



respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such Agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure described in § 2.34 of its Rules, the Commission hereby issues its Complaint, makes the following jurisdictional findings and enters the following Order:

1. Respondent Baxter International Inc. ("Baxter") is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Baxter Parkway, Deerfield, Illinois 60015.

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. "Respondent" or "Baxter" means Baxter International Inc., its predecessors, subsidiaries, divisions, groups and affiliates controlled by Baxter International Inc., and their respective directors, officers, employees, agents and representatives, and their respective successors and assigns. Baxter also includes Immuno International AG.

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

C. "Commission" means the Federal Trade Commission.

D. "FDA" means the United States Food and Drug Administration.

E. "Acquisition" means the acquisition by Baxter of the majority of Immuno voting stock.

F. "Factor VIII Inhibitor Treatments" means the activated prothrombin complex concentrates used to treat Factor VIII antibodies in hemophiliacs, approved by the FDA for sale in the United States.

G. "Autoplex" means the Factor VIII Inhibitor Treatments marketed by Baxter.

H. "FEIBA" means the Factor VIII Inhibitor Treatments marketed by Immuno.

I. "Autoplex Assets" means all of Baxter's assets and rights relating solely to the research, development, manufacture or sale of Factor VIII Inhibitor Treatments sold under the trade names Autoplex or Autoplex T, including all arrangements necessary to meet the requirements of Paragraph II.A. of this order. "Autoplex Assets" include, but are not limited to, all machinery, fixtures, equipment and other tangible personal property, rights to brand or trade names, formulations, inventory, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the 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.

J. "FEIBA Assets" means all of Immuno's assets and rights relating solely to the research, development, manufacture or sale of Factor VIII Inhibitor Treatments sold by Immuno, prior to the Acquisition, under the trade name FEIBA, including all arrangements necessary to meet the requirements of Paragraph IV.A. of this order. "FEIBA Assets" include, but are not limited to, all machinery, fixtures, equipment and other tangible personal property, rights to brand or trade names, formulations, inventory, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the 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.

K. "Divested Inhibitor Assets" means either the Autoplex Assets or the FEIBA Assets, as applicable.

L. "Acquirer" means the entity to whom Baxter shall divest the Autoplex Assets pursuant to Paragraph II. of this order.

M. "New Acquirer" means the entity to whom the trustee shall divest either the Autoplex Assets or the FEIBA Assets pursuant to Paragraph IV. of this order.

N. "Fibrin Sealant" means a topical biological product, in any form, including, but not limited to, freeze-dried and frozen, used to control bleeding or seal tissues together.

O. "Immuno Fibrin Sealant Assets" means all of Immuno's assets and rights relating to the research, development, manufacture or sale of any Fibrin Sealant developed by Immuno, as of the date this order becomes final. "Immuno Fibrin Sealant Assets" include, but are not limited to, all formulations, patents, patent applications, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the Fibrin Sealant Licensee 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.

P. "Fibrin Sealant Licensee" means the entity to whom Baxter shall license the Immuno Fibrin Sealant Assets pursuant to Paragraphs V. or VII. of this order.

Q. "Contract Manufacture" means the manufacture of Factor VIII Inhibitor Treatments or Fibrin Sealant, as applicable, by Baxter for sale to the Acquirer, the New Acquirer or the Fibrin Sealant Licensee, as applicable.

R. "Cost" means the manufacturer's average direct per unit cost of manufacturing Factor VIII Inhibitor Treatments or Fibrin Sealant, as applicable, plus costs of manufacturing Factor VIII Inhibitor Treatments or Fibrin Sealants, as applicable, that are directly attributable to FDA regulatory, quality control and compliance.

## II.

### IT IS FURTHER ORDERED that:

A. Within four (4) months of the date Baxter signed the Agreement Containing Consent Order in this matter, Baxter shall divest, absolutely and in good faith, the Autoplex Assets, effect all arrangements, including, but not limited to, the licensing of any Baxter patents and know-how not related solely to the research, development, manufacture or sale of Factor VIII Inhibitor Treatments, necessary to enable the Acquirer to manufacture and sell a Factor VIII Inhibitor Treatment using the Divested Inhibitor Assets, and execute an agreement that includes the provisions required by Paragraph II.C. of this order.

B. The Autoplex Assets shall be divested only to, and the agreement executed only with, an Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. In the event that the Acquirer does not choose to acquire all of the physical assets included in the Autoplex Assets because the Acquirer does not need such physical assets in order to engage in the manufacture and sale of Factor VIII Inhibitor Treatments, Respondent shall not be required to divest such assets. The purpose of the divestiture is to ensure the continued competition between Autoplex and FEIBA in the United States, in the same manner in which these products would compete absent the Acquisition, and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint.

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

1. Baxter shall grant to the Acquirer the right of reference to the data contained in Baxter's Product License Application ("PLA") No. 91-0649 (or to the New Acquirer the right of reference to the data contained in Immuno's PLA No. 82-027) for the Divested Inhibitor Assets on file with the FDA. Baxter shall make all necessary filings with the FDA authorizing the FDA to refer to the applicable PLA for the data in support of the PLA of the Acquirer or New Acquirer for a Factor VIII Inhibitor Treatment, including any supplemental PLAs or related PLAs. Provided, however, that the right of reference granted in this subparagraph does not constitute a general release of the data in Baxter's PLA No. 91-0649 (or Immuno's PLA No. 87-027), including any

supplemental PLAs or related PLAs, except as it may appear in labeling.

2. Baxter 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 Factor VIII Inhibitor Treatments specified in the Divestiture Agreement, at Baxter's Cost for a period not to exceed three (3) years from the date the Divestiture Agreement is approved, or four (4) months after the date the Acquirer or the New Acquirer obtains all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States, whichever is earlier; **provided, however,** that the time period may be extended by the Commission in twelve (12) month increments for a period not to exceed an additional forty-eight (48) months if the trustee appointed pursuant to Paragraph III. of this order submits to the Commission the certification provided for in subparagraph II.C.8. of this order.

3. Baxter shall make representations and warranties to the Acquirer or the New Acquirer that the Factor VIII Inhibitor Treatments that are Contract Manufactured by Baxter for the Acquirer or the New Acquirer meet the FDA approved specifications therefor and are not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. § 321, et seq. Baxter 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 Factor VIII Inhibitor Treatments Contract Manufactured by Baxter pursuant to subparagraph II.C.2. of this order to meet FDA specifications. This obligation shall be contingent upon the Acquirer or the New Acquirer giving Baxter prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting Baxter to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel. This obligation shall not require Baxter 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 Baxter to the Acquirer or the New Acquirer.

4. During the term of Contract Manufacturing, upon reasonable request by the Acquirer, the New Acquirer or the trustee appointed pursuant to Paragraph III. of this order,

Baxter shall make available to the trustee, or its agents or representatives, all records kept in the normal course of business that relate to the cost of manufacturing the Contract Manufactured Factor VIII Inhibitor Treatments.

5. Upon reasonable notice and request from the Acquirer or the New Acquirer to Respondent, Respondent shall provide: (a) such assistance and advice as is reasonably necessary to enable the Acquirer or the New Acquirer to obtain all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States; (b) such assistance as is reasonably necessary to enable the Acquirer to manufacture Factor VIII Inhibitor Treatments in substantially the same manner and quality employed or achieved by Baxter or, if divested to the New Acquirer, Immuno, prior to the Acquisition; and (c) consultation with knowledgeable employees of Baxter and training at a facility of the Acquirer's or the New Acquirer's choosing, for a period of time, not to exceed one (1) year, sufficient to satisfy the management of the Acquirer or the New Acquirer that its personnel are adequately trained in the manufacture of Factor VIII Inhibitor Treatments for sale in the United States. Such assistance shall include an on-site inspection of Baxter's facility that is performing the Contract Manufacturing, upon reasonable notice and request of the Acquirer or the New Acquirer. Respondent may require reimbursement from the Acquirer or the New Acquirer for all its direct out-of-pocket expenses incurred in providing the services required by this subparagraph II.C.5.

6. The Divestiture Agreement shall require the Acquirer or the New Acquirer to submit to the Commission, with the divestiture application filed by Respondent with the Commission requesting approval of the proposed divestiture, a certification attesting to the good faith intention of the Acquirer or the New Acquirer, including an actual plan by the Acquirer or the New Acquirer, to obtain in an expeditious manner all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States.

7. The Divestiture Agreement shall require the Acquirer or the New Acquirer to submit to the trustee appointed pursuant to Paragraph III. of this order, periodic verified written reports setting forth in detail the efforts of the Acquirer or the New Acquirer to sell Contract Manufactured Factor VIII Inhibitor Treatments in the United States and to obtain all FDA approvals necessary to manufacture its own Factor VIII Inhibitor Treatments for

sale in the United States. 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 Factor VIII Inhibitor Treatments for sale in the United States. The Divestiture Agreement shall also require the Acquirer or the New Acquirer to report to the Commission and the trustee within ten (10) days of its ceasing the sale of Contract Manufactured Factor VIII Inhibitor Treatments in the United States for any time period exceeding sixty (60) days or abandoning its efforts to obtain all necessary FDA approvals to manufacture its own Factor VIII Inhibitor Treatments for sale in the United States.

8. 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 Contract Manufactured Factor VIII Inhibitor Treatments in the United States prior to obtaining all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States; (b) abandons its efforts to obtain all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States; or (c) fails to obtain all necessary FDA approvals of its own to manufacture Factor VIII Inhibitor Treatments for sale in the United States within three (3) years from the date the Commission approves the Divestiture Agreement with the Acquirer or the New Acquirer; **provided, however,** that the time period may be extended by the Commission in twelve (12) month increments for a period not to exceed an additional forty-eight (48) months if the trustee appointed pursuant to Paragraph III. of this order certifies to the Commission that the Acquirer or the New Acquirer made good faith efforts to obtain all necessary FDA approvals for manufacturing Factor VIII Inhibitor Treatments for sale in the United States and that such FDA approvals appear likely to be obtained within such extended time period.



D. 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 research, develop, manufacture and sell both of the Factor VIII Inhibitor Treatments in the United States; (2) to maintain the viability and marketability of both of the Divested Inhibitor Assets as well as all tangible assets, including manufacturing facilities, needed to Contract Manufacture and sell Factor VIII Inhibitor Treatments; and (3) to prevent the destruction, removal, wasting, deterioration or impairment of any of the Divested Inhibitor Assets or tangible assets including the manufacturing facilities needed to Contract Manufacture and sell both of the Factor VIII Inhibitor Treatments, except for ordinary wear and tear.

### III.

**IT IS FURTHER ORDERED** that:

A. At any time after this order becomes final, the Commission may appoint a trustee to monitor whether Baxter and the Acquirer or the New Acquirer expeditiously perform their respective responsibilities as required by the Divestiture Agreement approved by the Commission and this order. Baxter shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the trustee appointed pursuant to this Paragraph:

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

2. The trustee shall have the power and authority to monitor Respondent's compliance with the terms of Paragraph II. of this order and with the Divestiture Agreement with the Acquirer or the New Acquirer.

3. Within ten (10) days after appointment of the trustee, Baxter shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the trustee all the rights and powers necessary to permit the trustee to monitor Respondent's compliance with the

terms of Paragraph II. of this order and monitor the efforts of the Acquirer or New Acquirer to obtain all necessary FDA approvals to manufacture and sell Factor VIII Inhibitor Treatments.

4. The trustee shall serve until such time as the Acquirer or the New Acquirer has received all necessary FDA approvals to research, develop, manufacture and sell Factor VIII Inhibitor Treatments in the United States.

5. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information relating to the research, development, manufacture or sale of Baxter's Factor VIII Inhibitor Treatments, or to any other relevant information, as the trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the cost of manufacturing Factor VIII Inhibitor Treatments. Respondent shall cooperate with any reasonable request of the trustee. Respondent shall take no action to interfere with or impede the trustee's ability to monitor Respondent's compliance with Paragraph II. of this order and the Divestiture Agreement with the Acquirer or the New Acquirer.

6. The trustee shall serve, without bond or other security, at the cost and expense of Baxter, on such reasonable and customary terms and conditions as the Commission may set. The trustee shall have authority to employ, at the cost and expense of Baxter, such consultants, accountants, attorneys and other representatives and

8. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in subparagraph III.A.1. of this order.

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

10. The 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 Factor VIII Inhibitor Treatments for sale in the United States and shall report in writing to the Commission every sixty (60) days concerning compliance by the Respondent and the Acquirer or the New Acquirer, with the provisions of Paragraph II. of this order and the efforts of the Acquirer or the New Acquirer to obtain all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States.

B. If the Commission terminates the Divestiture Agreement pursuant to subparagraph II.C.8. of this order, the Commission may direct the trustee to seek a New Acquirer, as provided for in Paragraph IV. of this order and the Divested Inhibitor Assets shall revert back to the Respondent.

#### IV.

**IT IS FURTHER ORDERED** that:

A. If Baxter fails to comply with the terms of Paragraph II. of this order and to divest absolutely and in good faith the Autoplex Assets within four (4) months from the date Respondent signed the Agreement Containing Consent Order, or if the Commission terminates the Divestiture Agreement pursuant to subparagraph II.C.8. of this order, then any executed Divestiture Agreement with the Acquirer shall be terminated and the Commission may appoint a trustee to: (a) divest either the Autoplex Assets or the FEIBA Assets; (b) effect all arrangements, including, but not limited to, the licensing of any Baxter patents and know-how not related solely to the research, development, manufacture or sale of Factor VIII Inhibitor Treatments, necessary to enable the New Acquirer to manufacture

and sell a Factor VIII Inhibitor Treatment using the Divested Inhibitor Assets; and (c) enter into a Divestiture Agreement with a New Acquirer that satisfies the requirements of Paragraph II.C. of this order. In the event that the New Acquirer does not choose to acquire all of the physical assets included in the Divested Inhibitor Assets because the New Acquirer does not need such physical assets in order to engage in the manufacture and sale of Factor VIII Inhibitor Treatments, Respondent shall not be required to divest such assets. The purpose of the divestiture is to ensure the continued competition between Autoplex and FEIBA, in the same manner in which these products would compete absent the Acquisition, and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint. Neither the decision of the Commission to appoint the trustee nor the decision of the Commission not to appoint the trustee to divest either the Autoplex or the FEIBA Assets under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5( 1) 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 trustee is appointed under Paragraph IV.A. of this order to divest either the Autoplex Assets or the FEIBA Assets to a New Acquirer and to enter into a Divestiture Agreement with the New Acquirer, Respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of Baxter, which consent shall not be unreasonably withheld. If Baxter 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 Baxter of the identity of any proposed trustee, Baxter shall be deemed to have consented to the selection of the proposed trustee. This trustee may be the same trustee as appointed pursuant to Paragraph III. of this order.

2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest either the Autoplex Assets or the FEIBA Assets to a New Acquirer and to enter into a Divestiture Agreement with the New Acquirer pursuant to the terms of Paragraph II.C. 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 trustee, Baxter 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 trustee all rights and powers necessary to permit the trustee to effect the divestiture required by Paragraph IV.A. of this order.

4. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in subparagraph IV.B.3. of this order to divest either the Autoplex Assets or the FEIBA Assets and to enter into a Divestiture Agreement with the New Acquirer that satisfies the requirements of Paragraph II.C. of this order. If, however, at the end of the twelve (12) month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the twelve (12) month 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 the twelve (12) month period only two (2) times.

5. The trustee shall have full and complete access to the personnel, books, records, data, facilities and technical information related to the manufacture, distribution, or sale of Factor VIII Inhibitor Treatments or to any other relevant information, as the trustee may request. Respondent shall develop such financial or other information as such trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the trustee's accomplishment of his or her responsibilities.

6. The 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 trustee's obligation to expeditiously accomplish the remedial purpose of the order; to assure that Baxter effects all arrangements necessary to enable the New Acquirer to produce a Factor VIII Inhibitor Treatment using the Divested Inhibitor Assets; to assure that Baxter enters into a Divestiture Agreement with the New Acquirer to acquire the Divested Inhibitor Assets that complies with the provisions of Paragraph II.C. of this order; and to assure that Baxter complies with the remaining provisions of Paragraph II.D. of this order. The divestiture shall be made to and the Divestiture Agreement shall be made with the New Acquirer in the manner set forth

in Paragraph II.C. of this order; provided, however, if the trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission.

7. The trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondent 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 locating a New Acquirer and assuring compliance with this order.

8. Respondent shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the 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 the misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

9. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph IV.B. 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 trustee issue such additional orders or directions as may be necessary or appropriate to comply with the terms of this order.

11. The trustee shall have no obligation or authority to operate or maintain the Divested Inhibitor Assets.

12. The trustee shall report in writing to Respondent and the Commission every sixty (60) days concerning his or her efforts to divest either the Autoplex Assets or the FEIBA Assets as required by this order.

**V.**

**IT IS FURTHER ORDERED** that:

A. Within four (4) months of the date Baxter signed the Agreement Containing Consent Order in this matter, Baxter shall grant a non-exclusive, royalty-free license, in perpetuity, and in good faith, of the Immuno Fibrin Sealant Assets, and shall execute an agreement that includes the provisions required by Paragraph V.C. of this order .

B. The Immuno Fibrin Sealant Assets shall be licensed only to a Fibrin Sealant Licensee 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 licensing of the Immuno Fibrin Sealant Assets is to ensure the continued research and development competition between Immuno's Fibrin Sealant and Baxter's Fibrin Sealant, to ensure the use of the Immuno Fibrin Sealant Assets for the research, development, manufacture and sale of a Fibrin Sealant approved by the FDA for sale in the United States, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's complaint.

C. Respondent's agreement with the Fibrin Sealant Licensee (hereinafter "License Agreement") shall not include any provision restricting the Fibrin Sealant Licensee's ability to sublicense the product. The License Agreement shall include the following and Baxter shall commit to satisfy the following:

1. Baxter shall grant to the Fibrin Sealant Licensee the right of reference to the data contained in Immuno's PLA No. 87-0509 for the Immuno Fibrin Sealant Assets on file with the FDA. Baxter shall make all necessary filings with the FDA authorizing the FDA to refer to Immuno's PLA No. 87-0509 for the data in support of the Fibrin Sealant Licensee's PLA for a Fibrin Sealant, including any supplemental PLAs or related PLAs. Provided, however, that the right of reference granted in this subparagraph does not

constitute a general release of the data in Immuno's PLA No. 87-0509, including any supplemental PLAs or related PLAs, except as it may appear in labeling.

2. Once all necessary FDA approvals are obtained by Baxter (or Immuno prior to the Acquisition) to manufacture and sell Immuno's Fibrin Sealant in the United States, Baxter shall Contract Manufacture and deliver to the Fibrin Sealant Licensee in a timely manner and under reasonable terms and conditions, a supply of Immuno's Fibrin Sealant specified in the License Agreement, at Baxter's Cost for a period not to exceed three (3) years from the date the License Agreement is approved, or four (4) months after the date the Fibrin Sealant Licensee obtains all necessary FDA approvals to manufacture Fibrin Sealant for sale in the United States, whichever is earlier; **provided, however,** that the time period may be extended by the Commission in twelve (12) month increments for a period not to exceed and additional forty-eight (48) months if the trustee appointed pursuant to Paragraph VI. of this order submits to the Commission the certification provided for in subparagraph V.C.8. of this order.

3. Baxter shall make representations and warranties to the Fibrin Sealant Licensee that the Fibrin Sealant that is Contract Manufactured by Baxter for the Fibrin Sealant Licensee meets the FDA approved specifications therefor and is not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. § 321, et seq. Baxter shall agree to indemnify, defend and hold the Fibrin Sealant Licensee harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Fibrin Sealant Contract Manufactured by Baxter pursuant to subparagraph V.C.2. of this order to meet FDA specifications. This obligation shall be contingent upon the Fibrin Sealant Licensee giving Baxter prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting Baxter to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel. This obligation shall not require Baxter to be liable for any negligent act or omission of the Fibrin Sealant Licensee or for any representations and warranties, express or implied, made by the Fibrin Sealant Licensee that exceed the representations and warranties made by Baxter to the Fibrin Sealant Licensee.



4. During the term of Contract Manufacturing, upon reasonable request by the Fibrin Sealant Licensee or the trustee appointed pursuant to Paragraph VI. of this order, Baxter shall make available to the trustee, or its agents or representatives, all records kept in the normal course of business that relate to the cost of manufacturing the Contract Manufactured Fibrin Sealant.

5. Upon reasonable notice and request from the Fibrin Sealant Licensee to Respondent, Respondent shall provide: (a) such assistance and advice as is reasonably necessary to enable the Fibrin Sealant Licensee to obtain all necessary FDA approvals to manufacture Fibrin Sealant for sale in the United States; (b) such assistance as is reasonably necessary to enable the Fibrin Sealant Licensee to manufacture Fibrin Sealant in substantially the same manner and quality employed or achieved by Baxter once it begins manufacturing the Immuno Fibrin Sealant; and (c) consultation with knowledgeable employees of Baxter and training at a either Immuno's or the Fibrin Sealant Licensee's facility, whichever the Fibrin Sealant Licensee chooses, for a period of time, not to exceed one (1) year, sufficient to satisfy the Fibrin Sealant Licensee's management that its personnel are adequately trained in the manufacture of Fibrin Sealant for sale in the United States. Such assistance shall include an on-site inspection of Baxter's facility that is performing the Contract Manufacturing, upon reasonable notice and request of the Fibrin Sealant Licensee. Respondent may require reimbursement from the Fibrin Sealant Licensee for all its direct out-of-pocket expenses incurred in providing the services required by this subparagraph V.C.5.

6. The License Agreement shall require the Fibrin Sealant Licensee to submit to the Commission, with the divestiture application filed by Respondent with the Commission requesting approval of the proposed license, a certification attesting to the good faith intention of the Fibrin Sealant Licensee, and including an actual plan by the Fibrin Sealant Licensee, to obtain in an expeditious manner all necessary FDA approvals to manufacture Fibrin Sealant for sale in the United States.

7. The License Agreement shall require the Fibrin Sealant Licensee to submit to the trustee appointed pursuant to Paragraph VI. of this order, periodic verified written reports setting forth in detail the efforts of the Fibrin Sealant Licensee to sell Contract Manufactured Fibrin Sealant in the United States and to obtain all FDA approvals

necessary to manufacture its own Fibrin Sealant for sale in the United States. The License Agreement shall require the first such report to be submitted 60 days from the date the Commission approves the License Agreement and every 90 days

Sealant Licensee pursuant to the provisions of Paragraph VII. of this order.

D. While the obligations imposed by Paragraphs V., VI. or VII. of this order are in effect, Respondent shall take such actions as are necessary: (1) to maintain and obtain all necessary FDA approvals to research, develop, manufacture and sell Immuno's Fibrin Sealant in the United States; (2) to maintain the viability and marketability of the Immuno Fibrin Sealant Assets as well as all tangible assets, including manufacturing facilities, needed to Contract Manufacture and sell Immuno's Fibrin Sealant; and (3) to prevent the destruction, removal, wasting, deterioration or impairment of any of the Immuno Fibrin Sealant Assets or tangible assets, including manufacturing facilities, needed to Contract Manufacture and sell Immuno's Fibrin Sealant, except for ordinary wear and tear.

## VI.

**IT IS FURTHER ORDERED** that:

A. At any time after this order becomes final, the Commission may appoint a trustee to monitor whether Baxter and the Fibrin Sealant Licensee expeditiously perform their respective responsibilities as required by the License Agreement approved by the Commission and this order. Baxter shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the trustee appointed pursuant to this Paragraph:

1. The Commission shall select the trustee, subject to the consent of Baxter, which consent shall not be unreasonably withheld. If Baxter 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 Baxter of the identity of any proposed trustee, Baxter shall be deemed to have consented to the selection of the proposed trustee. This trustee may be the same trustee appointed pursuant to Paragraphs III. or IV. of this order.

2. The trustee shall have the power and authority to monitor Respondent's compliance with the terms of Paragraph V. of this order and with the License Agreement with the Fibrin Sealant Licensee.



expenses result from the misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

8. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in subparagraph VI.A.1. of this order.

9. The Commission may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of Paragraph V. of this order and the License Agreement with the Fibrin Sealant Licensee.

10. The trustee shall evaluate reports submitted to it by the Fibrin Sealant Licensee with respect to the efforts of the Fibrin Sealant Licensee to obtain all necessary FDA approvals to manufacture Fibrin Sealant for sale in the United States and shall report in writing to the Commission every sixty (60) days concerning compliance by the Respondent and the Fibrin Sealant Licensee with the provisions of Paragraph V. of this order and the efforts of the Fibrin Sealant Licensee to obtain all necessary FDA approvals to manufacture Fibrin Sealant for sale in the United States.

B. If the Commission terminates the Divestiture Agreement pursuant to subparagraph V.C.8. of this order, the Immuno Fibrin Sealant Assets shall revert back to the Respondent and the Commission may direct the trustee to seek a new Fibrin Sealant Licensee, as provided for in Paragraph VII. of this order.

## VII.

**IT IS FURTHER ORDERED** that:

A. If Baxter fails to comply with the terms of Paragraph V. of this order and enter into a License Agreement with a Fibrin Sealant Licensee within four (4) months from the date Respondent signed the Agreement Containing Consent Order, the Commission may appoint a trustee to: (a) grant a non-exclusive, royalty-free license, in perpetuity, and in good faith, of the Immuno Fibrin Sealant Assets to a Fibrin Sealant Licensee; and (b) enter into a License Agreement with a Fibrin Sealant Licensee that satisfies the requirements of Paragraph V.C. of this order. The purpose of the licensing of the Immuno Fibrin Sealant Assets is to ensure

the continued research and development competition between Immuno's Fibrin Sealant and Baxter's Fibrin Sealant, to ensure the use of the Immuno Fibrin Sealant Assets for the research, development, manufacture and sale of Fibrin Sealant approved by the FDA for sale in the United States, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's complaint. Neither the decision of the Commission to appoint the trustee nor the decision of the Commission not to appoint the trustee to license the Immuno Fibrin Sealant Assets under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5( 1) 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 trustee is appointed under Paragraph VII.A. of this order to license the Immuno Fibrin Sealant Assets and enter into a License Agreement with a Fibrin Sealant Licensee, Baxter shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of Baxter, which consent shall not be unreasonably withheld. If Baxter 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 Baxter of the identity of any proposed trustee, Baxter shall be deemed to have consented to the selection of the proposed trustee. This trustee may be the same trustee as appointed pursuant to Paragraphs III., IV. or VI. of this order.

2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to grant a non-exclusive, royalty-free license of the Immuno Fibrin Sealant Assets to a Fibrin Sealant Licensee and to enter into a License Agreement with a Fibrin Sealant Licensee pursuant to the terms of Paragraph V.C. of this order, which License Agreement shall be subject to the prior approval of the Commission.

3. Within ten (10) days after appointment of the

necessary to permit the trustee to effect the non-exclusive, royalty-free license required by this order.

4. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in subparagraph VII.B.3. of this order to license the Immuno Fibrin Sealant Assets and enter into a License Agreement with a Fibrin Sealant Licensee that satisfies the requirements of Paragraph V.C. of this order. If, however, at the end of the twelve (12) month period, the trustee has submitted a plan of licensing or believes that licensing can be achieved within a reasonable time, the twelve (12) month 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 the twelve (12) month period only two (2) times.

5. The trustee shall have full and complete access to the personnel, books, records, data, facilities, and technical information related to the Immuno Fibrin Sealant Assets, or to any other relevant information, as the trustee may reasonably request. Respondent shall develop such financial or other information as such trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the trustee's ability to accomplish the licensing of the Immuno Fibrin Sealant Assets required by this order. Any delays in licensing the Immuno Fibrin Sealant Assets required by this order caused by Respondent shall extend the time under subparagraph VII.B.4. of the order for accomplishing the licensing of the Immuno Fibrin Sealant Assets required by this order in an amount equal to the delay, as determined by the Commission or, for the court-appointed trustee, by the court.

6. The 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 grant a license of the Immuno Fibrin Sealant Assets as required by this order at no minimum price and the trustee's obligation to expeditiously accomplish the remedial purpose of the order; to assure that Baxter enters into a License Agreement with a Fibrin Sealant Licensee to acquire the Immuno Fibrin Sealant Assets that complies with the provisions of Paragraph V.C. of this order; and to assure that Baxter complies with the remaining provisions of Paragraph V.D. of this order. The license shall be made to Fibrin Sealant Licensee in a manner set forth by this order; provided, however, if the trustee receives bona fide offers

from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the trustee shall grant a non-exclusive, royalty-free license to the acquiring entity selected by Respondent from among those approved by the Commission.



12. The trustee shall report in writing to Baxter and to the Commission every sixty (60) days concerning the trustee's efforts to grant a non-exclusive, royalty-free license of the Immuno Fibrin Sealant Assets as required by this order.

**VIII.**

**IT IS FURTHER ORDERED** that Respondent shall comply with all terms of the Interim Agreement, attached to this order and made a part hereof as Appendix I.

**IX.**

**IT IS FURTHER ORDERED** that:

A. Within sixty (60) days after the date this order becomes final and every ninety (90) days thereafter until Baxter has fully complied with the provisions of Paragraphs II., IV., V. and VII. of this order, Baxter shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with these Paragraphs of this order. Baxter shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with these Paragraphs of this order, including a description of all substantive contacts or negotiations for accomplishing the divestiture, entering into the Divestiture Agreement and entering into a license Agreement, required by this order, including the identity of all parties contacted. Baxter shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the Divestiture Agreement required by Paragraph II. and the License Agreement required by Paragraph V. of this order.

B. One (1) year from the date this order becomes final and annually until Respondent has complied with all terms of this order or until the Acquirer or New Acquirer has obtained all necessary FDA approvals to manufacture Factor VIII Inhibitor Treatments for sale in the United States and the Fibrin Sealant Licensee has obtained all necessary FDA approvals to manufacture Fibrin Sealant for sale in the United States, whichever is later, and at such other times as the Commission may require, Respondent shall file a verified written report with the Commission setting

forth in detail the manner and form in which it has complied and is complying with this order.

**X.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this order, and subject to any legally recognized privilege, upon written request and on reasonable notice to Respondent, Respondent shall permit any duly authorized 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 Respondent, relating to any matters contained in this order; and

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

**XI.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to any change in Respondent such as dissolution, assignment or sale resulting in the emergence of a successor, the creation or dissolution of subsidiaries or any other change that may affect compliance obligations arising out of the order.

By the Commission, Commissioner Starek recused.

Donald S. Clark  
Secretary

SEAL

ISSUED: March 24, 1997

APPENDIX I

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

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)  
In the Matter of )  
)  
**BAXTER INTERNATIONAL INC. ,** ) File No. 971-0002  
a corporation. )  
)  
)  
)  

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INTERIM AGREEMENT

This Interim Agreement is by and between Baxter International Inc. ("Baxter"), a corporation organized and existing under the laws of the State of Delaware, 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.*

PREMISES

**WHEREAS**, Baxter has proposed to acquire the majority of the outstanding voting common stock of Immuno International AG; and

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

**WHEREAS**, if the Commission accepts the Agreement Containing Consent Order ("Consent Agreement"), the Commission will place it on the public record for a period of at least sixty (60) days and subsequently may either withdraw such acceptance or issue and serve its Complaint and decision in disposition of the proceeding

pursuant to the provisions of Section 2.34 of the Commission's Rules; and

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

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

**WHEREAS**, Baxter understands that no act or transaction

including manufacturing facilities, needed to Contract Manufacture and sell Immuno's Fibrin Sealant; and (3) to prevent the destruction, removal, wasting, deterioration or impairment of any of the Immuno Fibrin Sealant Assets or tangible assets, including manufacturing facilities, needed to Contract Manufacture and sell Immuno's Fibrin Sealant, except for ordinary wear and tear.

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

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

b. the date the Commission finally issues its Complaint and its Decision and Order.

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

6. For the purpose of determining or securing compliance with this Interim Agreement, subject to any legally recognized privilege, and upon written request, and on reasonable notice, to Baxter made to its principal office, Baxter shall permit any duly authorized representative or representatives of the Commission:

a. access, during the office hours of Baxter 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 Baxter relating to compliance with this Interim Agreement; and

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

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

Dated:

FEDERAL TRADE COMMISSION BAXTER INTERNATIONAL INC.

By: \_\_\_\_\_  
Stephen Calkins  
General Counsel

By: \_\_\_\_\_  
Arthur F. Staubitz  
Senior Vice President  
and General Counsel

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