

IN THE MATTER OF

THE UPJOHN COMPANY, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket C-3638. Complaint, Feb. 8, 1996--Decision, Feb. 8, 1996*

This consent order requires, among other things, the respondents to divest, within 12 months, Pharmacia Aktiebolag's 9-AC assets, an inhibitor drug for the treatment of colorectal cancer, to a Commission-approved acquirer. If the transaction is not completed in the prescribed time, the Commission will be allowed to appoint a trustee.

Appearances

For the Commission: *Ann Malester, Claudia Higgins and William Baer.*

For the respondents: *Stuart Meiklejohn, Sullivan & Cromwell, New York, N.Y. and Steven Sunshine, Shearman & Sterling, Washington, D.C.*

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondents The Upjohn Company ("Upjohn"), a Michigan corporation subject to the jurisdiction of the Commission, and Pharmacia Aktiebolag ("Pharmacia"), a Swedish corporation subject to the jurisdiction of the Commission, have agreed to merge in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, ("FTC Act"), 15 U.S.C. 45; and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. RESPONDENTS

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.

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.

II. JURISDICTION

3. Respondents are, and at all times relevant herein have been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and are corporations whose business affects commerce as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. 44.

III. THE MERGER

4. Respondents propose to combine their respective businesses in a transaction valued at approximately \$13.9 billion, pursuant to the terms of a Combination Agreement dated August 20, 1995 ("the Merger").

IV. THE RELEVANT MARKET

5. The relevant line of commerce in which to analyze the effects of the Merger is the research, development, manufacture and sale of topoisomerase I inhibitors for the treatment of colorectal cancer. While no topoisomerase I inhibitor has yet been approved for sale in the United States, anticipated sales of all topoisomerase I inhibitors for the treatment of colorectal cancer will exceed \$100 million by 2002.

6. An estimated 443,000 people in the United States are diagnosed with colorectal cancer each year. For most solid tumors, the first method of treatment is surgery, with radiation therapy and chemotherapy typically used as adjuncts to the surgery. Current protocols for colorectal cancer suggest that patients be treated with the chemotherapy agents 5-fluorouracil ("5FU") and either leucovorin or levamisole. For those patients whose cancer recurs, the survival rate is only fifteen percent. Topoisomerase I inhibitors are expected to increase the rate of survival for colorectal cancer patients.

7. For purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger.

V. STRUCTURE OF THE MARKET

8. The relevant market set forth in paragraphs five and seven is highly concentrated. Upjohn and Pharmacia are two of only a very small number of firms currently in the advanced stages of developing topoisomerase I inhibitors for the treatment of colorectal cancer in the United States. Upjohn's product in development, CPT-11, is expected to be the first topoisomerase I inhibitor for the treatment of colorectal cancer on the market in the United States. Pharmacia plans to seek Food and Drug Administration ("FDA") approval for its topoisomerase I inhibitor, 9-Aminocamptothecin ("9-AC"), within the next few years.

VI. BARRIERS TO ENTRY

9. Entry into the relevant market is difficult and time consuming. Entry into the relevant market is governed by the requirements of the FDA which involve lengthy clinical trial periods, time consuming data collection and analysis from clinical trials, and expenditures of significant resources over a period of many years with no assurance that a viable commercial product will result. No company may reach advanced stages of development in the relevant market without engaging in scientific research that requires well over least two years time to complete.

VII. EFFECTS OF THE MERGER

10. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the relevant market 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, by, among other things:

a. Eliminating actual, direct and substantial competition in research and development between Upjohn and Pharmacia in the relevant market; and

b. Potentially decreasing the number of research and development tracks for topoisomerase I inhibitors for the treatment of colorectal cancer; and

c. Eliminating the potential for actual, direct and substantial price competition between Upjohn and Pharmacia in the relevant market.

VIII. VIOLATIONS CHARGED

11. The Combination Agreement described in paragraph four constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

12. The Merger described in paragraph four, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of the proposed 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 Section 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.

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 non-exclusive 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 Section 5(l) 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 non-exclusive 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 (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.

APPENDIX I

INTERIM AGREEMENT TO MAINTAIN RESEARCH AND DEVELOPMENT

This Interim Agreement to Maintain Research and Development ("Interim Agreement") is by and among Pharmacia Aktiebolag ("Pharmacia"), a corporation organized, existing, and doing business under and by virtue of the laws of Sweden, with its office and principal place of business at Frösundaviks allè 15, S-171 97 Stockholm, Sweden, The Upjohn Company ("Upjohn"), 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 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.* (collectively, the "Parties").

PREMISES

Whereas, on August 20, 1995, Pharmacia entered into a Combination Agreement with Upjohn providing for the combination of Pharmacia and Upjohn (hereinafter "Merger"); and

Whereas, Pharmacia is involved in, among other things, the research and development of 9-Amino-20(S)-camptothecin ("9-AC"), a topoisomerase I inhibitor; and

Whereas, Upjohn is involved in, among other things, the research and development of Camptosar ("CPT-11"), a topoisomerase I inhibitor; and

Whereas, the Commission is now investigating the Merger to determine whether it would violate any of the statutes enforced by the Commission; and

Whereas, if the Commission accepts the Agreement Containing Consent Order ("consent order"), the Commission must 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 the ongoing and future research of Pharmacia's 9-AC, as defined in paragraph I of the consent order,

during the period prior to the final acceptance of the consent order by the Commission (after the 60-day public comment period) and until the divestiture required by paragraphs II or III of the consent order has been accomplished may not be possible and divestiture resulting from any proceeding challenging the legality of the Merger might not be possible, or might be less than an effective remedy; and

Whereas, the Commission is concerned that if the Merger is consummated, it will be necessary to preserve the Commission's ability to require the divestiture of Pharmacia's 9-AC Assets, and the Commission's right to have Pharmacia's 9-AC Assets continue as viable assets independent of Upjohn; and

Whereas, the purpose of the Interim Agreement and the consent order is:

1. 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 Merger; and
2. To preserve the Commission's ability to remedy any anticompetitive effects of the Merger; and

Whereas, Pharmacia's and Upjohn's entering into this Interim Agreement shall in no way be construed as an admission by Pharmacia and Upjohn that the Merger is illegal; and

Whereas, Pharmacia and Upjohn understand 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, the Parties agree, upon the understanding that the Commission has not yet determined whether the Merger will be challenged, and in consideration of the Commission's agreement that, at the time it accepts the consent order for public comment, it will grant early termination of the Hart-Scott-Rodino waiting period, as follows:

1. Pharmacia and Upjohn agree to execute and be bound by the consent order.
2. Pharmacia agrees that from the date this Interim Agreement is accepted until the earliest of the time listed in subparagraphs 2.a. -

2.b., it will comply with the provisions of paragraph 4 of this Interim Agreement:

a. Three business days after the Commission withdraws its acceptance of the consent order pursuant to the provisions of Section 2.34 of the Commission's rules;

b. The time that the divestiture obligations required by the consent order are completed.

3. Pharmacia and Upjohn agree to take such actions as are necessary to prevent the destruction, removal, wasting, deterioration or impairment of Pharmacia's 9-AC Assets, except for ordinary wear and tear.

4. With respect to the continued research and development of Pharmacia's 9-AC, Pharmacia agrees:

a. To continue to pursue its obligations under the Cooperative Research and Development Agreement with the National Cancer Institute and the previously determined 9-AC research and development plan, as set forth in confidential Attachment A to this Interim Agreement; and

b. To fund the research and development of Pharmacia's 9-AC at levels no less than those contained in the budget for 1995, as set forth in confidential Attachment B to this Interim Agreement; and

c. To use its best efforts to support and defend Pharmacia's rights relating to 9-AC in U.S. Patent # 5,106,742 dated April 21, 1992 (Camptothecin Analogs as Potent Inhibitors of Topoisomerase I), U.S. Patent # 5,225,404 dated July 6, 1993 (Methods of Treating Colon Tumors with Tumor-Inhibiting Camptothecin Compounds), and U.S. Serial # 08/323,081 filed October 14, 1994 (pending patent application for Lyophilizate of Lipid Complex of Water Insoluble Camptothecins); and

d. To use its best efforts to obtain all necessary approvals and releases from the National Cancer Institute to accomplish the requirements of paragraphs II and III of the consent order; and

e. Within thirty days of acceptance of this Interim Agreement by the Commission, to have available for clinical trials at least sufficient inventory of Pharmacia's 9-AC sufficient to supply the clinical trials set forth in confidential Attachment A to this Interim Agreement that are likely to be initiated through November 1996.

5. Upjohn agrees to allow Pharmacia to fulfill its obligations under paragraphs 2 and 4 of this Interim Agreement, without restraint or interference from Upjohn.

6. Should the Commission seek in any proceeding to compel Pharmacia to divest itself of the Pharmacia 9-AC Assets, as provided in the consent order, or seek any other equitable relief relating to Pharmacia's 9-AC Assets, Pharmacia and Upjohn shall not raise any objection based on the expiration of the applicable Hart-Scott-Rodino Antitrust Improvements Act waiting period or the fact that the Commission has permitted the Merger. Pharmacia and Upjohn shall also waive all rights to contest the validity of this Interim Agreement.

7. Should the Commission, pursuant to paragraph II.D. of the consent order, act on a petition from Pharmacia and Upjohn to modify the consent order based on the circumstances described in subparagraph II.D.1, this Interim Agreement shall be automatically modified to reflect any changes made by the Commission.

8. For the purpose of determining or securing compliance with this Interim Agreement, subject to any legally recognized privilege, and upon written request with reasonable notice to Pharmacia and Upjohn made to its General Counsel, Pharmacia and Upjohn shall permit any duly authorized representative or representatives of the Commission:

a. Access during the office hours of Pharmacia and Upjohn 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 Pharmacia and Upjohn relating to compliance with this Interim Agreement; and

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

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

IN THE MATTER OF

GENETUS ALEXANDRIA, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3639. Complaint, Feb. 12, 1996--Decision, Feb. 12, 1996*

This consent order prohibits, among other things, the Virginia-based corporations and their officers from misrepresenting the nature or extent of a physician's participation in any treatment procedure, the safety or efficacy of any treatment procedure, and the extent to which a treatment is covered by a patient's medical insurance. The consent order requires the respondents to pay \$250,000 in consumer redress to the Commission.

Appearances

For the Commission: *Sondra L. Mills* and *Eric J. Bash*.

For the respondents: *Charles D. Nelson*, in-house counsel,
Washington, D.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that Genetus Alexandria, Inc., a corporation ("Genetus"), George Oprean, individually and as President and a director of said corporation, and Linda Huffman Oprean, individually and as an officer and a director of said corporation, have violated the provisions of the Federal Trade Commission Act, and that Galen Medical Centers, Ltd., a corporation, is a successor corporation to Genetus and is an *alter ego* of Genetus and/or George Oprean, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Genetus Alexandria, Inc. ("Genetus") is a corporation formed under the laws of the Commonwealth of Virginia with its office and principal place of business located at 2843 Duke Street, Alexandria, Virginia. From approximately March of 1991 through July of 1994, Genetus operated a clinic for the treatment of impotence at this location.