section 5 of the Clayton Act, the Commission has departed from past precedent in potential competition cases, *B.A.T. Industries, Ltd.*, 104 FTC 916 (1984), as well as from the *U.S. Department of Justice Merger Guidelines*, 4 Trade Reg. Rep. (CCH) ¶13,103 at §4.1. I dissent.

The consistent theme of case precedent and the Merger Guidelines is that before a merger will be challenged under a theory of actual potential competition, the prospective entrant must be willing and able imminently to enter a market which is not now performing competitively. In the instant case, the Commission alleged anticompetitive effect and took relief in markets where, in my judgment, there is substantial doubt that the prospective entrant is willing to enter; there is only speculation that the prospective entrant is able to enter; and/or it is certain that entry is not imminent. Moreover, there are as yet no firms or products in one market, so drawing conclusions about competitive performance in that market in the relatively distant future

is speculative at best. What appears to be the Commission's approach to entry in this potential competition case diverges from the position that the Commission has taken on entry in mergers between horizontal competitors. In the latter instance, the Commission looks at entry to determine whether firms not now in the market would defeat any anticompetitive behavior by firms currently in the market. Traditionally, under the standard used by the Commission, and in accord with Section 3.3 of the *Merger Guidelines*, new entry must generally be expected to take place within two years before the prospect of that entry will cause the Commission not to challenge a merger that would otherwise be objectionable. Further, as this Commission and its sister antitrust enforcement agency have recently made clear, the prospect of such entry must be supported by more than mere hypothesis. Consonant with these standards, *B.A.T. Industries* requires "clear proof" that entry would occur within the "near future" before a merger is challenged on the basis of actual potential competition. 104 FTC at 925-926.

In today's action, the Commission has apparently found that there is reason to believe that a merger would substantially lessen competition in markets where, in my opinion, there could not be competition between the firms for periods well in excess of two or three years, and it is debatable whether the support was more than "mere hypothesis". No justification for this divergence in the treatment of entry has been provided,¹ and the apparent inconsistency in antitrust analysis is troubling.

¹ While there may indeed be industries for which the appropriate time period to evaluate entry in horizontal merger cases and actual potential competition cases is longer than two years, this does not provide a basis for using a substantially longer time period for analysis of entry in potential competition cases than in horizontal competition cases.

IN THE MATTER OF
BUDGET RENT A CAR CORPORATION

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

Docket C-3316. Complaint, Dec. 27, 1990—Decision, Dec. 27, 1990

This consent order prohibits, among other things, Budget Rent A Car Corporation ("Budget") from failing to inspect and, if appropriate, repair its rental vehicles covered by manufacturers' safety recall notices within a reasonable period of time after receiving such notices. In addition, the consent order provides the respondent the option, if it chooses not to inspect and repair, to disclose to prospective renters of affected vehicles, prior to the signing of the rental agreement, that the vehicles are subject to safety recall notices and have not been inspected or repaired, and to describe to prospective renters the defect in question.

Appearances

For the Commission: *Steven H. Toporoff* and *Lydia B. Parnes*.

For the respondent: *John Baer, Keck, Mahin & Cate*, Chicago, IL.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Budget Rent A Car Corporation, a corporation, hereinafter sometimes referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereto would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Budget Rent A Car Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 200 North Michigan Avenue, Chicago, Illinois.

PAR. 2. Respondent is now, and for sometime in the past, has been engaged in the business of offering automobiles to the general public for rent.