

**UNITED STATES OF AMERICA  
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.

**Docket No. C-4060**

**DECISION AND ORDER**

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices by Respondent Biovail Corporation, hereinafter referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent 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 Respondent 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 Respondent has violated the said Acts, 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 modified the Decision and Order in certain respects, now in further conformity with the procedure prescribed in Commission Rule § 2.34, 16 C.F.R. § 2.34, the

Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Biovail Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the Province of Ontario, Canada, with its office and principal place of business located at 2488 Dunwin Drive, Mississauga, Ontario, Canada and offices in the United States at 3701 Concorde Parkway, Chantilly, Virginia.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

## **ORDER**

### **III.**

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

- A. “Respondent” means Biovail Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Biovail Corporation; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Assets To Be Divested” means all Exclusive Licenses to the DOV ‘463 patent in the Tiazac Field.
- D. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq.*
- E. “Divestiture Date” means the date on which the Respondent has fully completed the divestiture, pursuant to this Order, of the Assets To Be Divested to DOV.
- F. “DOV” means DOV Pharmaceuticals, Inc., a Delaware corporation which has its principal place of business at 433 Hackensack Avenue, Hackensack, New Jersey 07601.
- G. “DOV ‘463 Patent” means U.S. Patent No. 6,162,463 issued by the U.S. Patent and Trademark Office on December 19, 2000.
- H. “Exclusive License” means a license of intellectual property that (a) restricts the right of the licensor

to license the intellectual property to others or (b) grants to the licensee the right to enforce the intellectual property rights against others.

- I. "FDA" means the U.S. Food and Drug Administration.
- J. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b) *et seq.*
- K. "Notification and Report Form" means the form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended.
- L. "Person" means any natural person, partnership, corporation, company, association, trust, joint venture or other business or legal entity, including any governmental agency.
- M. "Orange Book" means the U.S. Food and Drug Administration publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations."
- N. "30-Month Stay" means the period of time established by 21 U.S.C. § 355(j)(5)(B)(iii) during which the FDA may not grant approval to an ANDA.
- O. "Tiazac Field" means any extended release formulation of diltiazem that has been approved by the FDA for sale pursuant to NDA 20-401, or that is described in any ANDA for which approval is sought by referencing NDA 20-401.
- P. "Dismissal Date" means the day after the date of the dismissal with prejudice of all of Respondent's claims relating to enforcement of the DOV '463 Patent, including those claims in *Biovail Corporation v. Andrx Pharmaceuticals, Inc.*, Civ. No. 01-CV-6548 (S.D. Fla.).

#### IV.

**IT IS FURTHER ORDERED** that:

- A. No later than thirty (30) days after this Order becomes final, Respondent shall divest, absolutely, in good faith, and only in a manner that receives the prior approval of the Commission, the Assets To Be Divested to DOV.

PROVIDED HOWEVER, Respondent shall not divest the Assets To Be Divested to DOV prior to the Dismissal Date.

- B. Any consideration received by Respondent in exchange for the Assets To Be Divested must be a fixed amount. In particular, such consideration cannot be a function of any revenue generated for DOV by the Assets To Be Divested. Respondent shall not accept any share of royalties or other fees paid by licensees of the DOV '463 Patent in the Tiazac Field.
- C. Respondent shall not enter into any agreement with DOV or any other Person that restricts the ability of such Person to provide information to the Commission.
- D. Respondent shall place no restrictions on DOV's use of the Assets To Be Divested, and shall not assist in, advise regarding, or act so as to affect in any manner DOV's (1) enforcement of the DOV '463 Patent in the Tiazac Field, (2) licensing of the DOV '463 Patent in the Tiazac Field, or (3) determination of royalties or other fees paid by others for the DOV '463 Patent in the Tiazac Field.
- E. Respondent shall not initiate, maintain, or be a party to any legal action to enforce the DOV '463 Patent in the Tiazac Field against any other Person.
- F. In order to comply with Paragraph II.E., Respondent shall, within 5 days of signing this Agreement Containing Consent Order, use its best efforts, including by moving for appropriate judicial relief and attaching this Order, to achieve dismissal with prejudice of any and all claims relating to enforcement of the DOV '463 Patent in the Tiazac Field, including, but not limited to, any and all claims asserted in *Biovail Corporation v. Andrx Pharmaceuticals, Inc.*, Civ. No. 01-CV-6548 (S.D. Fla.).

**V.**

**IT IS FURTHER ORDERED** that:

- A. If Respondent has not divested, absolutely and in good faith and with the Commission's prior approval, the Assets To Be Divested within the time and in the manner required by Paragraph II. of this Order, the Commission may appoint a trustee to divest those assets to DOV. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee 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 Section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

B. If a trustee is appointed by the Commission or a court pursuant to Paragraph III.A. of this Order, Respondent 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 Respondent, which consent shall not be unreasonably withheld. The trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not

opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after receipt of written notice by the staff of the Commission to Respondent of the identity of any proposed trustee, Respondent 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 the Assets To Be Divested.
3. Within ten (10) days after appointment of the trustee, Respondent 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 rights and powers necessary to permit the trustee to effect the divestiture required by this Order.
4. The trustee shall have twelve (12) months from the date the Commission or court approves the trust agreement described in Paragraph III.B.3. to accomplish the divestiture. 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 the period for no more than two (2) additional periods of twelve (12) months each.
5. The trustee shall have full and complete access to the personnel, books, records, and facilities related to the Assets To Be Divested, the Tiazac Field, 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 the divestiture. Any delays in divestiture caused by Respondent 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, subject to Respondent's absolute and unconditional obligation to divest expeditiously at no minimum price. The divestiture shall be made only in a manner that receives the prior approval of the Commission, and only to an acquirer that receives the prior approval of the Commission.
7. The trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and

responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of Respondent, and the trustee's power shall be terminated.

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 preparation for or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, 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 have no obligation or authority to administer or maintain the Assets To Be Divested.
12. The trustee shall report in writing to the Commission every thirty (30) days concerning the trustee's efforts to accomplish the divestiture required by this Order.
13. Respondent may require the trustee to sign a customary confidentiality agreement; provided, however, such agreement shall not restrict the trustee from providing any information to the Commission.

## VI.

**IT IS FURTHER ORDERED** that Respondent shall cease and desist from taking any action that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA Final Approval of ANDA No. 75-401.

## VII.

**IT IS FURTHER ORDERED** that Respondent shall not seek, certify to, or take any action in furtherance of, the listing or continued listing of any patent in the Orange Book in violation of applicable law, including, but not limited to, 21 U.S.C. § 355(b) and (c)(2) and 21 C.F.R. § 314.53 (b)-(c), as interpreted by the FDA and the courts.

## VIII.

**IT IS FURTHER ORDERED** that Respondent shall not, without providing prior written notification to the Commission in the manner described in Paragraph VII. (“Notification”), acquire a patent or an Exclusive License to a patent (hereinafter, the “Transaction”), if Respondent seeks or secures the patent’s listing in the Orange Book for an NDA which has received FDA approval.

## IX.

**IT IS FURTHER ORDERED** that Respondent shall provide the Notification required by Paragraph VI. in the form of a letter (“Notification Letter”) submitted to the Secretary of the Commission and containing the following information: (1) the docket number and caption name of this Order; (2) a statement that the purpose of the letter is to give the Commission prior notification of a Transaction as required by Paragraph VI. of this Order; (3) identification of the parties participating in the Transaction; (4) a copy of each patent acquired pursuant to the Transaction (“Acquired Patent”); (5) for each Acquired Patent, identification of the Approved NDA(s) in respect to which the Acquired Patent is, or will be, submitted for listing in the Orange Book; (6) for each such Approved NDA identified in the previous subpart, identification of all Persons who have filed with the FDA an ANDA which references the Approved NDA; (7) a copy of all transactional documents; and (8) a copy of all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the Transaction.

Respondent shall submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating any such Transaction (hereinafter referred to as the “First Waiting Period”). If, prior to expiration of the First Waiting Period, representatives of the Commission make a written request for additional information or documentary material (as if within the meaning of 16 C.F.R. § 803.20), Respondent shall not consummate the Transaction until expiration of thirty (30) days following submission of such additional information or documentary material. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Commission’s Bureau of Competition.

PROVIDED, HOWEVER, that, if the Transaction is subject to the reporting obligations of Section 7A



of the Clayton Act, 15 U.S.C. 18a (“HSR Act”), and if a complete and accurate Notification Letter for such Transaction is appended to, and submitted with, a Notification and Report Form filed pursuant to the HSR Act for such Transaction, then Respondent shall not be required to comply further with Paragraph VI. of this Order with respect to such Transaction; except that nothing in this Order shall be construed to relieve Respondent of any obligation to comply with any requirement of the HSR Act.

## X.

**IT IS FURTHER ORDERED** that:

- A. Within sixty (60) days after Respondent has divested the Assets To Be Divested pursuant to Paragraph II.A. of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied with Paragraph II.A. of this Order. Respondent shall include in this compliance report copies of all written communications to and from parties to the divestiture, all internal memoranda, and all reports and recommendations concerning the divestiture.
- B. Within sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until all applicable courts have dismissed with prejudice any and all claims of Respondent relating to enforcement of the DOV ‘463 Patent in the Tiazac Field, 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 Paragraph II.F. of this Order.
- C. One (1) year from the date this Order becomes final, annually thereafter on the anniversary of the date of this Order becoming final, 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 is complying, and has complied, with Paragraphs II., IV., and V. of this Order.

## XI.

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

**XII.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, upon written request, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent relating to any matters contained in this Order; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from it, to interview officers, directors, employees, agents or independent contractors of Respondent relating to any matters contained in this Order.

**XIII.**

**IT IS FURTHER ORDERED** that this Order will terminate on October 2, 2012.

By the Commission.

Donald S. Clark  
Secretary

SEAL:  
ISSUED: October 2, 2002