

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission "), having initiated an investigation of the Acquisition of certain stock of Immuno International AG ("Immuno") by Baxter International Inc. ("Baxter"), and it now appearing that Baxter, hereinafter sometimes referred to as "Proposed Respondent, " is willing to enter into an Agreement Containing Consent Order ("Agreement ") to divest certain assets, license certain assets, contract manufacture certain products, and provide for certain other relief:

IT IS HEREBY AGREED by and between Proposed Respondent, by its duly authorized officers and its attorneys, and counsel for the Commission that:

1. Proposed Respondent Baxter is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal place of business located at One Baxter Parkway, Deerfield, Illinois 60015.
2. Proposed Respondent admits all the jurisdictional facts set forth in the draft of complaint here attached.
3. Proposed Respondent waives:
 - (a) any further procedural steps;

(b) the requirement that the Commission 's decision contain a statement of findings of fact and conclusions of law;

(c) all rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this Agreement; and

(d) any claims under the Equal Access to Justice Act.

4. This Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify the Proposed Respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This Agreement is for settlement purposes only and does

once the order has been issued, it will be required to file one or more compliance reports showing it has fully complied with the order. Proposed Respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

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.

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

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

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.

9. The Divestiture Agreement with an Acquirer shall provide that if it is terminated, the Autoplex Assets shall revert back to the Respondent and either the Autoplex Assets or the FEIBA Assets shall be divested by the trustee to a New Acquirer pursuant to the provisions of Paragraph IV. of this order.

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 assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all expenses incurred. The Commission shall approve the account of the trustee, including fees for his or her services.

7. 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.

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.

B0 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.

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

resulting from the Acquisition as alleged in the Commission 's
complaint.

C0 Respondent 's agreement with the Fibrin Sealant Licensee
(hereinafter

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

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 thereafter until all necessary FDA approvals are obtained by the Fibrin Sealant Licensee to manufacture Fibrin Sealant for sale in the United States. The License Agreement shall also require the Fibrin Sealant Licensee to report to the Commission and the trustee within ten (10) days of its

Licensee shall provide that if it is terminated, the License Agreement shall be terminated and the trustee shall grant a new non-exclusive, royalty-free license to a new Fibrin Sealant Licensee pursuant to the provisions of Paragraph VII. of this order.

D0 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:

A0 At any time after this order becomes final, the

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 V. of this order and monitor the efforts of the Fibrin Sealant Licensee to obtain all necessary FDA approvals to manufacture and sell Fibrin Sealant.

4 The trustee shall serve until such time as the Fibrin Sealant Licensee has received all necessary FDA approvals to research, develop, manufacture and sell Fibrin Sealant 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 Immuno 's Fibrin Sealant, 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 Fibrin Sealant. 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 V. of this order and the License Agreement with the Fibrin Sealant Licensee.

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 assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all expenses incurred. The Commission shall approve the account of the trustee, including fees for his or her services.

7 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

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.

B0 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:

A0 If Baxter fails to comply with the terms of Paragraph V.

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 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.

7 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 or a court may set. The trustee shall have the authority to employ, at the cost and expense of Baxter, 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 licensing 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 Baxter 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 ability to grant a non-exclusive, royalty-free license of the Immuno Fibrin Sealant Assets.

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 VII.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 Immuno Fibrin Sealant Assets.

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:

A0 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.

B0 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:

A0 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

B0 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.

Signed this ____ day of _____, 1996

By: _____
Pamela L. Taylor
Christina R. Perez
Attorneys

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

APPROVED:

Michael Sennett
Bell Boyd & Lloyd
Counsel for Baxter
International Inc.

Ann Malester
Assistant Director

George S. Cary
Senior Deputy Director

William J. Baer
Director

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 contemplated by this Interim Agreement shall be deemed immune or exempt from the provisions of the antitrust laws or the Federal Trade Commission Act by reason of anything contained in this Interim Agreement.

NOW, THEREFORE, Baxter agrees, upon the understanding that the Commission has not yet determined whether the proposed Acquisition will be challenged, and in consideration of the Commission's agreement that, at the time it accepts the Consent Agreement for public comment, it will grant early termination of the Hart-Scott-Rodino waiting period, as follows:

1. That it will execute and be bound by the terms of the Order contained in the Consent Agreement, as if it were final, from the date Baxter signs the Consent Agreement.

2. That it will 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 manufacturing facilities needed to Contract Manufacture and sell both of the Factor VIII Inhibitor Treatments, except for ordinary wear and tear.

3. That it will 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.

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

7. 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

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of)

BAXTER INTERNATIONAL INC. ,)
a corporation.)

) Docket No.
)
)
)
)
)
)

COMPLAINT

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

1. ~~Respondent~~ **Baxter** is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal place of business located at One Baxter Parkway, Deerfield, Illinois 60015.
2. Respondent is, and at all times relevant herein has been, engaged in commerce as

"commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C.

in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C.

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

VI. BARRIERS TO ENTRY

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

VII. EFFECTS OF THE ACQUISITION

14. The effects of the Acquisition may be substantially to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:
 - a. by eliminating direct actual competition between Baxter and Immuno in the relevant markets;
 - b. by increasing the likelihood that Baxter will unilaterally exercise market power in the relevant markets; and
 - c. by creating a dominant firm in the relevant markets.

VIII. VIOLATIONS CHARGED

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

**ANALYSIS OF PROPOSED CONSENT ORDER
TO AID PUBLIC COMMENT**

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a proposed Consent Order ("Order") from Baxter International Inc. ("Baxter"), which remedies the anticompetitive effects of Baxter's acquisition of Immuno International AG ("Immuno"). The proposed order requires Baxter to divest assets and undertake certain actions to restore competition in the market for treatments of Factor VIII inhibitors in hemophiliacs, and to license assets and undertake certain actions to restore competition in the market for fibrin sealant. In addition, Baxter has signed an Interim Agreement providing that the terms of the Consent Agreement will become effective immediately.

for sale in the United States, and are likely to be two of the first companies to receive FDA approval to do so. The United States market for an FDA-approved fibrin sealants could be as large as \$400 million per year. The acquisition would eliminate the significant on-going competition between Baxter and Immuno in the research and development, as well as future competition in the manufacture and sale, of fibrin sealant in the United States.

The proposed Order remedies this loss of competition by requiring Baxter to license Immuno's product in development to a Commission-approved licensee within four months of the date Baxter signed the Consent Agreement.

The Order also requires Baxter to provide to the Commission a report of compliance with the divestiture and licensing provisions of the Order within sixty (60) days following the date the Order becomes final, and every ninety (90) days thereafter until Baxter has completed the divestiture and licensing. The Order also requires Baxter to notify the Commission at least thirty (30) days prior to any change in the structure of Baxter resulting in the emergence of a successor.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.