IN THE MATTER OF

ROCHE HOLDING LTD.

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-3809. Complaint, May 22, 1998--Decision, May 22, 1998

This consent order requires, among other things, the Switzerland-based corporation to divest Corange Limited's U.S. and Canadian Retavase businesses to Centecor Inc., and divest, to a Commission-approved acquirer, Corange's worldwide drug abuse testing reagent business, which uses Cloned Enzyme Donor Immuno-Assay ("CEDIA") reagents, and grant a non-exclusive license to all other CEDIA reagents.

Appearances

For the Commission: *Christina Perez, Andrew Topps, Ann Malester* and *William Baer.*

For the respondent: *Ronan Harty, Davis, Polk & Wardwell,* New York, N.Y.

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondent, Roche Holding Ltd ("Roche"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire 100% of the voting stock of Corange Limited ("Corange"), a corporation subject to the jurisdiction of the 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, 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. DEFINITIONS

1. "*Cardiac Thrombolytic Agents*" means all thrombolytic agents used to dissolve blood clots.

2. "*DAT Reagents*" means all diagnostic reagents used to test for any drug of abuse.

II. RESPONDENT

3. Respondent Roche 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, Basel, Switzerland 4002.

4. Respondent is engaged in, among other things, the research, development, manufacture and sale of Cardiac Thrombolytic Agents and DAT Reagents.

5. 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.

III. THE ACQUIRED COMPANY

6. Corange is a corporation organized, existing, and doing business under and by virtue of the laws of Bermuda, with its headquarters located at 22 Church Street, P.O. Box HM 2026, Hamilton, HM HX Bermuda.

7. Corange is engaged in, among other things, the research, development, manufacture and sale of Cardiac Thrombolytic Agents and DAT Reagents.

8. Corange 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.

IV. THE ACQUISITION

9. On May 24, 1997, Roche entered into a Stock Purchase Agreement with Corange to acquire 100% of Corange's voting stock for approximately $11 billion ("Acquisition").

V. THE RELEVANT MARKETS

10. 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 Cardiac Thrombolytic Agents; and

(b) The research, development, manufacture and sale of DAT Reagents used in workplace testing.

11. 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.

VI. STRUCTURE OF THE MARKETS

12. The market for the research, development, manufacture and sale of Cardiac Thrombolytic Agents is highly concentrated as measured by the Herfindahl-Hirschmann Index ("HHI"). The post merger HHI is 8,698 points, which is an increase of 3,220 points over the premerger HHI level. Roche and Corange are the two leading suppliers of Cardiac Thrombolytic Agents in the United States and produce the safest and most effective products on the market.

13. Roche and Corange are actual competitors in the relevant market for the research, development, manufacture and sale of Cardiac Thrombolytic Agents in the United States.

14. The market for the research, development, manufacture and sale of DAT Reagents used in workplace testing is highly concentrated as measured by the HHI. The post merger HHI is 4,878 points, which is an increase of 704 points over the premerger HHI level. Roche and Corange are two of only four suppliers of DAT Reagents used in workplace testing in the United States.

15. Roche and Corange are actual competitors in the relevant market for the research, development, manufacture and sale of DAT Reagents used in workplace testing in the United States.

VII. BARRIERS TO ENTRY

16. Entry into the market for the research, development, manufacture and sale of Cardiac Thrombolytic Agents is unlikely and would not occur in a timely manner to deter or counteract the adverse competitive effects described in paragraph eighteen because of, among other things, the time-consuming nature of research, development and U.S. Food and Drug Administration approval of these products.

17. Entry into the market for the research, development, manufacture and sale of DAT Reagents used in workplace testing is unlikely and would not occur in a timely manner to deter or counteract the adverse competitive effects described in paragraph eighteen because of, among other things, the difficulty of developing a full panel of DAT Reagents, as well as gaining brand name recognition and customer acceptance.

VIII. EFFECTS OF THE ACQUISITION

18. The effects of the Acquisition, if consummated, 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 actual, direct, and substantial competition between Roche and Corange in the markets for the research, development, manufacture and sale of Cardiac Thrombolytic Agents and DAT Reagents used in workplace testing;

(b) By increasing the likelihood that Roche will unilaterally exercise market power in the market for the research, development, manufacture and sale of Cardiac Thrombolytic Agents;

(c) By increasing the likelihood that consumers in the United States will be charged higher prices for Cardiac Thrombolytic Agents and DAT Reagents used in workplace testing;

(d) By reducing the likelihood of innovation in the market for the research, development, manufacture and sale of Cardiac Thrombolytic Agents; and

(e) By enhancing the likelihood of collusion or coordinated interaction between or among the firms in the market for the research, development, manufacture and sale of DAT Reagents used in workplace testing.

IX. VIOLATIONS CHARGED

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

20. The Acquisition described in paragraph nine, 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.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of the proposed acquisition by respondent of 100% of the voting stock of Corange Limited ("Corange"), 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 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 its charges in that respect, and having thereupon accepted the executed agreement containing consent order and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure described 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 Roche Holding Ltd ("Roche") 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, Basel, Switzerland 4002. Hoffmann-La Roche Inc., an indirect wholly-owned subsidiary of Roche Holding Ltd, is located at 340 Kingsland Street, Nutley, New Jersey.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, 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. "*Roche*" or "*respondent*" means Roche Holding Ltd, its predecessors, subsidiaries, divisions, groups and affiliates controlled by Roche, and their respective directors, officers, employees, agents and representatives, and their respective successors and assigns.

B. "*Corange*" means Corange Limited, a corporation organized, existing and doing business under the laws of Bermuda with its headquarters located at 22 Church Street, P.O. Box HM 2026,

Hamilton, HM HX Bermuda, including its predecessors, subsidiaries, divisions, groups and affiliates controlled by Corange, and their respective directors, officers, employees, agents and representatives, and their respective successors and assigns.

C. "*Acquirer*" means Centocor, Inc., a corporation organized, existing and doing business under the laws of Pennsylvania with its principal place of business located at 200 Great Valley Parkway, Malvern, Pennsylvania, or the entity to whom Roche shall divest the Reteplase Assets pursuant to paragraph II of this order, as applicable.

D. "*Acquisition*" means the acquisition by Roche, through a subsidiary, of 100% of the voting stock of Corange pursuant to a Stock Purchase Agreement dated May 24, 1997.

E. "*CEDIA Assets*" means all of Corange's assets, business, goodwill and rights that are not part of Corange's physical facilities at the Penzberg Plant, as of the date of the Divestiture Agreement described in paragraph V.B of this order, relating to the research, development, manufacture or sale of products that utilize the CEDIA Patents. "CEDIA Assets" also include, but are not limited to, all machinery, fixtures, equipment and other tangible real and personal property, trade names, trademarks, brand names, formulations, inventory, contractual rights, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, marketing and distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the New Reagent Acquirer to use such information) and all data, contractual rights, materials and information relating to FDA and other government or regulatory approvals relating to CEDIA Reagents.

F. "*CEDIA Method*" means a general detection principle used in diagnostic applications based on the bacterial enzyme B-galactosidase, where the enzyme has been genetically engineered into two fragments: the enzyme donor and the enzyme acceptor.

G. "*CEDIA Patents*" means all of the Patents and know-how world-wide, which cover the CEDIA Method, whether granted or applied for that are not divested pursuant to paragraph V.A.(i).

H. "*CEDIA Reagents*" means all of Corange's diagnostic reagents researched, developed, manufactured or sold that are based on the CEDIA Method, including, but not limited to, drugs of abuse testing, therapeutic drug monitoring, thyroid analysis, testing for anemia, and hormone testing.

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

J. "*Contract Manufacture*" means the manufacture of Reteplase or any CEDIA Reagents supplied pursuant to a Divestiture Agreement, as applicable, by Roche for sale to the Acquirer, New Acquirer, Reagent Acquirer, or New Reagent Acquirer, as applicable.

K. "*Cost*" means average direct per unit cost or, if the Acquirer is Centocor, the cost as stated in the Asset Purchase Agreement between Roche and Centocor, dated February 11, 1998.

L. "*DAT Applications*" means all diagnostic applications based on the CEDIA Patents for use in drugs of abuse testing.

M. "*DAT Reagent Assets*" means all of Corange's assets, business, goodwill and rights that are not part of Corange's physical facilities at the Penzberg Plant, as of the date this agreement containing consent order becomes final, relating to the research, development, manufacture and sale of DAT Reagents throughout the world. "DAT Reagent Assets" also include, but are not limited to, all machinery, fixtures, equipment and other tangible real and personal property, trade names, trademarks, brand names, formulations, inventory, U.S. Patent 5,573,955 and any other Patent that is related soley to the manufacture or sale of DAT Reagents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, marketing and distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the Reagent Acquirer or New Reagent Acquirer to use such information) and all data, contractual rights, materials and information relating to FDA and other government or regulatory approvals relating to DAT Reagents.

N. "*DAT Reagents*" means all Corange diagnostic reagents researched, developed, manufactured or sold for DAT Applications.

O. "*Designee*" means any entity that will manufacture Reteplase or any CEDIA Reagent for the Acquirer, New Acquirer, Reagent Acquirer, or New Reagent Acquirer, as applicable.

P. "*Divestiture Trustee*" means the trustee(s) appointed pursuant to paragraphs IV or VII of this order, as applicable.

Q. "*FDA*" means the United States Food and Drug Administration.

R. "*Governance Agreement*" means the Amended and Restated Governance Agreement dated October 25, 1995, between Roche Holdings, Inc. and Genentech, Inc. and any and all amendments thereof.

S. "*Interim Trustee*" means the trustee(s) appointed pursuant to paragraphs III or VI of this order, as applicable.

T. "*New Acquirer*" means the entity to whom the Divestiture Trustee shall divest the world-wide Reteplase Assets pursuant to paragraph IV of this order.

U. "*New Reagent Acquirer*" means the entity to whom the Divestiture Trustee shall divest the CEDIA Assets pursuant to paragraph VII of this order.

V. "*Non-DAT Applications*" means all diagnostic applications based on the CEDIA Patents other than DAT Applications.

W. "*Non-Reteplase Applications*" means any human pharmaceutical application that is not a Reteplase Application.

X. "*Patent*" means the patent and patent right, and patent applications, patents of addition, re-examinations, reissues, extensions, granted supplementary protection certificates, substitutions, confirmations, registrations, revalidations, revisions, additions and the like, of or to said patent and patent right and any and all continuations and continuations-in-part.

Y. "*Penzberg Plant*" means the current Corange facility located in Penzberg, Germany, or any Roche facility, that is used to manufacture Reteplase.

Z. "*Reagent Acquirer*" means the entity to whom respondent shall divest the DAT Reagent Assets and grant (i) an exclusive license to the CEDIA Patents for DAT Applications, and (ii) a non-exclusive license to the CEDIA Patents for Non-DAT Applications in the United States pursuant to paragraph V of this order.

AA."*Reteplase*" means recombinant reteplase ("rPA"), a recombinant, nonglycosylated plasminogen activator, containing amino acids 1-3 and 176-527 of the amino acid sequence of the tissue-type plasminogen activator or any future presentation, formulation, application or therapeutic use of the active ingredient.

BB."*Reteplase Applications*" means all applications based on the Reteplase Patents, that contain the Reteplase active ingredient or any future presentation, formulation, application or therapeutic use of the active ingredient.

CC."*Reteplase Assets*" means all of Corange's assets, business, goodwill and rights that are not part of Corange's physical facilities, as of the date this agreement containing consent order becomes final, relating to the research, development, manufacture and sale of Reteplase for sale in the United States and Canada. "Reteplase Assets" also include, but are not limited to, all trade names, trademarks, brand names, formulations, inventory, U.S. Patent 5,223,256, U.S. Patent 5,510,330, U.S. Patent 5,500,411 and any other U.S. or Canadian Patent related solely to the manufacture or sale of Reteplase, trade secrets, technology, know-how, specifica-

tions, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, marketing and distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the Acquirer or New Acquirer to use such information), and all data, contractual rights, materials and information relating to FDA and other government or regulatory approvals for the United States and Canada relating to Reteplase.

DD."*Reteplase Patents*" means: (1) all of the Patents and know-how, as of the date the agreement containing consent order becomes final, that are related to the manufacture or sale of Reteplase and are not divested pursuant to paragraph II.A.(i); and (2) any new Patent or know-how that respondent uses to manufacture Reteplase during the term of the Contract Manufacturing of Reteplase unless the changes are being made solely to obtain regulatory approval outside the United States or Canada.

EE."*World-wide Reteplase Assets*" means all of Corange's assets, business, goodwill and rights that are not part of Corange's physical facilities, as of the date this agreement containing consent order becomes final, relating to the research, development, manufacture and sale of Reteplase throughout the world. "world-wide Reteplase Assets" also include, but are not limited to, all trade names, trademarks, brand names, formulations, inventory, all world-wide Patents related solely to the manufacture or sale of Reteplase, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, marketing and distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the Acquirer or New Acquirer to use such information), and all data, contractual rights, materials and information relating to FDA and other government or regulatory approvals for the United States and Canada relating to Reteplase.

II.

It is further ordered, That:

A. Respondent shall: (i) divest, absolutely and in good faith, the Reteplase Assets as a competitively viable, on-going product line; (ii) grant an exclusive, royalty-free license, in perpetuity, to the Reteplase Patents for Reteplase Applications in the United States and Canada, and (iii) grant a royalty-bearing, non-exclusive license, in perpetuity, to the Reteplase Patents for Non-Reteplase Applications in the United

States and Canada to: (1) Centocor, in accordance with the Asset Purchase Agreement dated February 11, 1998; or (2) at no minimum price, to an Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission within ninety (90) days of the date on which this order becomes final. The purpose of the divestiture of the Reteplase Assets is to ensure their continued use in the research, development, manufacture, and sale for the treatment of acute myocardial infarction and other applications that may be further developed or found in the future and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint.

B. Respondent's agreement with the Acquirer or the New Acquirer (hereinafter "Divestiture Agreement") shall include the following provisions, and respondent shall commit to satisfy the following:

1. Respondent shall Contract Manufacture and deliver to the Acquirer or the New Acquirer in a timely manner and under reasonable terms and conditions, a supply of Reteplase, specified in the Divestiture Agreement at cost for a period not to exceed four (4) years from the date the Divestiture Agreement is approved, or three (3) months after the date the Acquirer or the New Acquirer obtains all necessary FDA approvals to manufacture and sell Reteplase in the United States, whichever is earlier; provided, however, that the four (4) year period may be extended by the Commission in twelve (12) month increments for a period not to exceed two (2) years.

2. After respondent commences delivery of Reteplase to the Acquirer or the New Acquirer pursuant to the Divestiture Agreement and for the term of the Contract Manufacturing arrangement for Reteplase, referred to in paragraph II.B of this order, respondent will make inventory of Reteplase available for sale or resale (i) in the United States or Canada only to the Acquirer or (ii) world-wide only to the New Acquirer.

3. Respondent shall make representations and warranties that the Reteplase supplied pursuant to the Divestiture Agreement meets the FDA approved specifications. Respondent shall agree to indemnify, defend and hold the Acquirer or the New Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Reteplase supplied to the Acquirer or New Acquirer pursuant to the Divestiture Agreement by respondent to meet FDA specifications. This obligation shall be contingent upon the Acquirer or the New Acquirer giving respondent prompt, adequate notice of such claim, cooperating fully in the

defense of such claim, and permitting respondent to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel; provided, however, any such defense and/or settlement shall be consistent with the obligations assumed by respondent under this order. This obligation shall not require respondent to be liable for any negligent act or omission of the Acquirer or the New Acquirer or for any representations and warranties, express or implied, made by the Acquirer or the New Acquirer that exceed the representations and warranties made by respondent to the Acquirer or the New Acquirer.

4. Respondent shall make representations and warranties that respondent will hold harmless and indemnify the Acquirer or New Acquirer for any liabilities or loss of profits resulting from the failure by respondent to deliver Reteplase in a timely manner as required by the Divestiture Agreement unless respondent can demonstrate that its failure was entirely beyond the control of respondent and in no part the result of negligence or willful misconduct on respondent's part.

5. During the term of the Contract Manufacturing between respondent and the Acquirer or the New Acquirer, upon request by the Acquirer, New Acquirer or the Interim Trustee, respondent shall make available to the Interim Trustee all records that relate to the manufacture of Reteplase.

6. Upon reasonable notice and request from the Acquirer or the New Acquirer to respondent, respondent shall provide in a timely manner: (a) assistance and advice to enable the Acquirer or the New Acquirer (or the Designees of the Acquirer or New Acquirer) to obtain all necessary FDA approvals to manufacture and sell Reteplase; (b) assistance to the Acquirer or New Acquirer (or the Designee thereof) as is necessary to enable the Acquirer or New Acquirer (or the Designee thereof) to manufacture Reteplase in substantially the same manner and quality employed or achieved by Corange; and (c) consultation with knowledgeable employees of respondent and training, at the request of and at the facility of the Acquirer's or the New Acquirer's choosing, until the Acquirer or New Acquirer (or the Designee thereof) receives certification from the FDA or abandons its efforts for certification from the FDA, sufficient to satisfy the management of the Acquirer or New Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of Reteplase. Such assistance shall include on-site inspections of the Penzberg Plant, at the Acquirer's or New Acquirer's request, which is the specified source of supply of the Contract Manufacturing. Respondent may require reimbursement from the Acquirer or New Acquirer for all its direct out-of-pocket

expenses incurred in providing the services required by this paragraph II.B.6.

7. The Divestiture Agreement shall require the Acquirer or the New Acquirer to submit to the Commission within 10 days of signing the Divestiture Agreement a certification attesting to the good faith intention of the Acquirer or the New Acquirer, including a plan by the Acquirer or the New Acquirer, to obtain in an expeditious manner all necessary FDA approvals to manufacture and sell Reteplase.

8. The Divestiture Agreement shall require the Acquirer or the New Acquirer to submit to the Commission and Interim Trustee periodic verified written reports, setting forth in detail the efforts of the Acquirer or the New Acquirer to sell Reteplase obtained pursuant to the Divestiture Agreement and to obtain all FDA approvals necessary to manufacture and sell Reteplase. The Divestiture Agreement shall require the first such report to be submitted 60 days from the date the Divestiture Agreement is approved by the Commission and every 90 days thereafter until all necessary FDA approvals are obtained by the Acquirer or the New Acquirer to manufacture and sell Reteplase in the United States. The Divestiture Agreement shall also require the Acquirer or the New Acquirer to report to the Commission and the Interim Trustee within ten (10) days of its ceasing the sale in the United States of Reteplase obtained pursuant to the Divestiture Agreement for any time period exceeding sixty (60) days or abandoning its efforts to obtain all necessary FDA approvals to manufacture and sell Reteplase in the United States. The Acquirer or New Acquirer shall provide the Interim Trustee access to all records and all facilities that relate to its efforts, pursuant to the Divestiture Agreement, to sell or manufacture Reteplase or obtain FDA approvals.

9. The Divestiture Agreement shall provide that the Commission may terminate the Divestiture Agreement if the Acquirer or the New Acquirer: (a) voluntarily ceases for sixty (60) days or more the sale of, or otherwise fails to pursue good faith efforts to sell, Reteplase in the United States prior to obtaining all necessary FDA approvals to manufacture and sell Reteplase in the United States; (b) fails to pursue good faith efforts to obtain all necessary FDA approvals to manufacture and sell Reteplase in the United States; or (c) fails to obtain all necessary FDA approvals of its own to manufacture and sell Reteplase in the United States within four (4) years from the date the Commission approves the Divestiture Agreement between respondent and the Acquirer or the New Acquirer; provided, however, that the four (4) year period may be extended by the Commission in twelve (12) month increments for a period not to