UNITED STATES OF AMERICA **011-0132**
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

In the Matter of BIOVAIL CORPORATION, a corporation, and ELAN CORPORATION, PLC, a corporation.	Docket No. ___

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Biovail Corporation (“Biovail”) and Elan Corporation, plc (“Elan”), hereinafter sometimes referred to as Respondents, and 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 violation of 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 Consent Order ("Consent Agreement"), containing an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent 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 Act, and that a Complaint should issue

stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to section 2.34 of its Rules, hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order:

1. Respondent Biovail is a corporation organized under the laws of the Province of Ontario, Canada, with its principal place of business at 2488 Dunwin Drive, Mississauga, Ontario, Canada. Biovail's subsidiary, Biovail Technologies, Ltd., has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia 20151.

2. Respondent Elan is a corporation organized under the laws of Ireland, with its principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. Elan's subsidiary, Elan Pharmaceutical Research Corporation, has offices in the United States located at 1300 Gould Drive, Gainesville, Georgia 30504.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of 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. "Respondent Biovail" means Biovail Corporation and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Biovail; and the officers, directors, employees, agents and representatives, successors, and assigns of each.

B. "Respondent Elan" means Elan Corporation, plc, and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Elan; and the officers, directors, employees, agents and representatives, successors, and assigns of each.

C. "Respondents" means Respondent Biovail and Respondent Elan.

D. "Commission" means the Federal Trade Commission.

E. "Adalat CC Agreement" means the "License, Distribution & Supply Agreement" covering generic Adalat CC that Biovail and Elan executed on October 4, 1999; the subsequently

modified separate agreements executed on December 29, 2000, and titled "Amended and Restated Licensing and Supply Agreement (30 mg Nifedipine O.D.)" and "Amended and Restated Licensing and Supply Agreement (60 mg Nifedipine O.D.);" and all other agreements and understandings that relate to or modify the agreements executed on October 4, 1999, and December 29, 2000. The October 4, 1999, "License, Distribution & Supply Agreement" is attached to this Order as a Confidential Appendix.

F. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.

G. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C.§ 355(j), *et seq.*

H. "Cost" means Elan's actual manufacturing cost. In no case shall Cost exceed fully allocated cost, which is the sum total of all production-related costs, packaging, and labeling for the product (direct labor, direct materials, facility overhead, and other overhead and expenses, including manufacturing charges for material adjustments, handling losses, physical adjustments, salvage and start-up costs, quality assurance, quality control, analytical charges, packaging, and regulatory compliance costs for the product including stability and FDA fees), together with insurance costs accounted for in accordance with United States Generally Accepted Accounting Principles and in a manner consistent with expenses and overhead allocated to other products manufactured by Elan. "Cost" shall *not* include any costs associated with (a) Elan's or Biovail's litigation against Bayer (including, but not limited to, attorneys' fees, court fees, and actual or expected financial settlements with or payments to Bayer) and (b) compliance with this Order (including, but not limited to, attorneys' fees and allocations for time spent by Respondents' employees in complying with this Order).

I. "Drug Delivery Technology" means a technology that controls the release rate, or enhances the absorption or utilization, of a pharmaceutical compound. "Drug Delivery Technology" does not include a Drug Product.

J. "Drug Product" means a finished dosage form (*e.g.*, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

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

L. "Generic Adalat CC" means the Drug Products that include Biovail ANDAs 75-269 and 75-359 and Elan ANDAs 75-128 and 75-659.

M. "Launch" means the delivery of commercial quantities of Generic Adalat CC to a viable pharmaceutical distributor pursuant to a commercially reasonable multi-year contract.

N. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b), *et seq*.

O. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

P. "Teva" means Teva Pharmaceuticals, Inc.

Q. "Therapeutic Class" means a class of drugs categorized at the fourth-level (xxxx-0) or, if no fourth-level exists for such class of drugs, then at the third-level (xxx-00) in the Unified System of Classification (USC) contained in the most recent version of the IMS Health Incorporated publication *Market Research Database: Product Directory*.

II.

IT IS FURTHER ORDERED that each Respondent, directly or indirectly, or through any corporate or other device, in connection with the manufacture or sale of a Drug Product in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, forthwith cease and desist from entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or facilitating any Agreement with any other person on the price, production, volume, marketing, distribution, or sale of a Drug Product where the ANDAs for that Drug Product of Respondent and of the other person reference the same NDA.

III.

IT IS FURTHER ORDERED that no later than the date on which this Order becomes final, Respondents shall terminate all rights, under the Adalat CC Agreement, of Respondent Biovail to import, use, offer for sale, sell, or distribute Respondent Elan's Generic Adalat CC, and restore such rights to Respondent Elan. The purpose of the reallocation of rights is to restore competitive incentives to the Generic Adalat CC market and to remedy any lessening of competition resulting from the alleged anticompetitive practices stated in the Commission's complaint.

PROVIDED that, without affecting the foregoing, Respondents may resolve financial issues, if any, connected with the termination of the Adalat CC Agreement on mutually agreeable terms. Such resolution shall not be measured directly or indirectly by sales, revenues, or profits generated by Generic Adalat CC or any other Drug Product, and shall not include compensation in the form of the United States rights relating to any Drug Product.

IV.

IT IS FURTHER ORDERED that Respondent Elan shall not sell, directly or indirectly, commercial quantities of Generic Adalat CC to Respondent Biovail or to Teva.

PROVIDED that Respondent Elan shall supply, to Respondent Biovail, Respondent Elan's 30 mg Generic Adalat CC for sale through Teva in the United States, subject to each of the following conditions:

(1) Respondent Elan shall supply to Respondent Biovail amounts of 30 mg Generic Adalat CC requested by Respondent Biovail, up to the amounts to which Respondent Biovail would be entitled under Clause 7.6 of the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement," but in no event shall Respondent Elan, in any quarter, supply to Respondent Biovail more than 125 per cent of the quantity of 30 mg Generic Adalat CC than it supplied during the corresponding quarter of the previous year;

(2) Respondents Biovail and Elan shall order and deliver, respectively, Respondent Elan's 30 mg Generic Adalat CC product in accordance with the procedures in the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement;"

(3) Respondent Elan shall charge Respondent Biovail no more than Respondent Elan's Cost;

(4) On the day Respondent Biovail begins manufacturing sufficient commercial quantities of 30 mg Generic Adalat CC to supply Teva, Respondent Biovail shall notify Respondent Elan in writing of that fact;

(5) Respondent Elan shall not fill any order from Respondent Biovail or Teva for 30 mg Generic Adalat CC more than thirty (30) days after it receives the notice pursuant to clause (4) above;

(6) In no event shall Respondent Elan supply Respondent Biovail with 30 mg Generic Adalat CC later than May 31, 2003;

(7) Respondent Elan shall permit Respondent Biovail to verify that it is charging Respondent Biovail no more than Respondent Elan's Cost, but only if Respondent Biovail uses an independent auditing firm that does not disclose to Respondent Biovail or any other person, confidential, proprietary information about Respondent Elan's costs;

however, the independent auditing firm may reveal confidential, proprietary information only for the purpose of prosecuting a bona fide court or arbitration action regarding a dispute on the price charged Respondent Biovail for Respondent Elan's 30 mg Generic Adalat CC, and then only pursuant to a protective order or confidentiality agreement assuring that such information will be used only for the purpose of resolving the dispute; and

(8) In the event that a Court of competent jurisdiction holds that Respondent Biovail's sale of Respondent Elan's 30 mg Generic Adalat CC infringes any patent, Respondents shall resolve issues of indemnification in accordance with the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement," unless Respondents mutually agree otherwise and so long as their agreement complies with all other provisions of this Order.

V.

IT IS FURTHER ORDERED that:

A. Respondent Elan shall use best efforts to manufacture and launch, as promptly as possible, its 30 mg and 60 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Biovail or Teva.

B. Respondent Biovail shall use best efforts to manufacture and launch, as promptly as possible, its 30 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Elan's Generic Adalat CC distributor. Respondent Biovail shall use best efforts to continue to manufacture and distribute its 60 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Elan's Generic Adalat CC distributor.

C. The purpose of Paragraphs V.A and V.B is to restore competitive incentives in the market for Generic Adalat CC and to remedy any lessening of competition resulting from the alleged anticompetitive practices stated in the Commission's complaint.

VI.

IT IS FURTHER ORDERED that:

A. Each Respondent shall notify the Commission of any agreement with another person relating to the price, production, volume, marketing, distribution, or sale of a Drug Product:

(1) Where, at the time of the agreement:

(a) Respondent and the other party to the agreement each own, control, or license a Drug Product that:

(i) Respondent knows, after diligent inquiry, is the subject of an NDA or ANDA pending with or approved by the FDA; and

(ii) Are in the same Therapeutic Class; and

(b) The agreement covers one or both such Drug Products.

(2) For which, at the time of the agreement, Respondent or the other party has an ANDA for the Drug Product that references an NDA that the other party owns, controls, or licenses.

PROVIDED that Paragraph VI.A.1 does not apply to any agreement that only transfers a Drug Delivery Technology solely in exchange for a commercially reasonable cash royalty not to exceed 5 per cent of revenue.

B. Such notice to the Commission shall occur no later than five (5) days after execution of said agreement.

C. Such notice to the Commission shall include:

(1) The agreement;

(2) The names of the parties to the agreement, including the name, address, and phone number of the chief executive officer of each party;

(3) The name, address, and phone number of each person who has filed an ANDA with the FDA for any Drug Product to which the agreement relates and, to the extent known, the status of such ANDA; and

(4) The last two annual marketing plans for the Drug Product(s) that the agreement covers and any documents that Respondent's board of directors received concerning the agreement.

VII.

IT IS FURTHER ORDERED that:

A. Each Respondent shall distribute a copy of this Order and the Complaint, within

thirty (30) days after the date on which this Order becomes final, to each of its officers, members of its board of directors, and managers with responsibility for prescription drug business development, licensing, sales, and marketing.

B. Respondent Biovail shall provide to Teva a copy of this Order and the Complaint, within five (5) days after the date on which this Order becomes final.

C. Respondent Elan shall provide to each person Respondent Elan appoints as a distributor of its Generic Adalat CC a copy of this Order and the Complaint, within five (5) days of such appointment.

D. Each Respondent shall distribute a copy of this Order and the Complaint, for a period of five (5) years after the date this Order becomes final, within five (5) days of appointment, to: (1) each new officer, member of its board of directors, and manager with responsibility for prescription drug business development, licensing, sales, or marketing; and (2) each person Respondent appoints as a United States distributor of its Generic Adalat CC.

VIII.

IT IS FURTHER ORDERED that:

A. Within thirty (30) days after the date this Order becomes final, each Respondent 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 Paragraphs III, IV, and V of this Order. Each Respondent shall submit such a compliance report every thirty (30) days until it has complied fully with Paragraphs III, IV, and V of this Order. Each Respondent shall include in such compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs III, IV, and V of this Order.

B. As part of its obligation under Paragraph VIII.A:

(1) Respondent Elan shall include in its compliance reports (a) a description of all substantive contacts or negotiations concerning the launches provided for in Paragraph V and the identity of all parties contacted, and (b) copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the launches provided for in Paragraph V. Respondent Elan's final compliance report under Paragraph VIII.A shall include a statement that the launches provided for in Paragraph V have been accomplished and shall include the date they were accomplished.

(2) Respondent Biovail shall include in its compliance reports (a) a description of all substantive contacts with suppliers and/or Teva regarding obstacles to launch, and

(b) copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning obstacles to launch. Respondent Biovail's final compliance report under Paragraph VIII.A shall include a statement that the launch provided for in Paragraph V of this Order has been accomplished and shall include the date it was accomplished.

C. One year (1) from the date this Order becomes final, annually for the next four (4) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, each 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.

IX.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty days prior to (1) any dissolution, assignment, or sale resulting in the emergence of a successor corporation, or (2) the creation or dissolution of subsidiaries or any other change in the Respondent that may affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each Respondent shall permit any duly authorized representative of the Commission, in the presence of Respondent's counsel:

A. Access, during office hours, to all facilities and to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of each Respondent relating to compliance with this Order; and

B. Without restraint or interference from each Respondent, to interview officers, directors, or employees of each Respondent relating to compliance with this Order.

PROVIDED that each Respondent:

(1) Shall receive five (5) days' written notice;

(2) May assert any legally authorized privilege; and

(3) May have counsel present during any inspection or interview.

XI.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years after the date this Order becomes final.

By the Commission.

Donald S. Clark
Secretary

ISSUED:
SEAL