

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, HMHX 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 solely 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

exceed an additional two (2) years if it appears that such FDA approvals are likely to be obtained within such extended time period.

10. The Divestiture Agreement shall provide that if it is terminated, the Reteplase Assets shall revert back to Roche and the world-wide Reteplase Assets shall be divested by the Divestiture Trustee to a New Acquirer pursuant to the provisions of paragraph IV of this order.

C. During the pendency of any Patent dispute that: (1) challenges or seeks to render invalid any of the Patents divested or licensed pursuant to paragraph II.A; (2) could affect the manufacture or sale of Reteplase; and (3) is brought by Genentech, Inc., Boehringer Ingelheim, or Roche, including, but not limited to, the *Genentech Inc. v. Boehringer Mannheim* patent litigation, Civil Action 96-11090, respondent shall commit to satisfying the following:

1. Respondent shall provide, at its own expense, cooperation and assistance in connection with the pursuit or defense of such dispute as requested by the Acquirer or New Acquirer, including but not limited to:

(a) Full access to and cooperation from any employee or agent of Corange for the purposes of this paragraph II.C, including ensuring that the availability of such individuals shall not be interfered with by reason of their employment with respondent;

(b) Continued cooperation and assistance, to the extent of respondent's best efforts, of any Corange employee who has left the employ of Corange or Roche, including, but not limited to, expenses related to obtaining cooperation of any former Corange employee no longer employed by respondent and agreeing to reimburse the former employee's new employer for all reasonable direct out-of-pocket expenses associated with cooperating with and assisting the Acquirer or New Acquirer pursuant to this paragraph II.C;

(c) Copies of all documents, as requested by the Acquirer or New Acquirer, in the possession, custody or control of Corange relevant to, or likely to lead to information relevant to, the pursuit or defense of such dispute, along with information in respondent's possession or control sufficient to legally authenticate such documents; and

(d) Reimbursement for half of all expenses relating to the dispute submitted in the manner specified in paragraph II.C.5 of this order, including, but not limited to, fees paid to attorneys (who are not employees of the Acquirer or the New Acquirer) and fees paid to agents, experts, and courts.

2. Respondent shall not enter into any new agreement, or enforce any existing agreement, with any employee or former employee regarding confidential information that would otherwise prevent or hinder an employee or former employee from providing cooperation and assistance in connection with any dispute referred to in this paragraph II.C.

3. Respondent shall be financially responsible for any payments determined to be owed as a result of any sales of Reteplase prior to divestiture of the Reteplase Assets pursuant to this order, and for any sales of Reteplase outside of the United States or Canada.

4. Respondent shall ensure that no employee of respondent is penalized in any manner as a result of his or her full cooperation with the Acquirer or New Acquirer in connection with the obligations imposed pursuant to this order.

5. All requests for payments due from respondent pursuant to this paragraph II.C shall be submitted to the Interim Trustee or an agent of the Interim Trustee for verification. The Interim Trustee shall submit verified costs to respondent on a periodic basis. Such submissions shall contain only aggregate information about expenses incurred that reveals no privileged or confidential information. Respondent shall make payments to the Acquirer or New Acquirer pursuant to the Interim Trustee's submissions in a timely manner as specified by the Interim Trustee.

6. Respondent shall not, absent the prior written consent of the Acquirer or New Acquirer, provide, disclose or otherwise make available to Genentech, Inc. any information relating to any Patent dispute involving the Reteplase Assets.

7. In the event that the Governance Agreement allows respondent to control Genentech, Inc. or respondent obtains 100% of the stock of Genentech, Inc., respondent shall cause to be dismissed, with prejudice, any pending litigation by Genentech, Inc. against the Acquirer or New Acquirer regarding Patent rights for the research, development, manufacture or sale of Reteplase and shall refrain from instituting any new litigation against the Acquirer or New Acquirer challenging or seeking to render invalid any of the Patents divested or licensed pursuant to paragraph II.A.

D. By the time the Divestiture Agreement between respondent and the Acquirer or New Acquirer of the Reteplase Assets is signed, respondent shall provide the Acquirer or New Acquirer with a complete list of all employees who were engaged in the sale or marketing of Reteplase on the date of the Acquisition, as well as all employees engaged in the sale or marketing of Reteplase on the date

of the Divestiture Agreement. Such list(s) shall state each such individual's name, position, address, business telephone number, or if no business telephone number exists, a home telephone number, if available and with the consent of the employee, and a description of the duties and work performed by the individual in connection with the Reteplase Assets. Respondent shall provide the Acquirer or New Acquirer the opportunity to enter into employment contracts with such individuals provided that such contracts are contingent upon the Commission's approval of the Divestiture Agreement.

E. Following the signing of the Divestiture Agreement and subject to the consent of the employees, respondent shall provide the Acquirer or New Acquirer with an opportunity to inspect the personnel files and other documentation relating to the individuals identified in paragraph II.D of this order to the extent possible under applicable laws. For a period of two (2) months following the divestiture, respondent shall provide the Acquirer or New Acquirer with a further opportunity to interview such individuals and negotiate employment contracts with them.

F. Respondent shall provide all employees identified in paragraph II.D of this order with reasonable financial incentives to continue in their employment positions pending divestiture of the Reteplase Assets in order that such employees may be in a position to accept employment with the Acquirer or New Acquirer at the time of the divestiture. Such incentives shall include continuation of all employee benefits offered by respondent until the date of the divestiture, and vesting of all pension benefits (as permitted by law). In addition, respondent shall not enforce any confidentiality or non-compete restrictions relating to the Reteplase Assets that apply to any employee identified in paragraph II.D who accepts employment with any Acquirer or New Acquirer.

G. For a period of one (1) year commencing on the date of the individual's employment by the Acquirer or New Acquirer, respondent shall not re-hire any of the individuals identified in paragraph II.D of this order who accept employment with the Acquirer or New Acquirer, unless such individual has been separated from employment by the Acquirer or New Acquirer against that individual's wishes.

H. Prior to divestiture, respondent shall not transfer, without consent of the Acquirer or New Acquirer, any of the individuals identified in paragraph II.D of this order to any other position.

I. While the obligations imposed by paragraphs II, III or IV of this order are in effect, respondent shall take such actions as are necessary: (1) to maintain all necessary FDA approvals to

manufacture and sell Reteplase; (2) to maintain the viability and marketability of the world-wide Reteplase Assets consistent with general practices in the pharmaceutical industry, as well as all tangible assets, including respondent's facilities, used to manufacture and sell Reteplase; and (3) to prevent the destruction, removal, wasting, deterioration or impairment of the world-wide Reteplase Assets and the Penzberg Plant, except for ordinary wear and tear.

III.

It is further ordered, That:

A. At any time after respondent signs the agreement containing consent order in this matter, the Commission may appoint an Interim Trustee to ensure that respondent and the Acquirer or New Acquirer expeditiously perform their respective responsibilities as required by this order and the Divestiture Agreement approved by the Commission. Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Trustee appointed pursuant to this paragraph III:

1. The Commission shall select the Interim Trustee, subject to the consent of respondent, which consent shall not be unreasonably withheld. If respondent has 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 respondent of the identity of any proposed trustee, respondent shall be deemed to have consented to the selection of the proposed trustee.

2. The Interim Trustee shall have the power and authority to monitor respondent's compliance with the terms of this order and with the terms of the Divestiture Agreement with the Acquirer or New Acquirer.

3. Within ten (10) days after appointment of the Interim Trustee, respondent shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Interim Trustee all the rights and powers necessary to permit the Interim Trustee to monitor respondent's compliance with the terms of this order and with the Divestiture Agreement with the Acquirer or New Acquirer, and to monitor the compliance of the Acquirer or New Acquirer under the Divestiture Agreement.

4. The Interim Trustee shall serve until such time as the Acquirer or New Acquirer has received all necessary FDA approvals to manufacture and sell Reteplase.

5. The Interim Trustee shall have full and complete access to respondent's personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of Reteplase, or to any other relevant information, as the Interim Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of Reteplase. Respondent shall cooperate with any reasonable request of the Interim Trustee. Respondent shall take no action to interfere with or impede the Interim Trustee's ability to monitor respondent's compliance with paragraphs II, III and IV of this order and the Divestiture Agreement between respondent and the Acquirer or New Acquirer.

6. The Interim Trustee shall serve, without bond or other security, at the expense of respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Trustee shall have authority to employ, at the expense of respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Trustee's duties and responsibilities. The Interim Trustee shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.

7. Respondent shall indemnify the Interim Trustee and hold the Interim Trustee harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Interim Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparations 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 Interim Trustee.

8. If the Commission determines that the Interim Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute trustee in the same manner as provided in paragraph III.A.1 of this order.

9. The Commission may on its own initiative or at the request of the Interim Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this order and the Divestiture Agreement with the Acquirer or New Acquirer.

10. The Interim Trustee shall evaluate reports submitted to it by the Acquirer or the New Acquirer with respect to the efforts of the

Acquirer or the New Acquirer to obtain all necessary FDA approvals to manufacture and sell Reteplase. The Interim Trustee shall report in writing, concerning compliance by respondent and the Acquirer or New Acquirer with the provisions of paragraphs II and III to the Commission every two (2) months from the date the Divestiture Agreement is signed until the Acquirer or New Acquirer obtains, or abandons efforts to obtain, all necessary FDA approvals to manufacture and sell Reteplase in the United States. Such reports shall include at least the following:

- a. Whether respondent has supplied Reteplase in conformity with the requirements of paragraph II.B of this order;
- b. Whether respondent has given the Interim Trustee access to records pursuant to paragraph II.B.5 of this order;
- c. Whether the Acquirer or New Acquirer has given the Interim Trustee reports and access pursuant to paragraph II.B.8 of this order;
- d. Whether the Acquirer or New Acquirer is making good faith efforts to sell Reteplase and obtain all necessary FDA approvals to manufacture and sell Reteplase and whether these actions meet the projections of the business plan of the Acquirer or New Acquirer as required by paragraphs II.B.7 and II.B.8 of this order;
- e. If three (3) years and six (6) months have elapsed from the date of approval of the Divestiture Agreement and the Acquirer or New Acquirer has not obtained all necessary FDA approvals to manufacture and sell Reteplase in the United States, whether such approvals are likely to be obtained if the Commission extends the four (4) year period specified in paragraph II.B.9 of this order; and
- f. Whether respondent has maintained the world-wide Reteplase Assets as required in paragraph II.I of this order.

B. If the Commission terminates the Divestiture Agreement pursuant to paragraph II.B.9 of this order, the Commission may direct the Divestiture Trustee to seek a New Acquirer, as provided for in paragraph IV of this order.

IV.

It is further ordered, That:

A. If respondent fails to divest absolutely and in good faith, and with the Commission's prior approval, the Reteplase Assets and to comply with the requirements of paragraph II of this order, or if the Acquirer abandons its efforts or fails to obtain all necessary regulatory approvals in the manner set out in paragraph II.B.9, then any executed Divestiture Agreement between respondent and the

Acquirer shall be terminated and the Commission may appoint a Divestiture Trustee to divest the world-wide Reteplase Assets and execute a new Divestiture Agreement that satisfies the requirements of paragraph II of this order. The Divestiture Trustee may be the same person as the Interim Trustee and will have the authority and responsibility to divest the world-wide Reteplase Assets absolutely and in good faith, and with the Commission's prior approval. Neither the decision of the Commission to appoint the Divestiture Trustee, nor the decision of the Commission not to appoint the Divestiture Trustee, to divest any of the assets under this paragraph IV.A 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 the respondent to comply with this order.

B. If a Divestiture Trustee is appointed by the Commission or a court pursuant to paragraph IV.A to divest the world-wide Reteplase Assets to a New Acquirer, respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

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

2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the world-wide Reteplase Assets to a New Acquirer pursuant to the terms of this order and to enter into a Divestiture Agreement with the New Acquirer pursuant to the terms of this order, which Divestiture Agreement shall be subject to the prior approval of the Commission.

3. Within ten (10) days after appointment of the Divestiture Trustee, respondent shall execute a (or amend the existing) trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to divest the world-wide Reteplase Assets to a

New Acquirer and to enter into a Divestiture Agreement with the New Acquirer.

4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in paragraph IV.B.3 of this order to divest the world-wide Reteplase Assets and to enter into a Divestiture Agreement with the New Acquirer that satisfies the requirements of paragraph II of this order. If, however, at the end of the applicable twelve (12) month period, the Divestiture Trustee has submitted to the Commission 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 such divestiture period only two (2) times.

5. The Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities of respondent related to the manufacture, distribution, or sale of the world-wide Reteplase Assets or to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of his or her responsibilities.

6. The Divestiture Trustee shall use reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to respondent's absolute and unconditional obligation to divest at no minimum price and the Divestiture Trustee's obligation to expeditiously accomplish the remedial purpose of the order; to assure that respondent enters into a Divestiture Agreement that complies with the provisions of paragraph II.B; to assure that respondent complies with the remaining provisions of paragraph IV of this order; and to assure that the New Acquirer obtains all necessary FDA approvals to manufacture and sell Reteplase. The divestiture shall be made to, and the Divestiture Agreement executed with, the New Acquirer in the manner set forth in paragraph II of this order; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one (1) such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by respondent from among those approved by the Commission.

7. The Divestiture Trustee shall serve, without bond or other security, at the expense of respondent, on such reasonable and

customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the expense of respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture 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 respondent. The Divestiture Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Divestiture Trustee's locating a New Acquirer and assuring compliance with this order.

8. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 Divestiture Trustee.

9. If the Commission determines that the Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute trustee in the same manner as provided in paragraph IV of this order.

10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to comply with the terms of this order.

11. The Divestiture Trustee shall have no obligation or authority to operate or maintain the world-wide Reteplase Assets.

12. The Divestiture Trustee shall report in writing to respondent and the Commission every two months concerning his or her efforts to divest the relevant assets, respondent's compliance with the terms of this order, and the New Acquirer's efforts to obtain all necessary FDA approvals to manufacture and sell Reteplase.

V.

It is further ordered, That:

A. Within two (2) months of the date on which this order becomes final respondent shall: (i) divest, absolutely and in good faith, at no minimum price, the world-wide DAT Reagent Assets as a competitively viable, on-going product line; (ii) grant an exclusive, world-wide royalty-free license, in perpetuity, to the CEDIA Patents for DAT Applications, and (iii) grant a non-exclusive, royalty-free license, in perpetuity, to the CEDIA Patents for Non-DAT Applications in the United States, to a Reagent 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 the divestiture of the DAT Reagent Assets is to ensure the continued research, development, manufacture, and sale of the DAT Reagents as a viable competitive alternative for screening for the use of drugs of abuse, to establish a viable competitor and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint. In the event that the Reagent Acquirer does not choose to acquire all of the physical assets included in the DAT Reagent Assets because the Reagent Acquirer does not require such assets in order to engage in the manufacture and sale of DAT reagents, respondent shall not be required to divest such assets.

B. Respondent's agreement with the Reagent Acquirer or New Reagent 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 Reagent Acquirer or New Reagent Acquirer in a timely manner, a supply of all of the CEDIA Reagents specified in the Divestiture Agreement at cost for a period not to exceed one (1) year from the date the Divestiture Agreement is approved, or three (3) months after the date the Reagent Acquirer or the New Reagent Acquirer obtains all necessary FDA approvals to manufacture and sell all of the CEDIA Reagents in the United States, whichever is earlier; provided, however, that the one (1) year period may be extended by the Commission in three (3) month increments for a period not to exceed one (1) year. In the event that the Reagent Acquirer does not choose to have all of the CEDIA Reagents Contract Manufactured because the Reagent Acquirer does not require such reagents in order to manufacture or sell DAT Reagents in a competitive manner, respondent shall not be required to Contract Manufacture those reagents the Reagent Acquirer does not require.

2. After respondent commences delivery of all of the CEDIA Reagents to the Reagent Acquirer or the New Reagent Acquirer pursuant to the Divestiture Agreement required by paragraph V.B of this order, all inventory of the DAT Reagents acquired by respondent through the Acquisition may be made available by respondent only to the Reagent Acquirer or the New Reagent Acquirer.

3. Respondent shall make representations and warranties to the Reagent Acquirer or the New Reagent Acquirer that all of the CEDIA Reagents supplied pursuant to the Divestiture Agreement by respondent to the Reagent Acquirer or the New Reagent Acquirer meet the FDA approved specifications. Respondent shall agree to indemnify, defend and hold the Reagent Acquirer or the New Reagent Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of any of the CEDIA Reagents supplied to the Reagent Acquirer or New Reagent Acquirer pursuant to the Divestiture Agreement by respondent to meet FDA specifications. This obligation shall be contingent upon the Reagent Acquirer or the New Reagent 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 Reagent Acquirer or the New Reagent Acquirer or for any representations and warranties, express or implied, made by the Reagent Acquirer or the New Reagent Acquirer that exceed the representations and warranties made by respondent to the Reagent Acquirer or the New Reagent Acquirer.

4. Respondent shall make representations and warranties that respondent will hold harmless and indemnify the Reagent Acquirer or New Reagent Acquirer for any liabilities or loss of profits resulting from the failure by respondent to deliver in a timely manner any of the CEDIA Reagents 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 Reagent Acquirer or the New Reagent Acquirer, upon request by the Reagent Acquirer, New Reagent Acquirer or the Interim Trustee, respondent shall make available to the Interim

Trustee all records that relate to the manufacture of any of the CEDIA Reagents supplied pursuant to the Divestiture Agreement.

6. Upon reasonable notice and request from the Reagent Acquirer or the New Reagent Acquirer to respondent, respondent shall provide in a timely manner: (a) assistance and advice to enable the Reagent Acquirer or the New Reagent Acquirer (or the Designee of the Reagent Acquirer or New Reagent Acquirer) to obtain all necessary FDA approvals to manufacture and sell all of the CEDIA Reagents supplied pursuant to the Divestiture Agreement; (b) assistance to the Reagent Acquirer or New Reagent Acquirer (or the Designee thereof) as is necessary to enable the Reagent Acquirer or New Reagent Acquirer (or the Designee thereof) to manufacture all of the CEDIA Reagents supplied pursuant to the Divestiture Agreement in substantially the same manner and quality employed or achieved by Corange at the time this agreement containing consent order is signed; and (c) consultation with knowledgeable employees of respondent and training, at the request of and at the facility of the Reagent Acquirer's or the New Reagent Acquirer's choosing until the Reagent Acquirer or New Reagent 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 Reagent Acquirer or New Reagent Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of all of the CEDIA Reagents supplied pursuant to the Divestiture Agreement. Such assistance shall include on-site inspections of the Roche facility, at the Reagent Acquirer's or New Reagent Acquirer's request, that is the specified source of supply of the Contract Manufacturing. Respondent may require reimbursement from the Reagent Acquirer or New Reagent Acquirer for all its direct out-of-pocket expenses incurred in providing the services required by this paragraph V.B.6.

7. The Divestiture Agreement shall require the Reagent Acquirer or the New Reagent Acquirer to submit to the Commission, at the same time that respondent submits its application for approval of divestiture, a certification attesting to the good faith intention of the Reagent Acquirer or the New Reagent Acquirer, including a plan by the Reagent Acquirer or the New Reagent Acquirer, to obtain in an expeditious manner all necessary FDA approvals to manufacture and sell DAT Reagents.

8. The Divestiture Agreement shall require the Reagent Acquirer or the New Reagent Acquirer to submit to the Commission and the Interim Trustee periodic verified written reports, setting forth in detail the efforts of the Reagent Acquirer or the New Reagent

Acquirer to sell DAT Reagents obtained pursuant to the Divestiture Agreement and to obtain all FDA approvals necessary to manufacture and sell DAT Reagents. The Divestiture Agreement shall require the first such report to be submitted sixty (60) days from the date the Divestiture Agreement is approved by the Commission and every ninety (90) days thereafter until all necessary FDA approvals are obtained by the Reagent Acquirer or the New Reagent Acquirer to manufacture and sell DAT Reagents. The Divestiture Agreement shall also require the Reagent Acquirer or the New Reagent Acquirer to report to the Commission and the Interim Trustee within ten (10) days of its ceasing the sale of all or substantially all of the DAT Reagents 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 DAT Reagents. The Reagent Acquirer or New Reagent Acquirer shall provide the Interim Trustee access to all records and facilities that relate to its efforts, pursuant to the Divestiture Agreement, to sell or manufacture any of the CEDIA Reagents or obtain FDA approvals.

9. The Divestiture Agreement shall provide that the Commission may terminate the Divestiture Agreement if the Reagent Acquirer or the New Reagent Acquirer: (a) voluntarily ceases for sixty (60) days or more the sale of, or otherwise fails to pursue good faith efforts to sell, all or substantially all of the DAT Reagents prior to obtaining all necessary FDA approvals to manufacture and sell DAT Reagents; (b) fails to pursue good faith efforts to obtain all necessary FDA approvals to manufacture and sell the DAT Reagents; or (c) fails to obtain all necessary FDA approvals to manufacture and sell DAT Reagents in the United States within one (1) year from the date the Commission approves the Divestiture Agreement between respondent and the Reagent Acquirer or the New Reagent Acquirer; provided, however, that the one (1) year period may be extended by the Commission in three (3) month increments for a period not to exceed an additional one (1) year if it appears that such FDA approvals are likely to be obtained within such extended time period.

10. The Divestiture Agreement shall provide that if it is terminated, the DAT Reagent Assets shall revert back to respondent, all licences to the CEDIA Patents shall be rescinded, and the CEDIA Assets shall be divested by the Divestiture Trustee to a New Reagent Acquirer pursuant to the provisions of paragraph VII of this order.

C. By the time the Divestiture Agreement between respondent and the Reagent Acquirer or New Reagent Acquirer is signed, respondent shall provide the Reagent Acquirer or New Reagent

