

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Robert Pitofsky, Chairman
 Mary L. Azcuenaga
 Janet D. Steiger
 Roscoe B. Starek, III
 Christine A. Varney

In the Matter of

THE UPJOHN COMPANY,
 a corporation, and

PHARMACIA AKTIEBOLAG,
 a corporation.

Docket No. C-3638

Decision and Order

The Federal Trade Commission having initiated an investigation of the proposed merger by respondents The Upjohn Company ("Upjohn") and Pharmacia AB ("Pharmacia"), and the respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement containing a Consent Order, an admission by respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have 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 Upjohn 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 7000 Portage Road, Kalamazoo, Michigan 49001.

2. Respondent Pharmacia is a corporation organized, existing, and doing business under and by virtue of the laws of Sweden, with its principal place of business located at Frösundaviks allé 15, S-171 97 Stockholm, Sweden.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

A. "Upjohn" means The Upjohn Company, its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Upjohn; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

B. "Pharmacia" means Pharmacia Aktiebolag, its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Pharmacia; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

- C. "Respondents" means Upjohn and Pharmacia.
- D. "Commission" means the Federal Trade Commission.
- E. "NCI" means the National Cancer Institute.
- F. "Merger" means the combination of Upjohn and Pharmacia pursuant to a Combination Agreement dated August 20, 1995.
- G. "9-AC" or "9-amino-20(S)-camptothecin" means the semisynthetic compound which refers to the compound 1-pyrano [3',4':6,7] indolizino [1,2-b] quinoline-3,14 (4H,12H)-dione, 10-amino-4-ethyl-4-hydroxy-(S) in respect of its therapeutic indication for the treatment of cancer.
- H. "CPT-11" or "irinotecan hydrochloride trihydrate" means the chemical compound which refers to the compound (+) - (4S) -4, 11 - diethyl - 4 - hydroxy - 9 - [(4 - piperidinopiperidino) carbonyl - oxy] - 1H - pyrano [3', 4' :6, 7] indolizino [1, 2 - b] quinoline - 3, 14 (4H, 12H) - dione hydrochloride trihydrate.
- I. "Pharmacia's 9-AC Assets" means an exclusive license to all Pharmacia's assets relating to the research and development of 9-AC for sale in the United States that are not part of Pharmacia's physical facilities or other tangible assets. "Pharmacia's 9-AC Assets" includes, but is not limited to, all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, testing and quality control data, research data, technical information, information stored on management information systems (and specifications sufficient for the Acquirer to use such information), proprietary software used in connection with Pharmacia's 9-AC, and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States for Pharmacia's 9-AC. "Pharmacia's 9-AC Assets" also includes the assignment of all rights of Pharmacia to NCI patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, testing and quality control data, research materials, technical information, information stored on management information systems (and specifications sufficient for the Acquirer to use such information), proprietary software used in connection with Pharmacia's 9-AC and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States for Pharmacia's 9-AC.
- J. "Acquirer" means the entity to whom the Respondents shall divest Pharmacia's 9-AC Assets pursuant to this Order.

K. "Cost" means Pharmacia's actual per unit cost of manufacturing Pharmacia's 9-AC, which may be adjusted once annually to reflect any increases in Pharmacia's actual cost, provided, however, that for any year, the total rate of such adjustment with respect to all components of cost other than material and labor shall not exceed the rate of increase in the Consumer Price Index for such year.

II.

IT IS FURTHER ORDERED that:

A. Respondents shall divest, absolutely and in good faith, within twelve (12) months of the date this Order becomes final, Pharmacia's 9-AC Assets.

B. Respondents shall divest Pharmacia's 9-AC Assets only to an Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. Respondents shall obtain all necessary approvals and releases for such divestiture from NCI as a condition of the Commission's prior approval. The purpose of the divestiture of Pharmacia's 9-AC Assets is to ensure continued research and development of Pharmacia's 9-AC, in the same manner in which Pharmacia's 9-AC would be researched and developed absent the proposed Merger, and to remedy the lessening of competition resulting from the proposed Merger as alleged in the Commission's Complaint.

C. At the Acquirer's option, Respondents shall enter into a supply agreement with the Acquirer. Such agreement, if entered into, shall be provided to the Commission as part of Respondents' application to the Commission for approval of the divestiture. This supply agreement shall include the following and Respondents shall commit to satisfy the following:

1. Respondents shall manufacture and deliver to the Acquirer in a timely manner the Acquirer's requirements for 9-AC at Respondents' Cost for a period not to exceed three (3) years from the date the divestiture is approved. This supply agreement can be cancelled at the request of the Acquirer.

2. Respondents shall make representations and warranties to the Acquirer that the 9-AC manufactured by Respondents for the Acquirer meets the United States Food and Drug Administration 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. Respondents shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions,

demands, liabilities, expenses or losses alleged to result from the failure of the 9-AC manufactured for the Acquirer by Respondents to meet FDA specifications. This obligation shall be contingent upon the Acquirer giving Respondents prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting Respondents 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 Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the Acquirer.

3. During the term of the supply agreement, upon reasonable request by the Acquirer, Respondents shall make available to the Acquirer all records kept in the normal course of business that relate to the cost of manufacturing 9-AC.

D. The time period for divestiture pursuant to Paragraph II. of this Order shall be tolled if and when Respondents:

1. provide to the Commission objective evidence, including, but not limited to, results of clinical trials indicating that, based on 9-AC's or CPT-11's medical profile, and through no fault of Respondents, either Pharmacia's 9-AC or Upjohn's CPT-11 is not medically safe or efficacious for use in the treatment of colorectal cancer; and

2. petition the Commission to modify this Order, pursuant to section 5(b) of the FTC Act and Section 2.51 of the Commission's Rules of Practice, based on the circumstances described in Subparagraph II.D.1 of this Order.

This tolling of the time period for divestiture shall end when the Commission rules on Respondents' petition to modify this Order.

III.

IT IS FURTHER ORDERED that:

A. If Upjohn and Pharmacia have not divested, absolutely and in good faith and with the Commission's prior approval, Pharmacia's 9-AC Assets within the time required by Paragraph II.A. of this Order, the Commission may appoint a trustee to divest, at Pharmacia's option, either (1) an exclusive United

States license and a nonexclusive worldwide (excluding the United States) license in perpetuity, and in good faith, to all Pharmacia's assets relating to the research and development of 9-AC for sale throughout the world or (2) an exclusive worldwide license, in perpetuity, and in good faith, to all Pharmacia's assets relating to the research and development of 9-AC for sale throughout the world. The trustee shall obtain all necessary approvals and releases for the applicable license from NCI. Neither the decision of the Commission to direct the trustee nor the decision of the Commission not to direct the trustee to divest a license 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 Respondents to comply with this Order.

B. If the trustee is directed under Subparagraph A. of this Paragraph to divest, at Pharmacia's option, either (1) an exclusive United States license and a nonexclusive worldwide (excluding the United States) license or (2) an exclusive worldwide license, Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

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

2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest, at Pharmacia's option, either (1) an exclusive United States license and a nonexclusive worldwide (excluding the United States) license or (2) an exclusive worldwide license.

3. Within ten (10) days after the appointment of the trustee, Respondents shall execute a 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 the rights and powers necessary to permit the trustee to assure Respondents' compliance with the terms of this Order. As part of the trustee agreement, the trustee shall execute confidentiality agreement(s) with Respondents.

4. The trustee shall have twelve (12) months from the date the Commission approves the appointment of the trustee to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend this period only two (2) times.

5. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to Pharmacia's 9-AC, or to any other relevant information, as the trustee may reasonably request, including but not limited to all records kept in the normal course of business that relate to research and development of, and the cost of manufacturing, Pharmacia's 9-AC. Respondents shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.

6. The trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made in the manner and to the Acquirer as set out in Paragraphs II and III of this order, as appropriate; 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 Respondents from among those approved by the Commission. If requested by the trustee or Acquirer, Respondents shall provide the Acquirer with the assistance required by Paragraph IV. of this Order.

7. The trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The trustee shall have the authority to employ, at the cost and expense of Respondents, 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 monies derived from the sale 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 Respondents. The trustee's compensation shall be based at least in significant part on a commission arrangement based on a percentage of the selling price of the assets divested.

8. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, 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 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 III.A. 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 accomplish the divestiture required by this Order.

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

12. If a divestiture application filed pursuant to this Paragraph III. is pending before the Commission, and Respondents petition the Commission to modify this Order based on the conditions in Paragraph II.D., then the Commission shall not approve the divestiture application until it rules on the petition to modify.

IV.

IT IS FURTHER ORDERED that:

A. Upon reasonable notice and request from the Acquirer to Respondents, Respondents shall provide information, technical assistance and advice to the Acquirer with respect to Pharmacia's 9-AC Assets such that the Acquirer will be capable of continuing the current research and development. Such assistance shall

include reasonable consultation with knowledgeable employees of Respondents and training at the Acquirer's facility for a period of time sufficient to satisfy the Acquirer's management that its personnel are adequately knowledgeable about Pharmacia's 9-AC Assets. However, Respondents shall not be required to continue providing such assistance for more than one (1) year after divestiture of Pharmacia's 9-AC Assets. Respondents may require reimbursement from the Acquirer for all of their own direct costs incurred in providing the services required by this Paragraph. Direct costs, as used in this Paragraph, means all actual costs incurred exclusive of overhead costs.

B. Upon reasonable notice and request from the Acquirer, Respondents shall provide information, technical assistance and advice sufficient to assist the Acquirer in obtaining all necessary FDA approvals to manufacture 9-AC for use in clinical trials in the United States. Upon reasonable notice and request from the Acquirer, Respondents shall also provide consultation with knowledgeable employees of Respondents and training at the Acquirer's facility for a period of time, not to exceed one (1) year, sufficient to satisfy the Acquirer's management that its personnel are adequately trained in the manufacture of 9-AC. Respondents may require reimbursement from the Acquirer for all of their own direct costs incurred in providing the services required by this Paragraph. Direct costs, as used in this Paragraph, means all actual costs incurred exclusive of overhead costs.

V.

IT IS FURTHER ORDERED that Respondents shall comply with all terms of the Interim Agreement, attached to this order and made a part hereof as Appendix I. Said Interim Agreement shall continue in effect until the provisions in Paragraphs II., III. and IV. of this Order are complied with or until such other time as is stated in said Interim Agreement.

VI.

IT IS FURTHER ORDERED that if, following approval of the divestiture required by Paragraph II. of this Order, disputes arise between Respondents and the Acquirer regarding: (1) fulfillment of the terms of the supply agreement described in Paragraph II.C of this Order; (2) the continuation of the clinical trials for the testing of 9-AC described in Attachment A to Appendix I of this Order; or (3) the continuation of the defense of existing patents and the pursuit of the filing of new patents relating to Pharmacia's 9-AC, the Acquirer may elect to cause the issue to be submitted to outside, independent, binding arbitration in the District of Columbia. In the event the Acquirer so elects, Respondents shall agree to submit to such arbitration, and the issue shall be settled by arbitration in

accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") and AAA's Supplementary Procedures for International Commercial Arbitration or any successor rules thereto. Judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The decision of the arbitrator, after confirmation by the court pursuant to 9 U.S.C. § 9, or succeeding statutory provisions, shall be final and binding upon the parties, and the failure of the Respondents thereafter to abide by the arbitrator's award shall be a violation of this Order.

VII.

IT IS FURTHER ORDERED that:

A. Within sixty (60) days after the date this Order becomes final and every sixty days (60) days thereafter until Respondents have fully complied with the provisions of Paragraphs II.A. and II.B. or III. of this Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs II., III., IV. and V. of this Order, including a description of all substantive contacts or negotiations for accomplishing the divestiture and the identity of all parties contacted. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

B. One (1) year from the date this Order becomes final, annually on the anniversary of the date this Order becomes final, and at all other times as the Commission may require, until Respondents have fully complied with Paragraphs II.C., IV. and V., Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with Paragraphs II.C., IV. and V. of this Order.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representatives of the Commission:

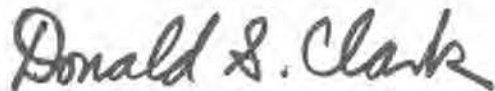
A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents, relating to any matters contained in this Order; and

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

IX.

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

By the Commission.



Donald S. Clark
Secretary

SEAL

ISSUED: February 8, 1996