

Complaint

IN THE MATTER OF

BIOVAIL CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4060; File No. 0110094
Complaint, October 2, 2002--Decision, October 2, 2002

This consent order addresses practices used by Respondent Biovail Corporation – a Canadian manufacturer of branded and generic pharmaceutical products – with respect to an Abbreviated New Drug Application filed by Andrx Pharmaceuticals, Inc. to make and sell a generic version of Tiazac, a once-a-day diltiazem-based prescription drug used to treat high blood pressure and to reduce the occurrence of chronic chest pain . The order, among other things, requires the respondent to divest to DOV Pharmaceuticals, Inc. the exclusive rights to the ‘463 patent – which the respondent listed in the United States Food and Drug Administration Orange Book as claiming Tiazac – previously acquired from DOV. The order also prohibits the respondent from taking any actions that would result in an additional 30-month stay of final FDA approval for a generic form of Tiazac, and from wrongfully listing any patents in the Orange Book in violation of applicable law. In addition, the order prohibits the respondent from participating in any lawsuits to enforce the ‘463 patent in the Tiazac Field, and requires the respondent to dismiss a pending patent infringement claim against Andrx. The order also requires the respondent to give the Commission prior notice before it acquires an exclusive license to any patent that it plans to list in the Orange Book for a product for which it already has an FDA-approved New Drug Application.

Participants

For the Commission: *Markus H. Meier, Bradley S. Albert, Oscar Voss, George Bellack, David Dudley, Jerod Klein, Mary Connelly-Draper, Daniel Bress, Rendell A. Davis, Jr., Roberta S. Baruch, Abraham Wickelgren, Leslie Farber, and Mary T. Coleman.*

For the Respondent: *Ron Rauchberg, Proskauer Rose LLP, and Ken Cancellara, Biovail.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that respondent Biovail Corporation has engaged in conduct that violates Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, 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. Nature of the Case

1. This matter concerns Biovail Corporation's illegal acquisition of an exclusive patent license and its wrongful listing of the patent with the U.S. Food and Drug Administration. Each of these actions independently had the potential to block the entry of any bioequivalent generic drug capable of competing with Biovail's lucrative branded Tiazac product and deprives consumers of the substantial benefits of lower-priced generic Tiazac that might have occurred absent Biovail's conduct.

II. Respondent Biovail Corporation

2. Respondent Biovail Corporation ("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 has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia.

3. Biovail manufactures branded and generic pharmaceutical products, and is involved in all stages of pharmaceutical development, from research and development, through clinical testing and regulatory filings, to full-scale manufacturing. For the first six months of 2001, Biovail had product sales of over \$237 million, and revenues of nearly \$253 million. Tiazac, the drug at

Complaint

issue in this matter, is an extended-release, diltiazem-based drug that is one of Biovail's largest selling products.

III. DOV Pharmaceuticals, Inc.

4. DOV Pharmaceuticals, Inc. ("DOV") was formed in 1995. It is incorporated under the laws of the State of Delaware, with its principal place of business in New Jersey. DOV develops drugs to advanced stages in preclinical and clinical development, and then seeks strategic partnerships, joint ventures, or sub-licensing arrangements with larger pharmaceutical companies for the final development and marketing of products. DOV has no commercial manufacturing capability or experience, and, to date, it has not generated revenue from the sale of any pharmaceutical products.

5. DOV owns the rights to U.S. Patent Number 6,162,463 ("the '463 patent"), the patent at issue in this matter, which it has licensed to Biovail on an exclusive basis. The pharmaceutical product described in the '463 patent is a unique formulation of diltiazem (the active pharmaceutical ingredient in Biovail's Tiazac) that combines both an immediate-release and an extended-release form of diltiazem.

IV. Jurisdiction and Interstate Commerce

6. Biovail is, and at all relevant times herein has been, a corporation within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

7. Biovail's general business activities, its acquisition of exclusive rights to the '463 patent from DOV, and its unfair methods of competition alleged below, are "in or affecting commerce" within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

Complaint

V. Statutory and Regulatory Background

8. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, *codified* at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), commonly known as the “Hatch-Waxman Act,” requires approval by the U.S. Food and Drug Administration (“FDA”) before a company may market or sell a pharmaceutical product in the United States. A company may obtain approval to make and sell a new or branded drug by filing a New Drug Application (“NDA”) with the FDA.

9. A generic drug is one that the FDA has found to be “bioequivalent” to a branded drug. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate, and extent to which, the products are absorbed in the human body under similar experimental conditions, when administered at the same dose. *See* Food, Drug and Cosmetic Act, 21 U.S.C. § 505(j)(8)(B).

10. Although therapeutically identical to their branded counterparts, generic drugs are typically sold at substantial discounts from the price of the branded drug. In fact, the first generic drug to enter the market often does so at a price 25 percent or more below that of the branded product.

11. The Hatch-Waxman Act establishes a procedure for a branded-drug company to identify to prospective generic competitors all patents that it believes claim the branded drug. The Act also establishes a process for addressing potential claims of patent infringement against the manufacturer of a proposed generic product.

12. The FDA makes public the patents identified by branded-drug companies as claiming a given product in a publication entitled “Approved Drug Products with Therapeutic Equivalence

Complaint

Evaluations,” which is commonly referred to as the “Orange Book.”

13. The FDA views its role in listing patents in the Orange Book as “purely ministerial,” because it has neither the expertise nor the resources to resolve complex patent coverage issues. 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994). Consequently, the FDA does not scrutinize a party’s bases for listing patents in the Orange Book, as long as all the information required by statute has been submitted. Should one company challenge the validity of another’s Orange Book listing, the FDA requests only that the NDA holder provide written confirmation that the patent is properly listed.

14. A company may obtain approval to make and sell a generic version of a branded drug by filing an Abbreviated New Drug Application (“ANDA”) with the FDA. If a company seeks to market a generic version of a branded drug prior to the expiration of one or more of the patents listed in the Orange Book as relating to that drug, the generic applicant must provide a certification to the FDA with respect to each such patent.

15. One type of certification a generic applicant may make to the FDA is a “Paragraph IV Certification,” in which the applicant claims that the branded-drug company’s patent is invalid or will not be infringed by the manufacture, use, or sale of the generic product. This is the form of certification at issue in this matter.

16. When making a Paragraph IV Certification, the generic applicant must provide notice to each patent owner and the branded-drug company listed in the Orange Book.

17. The Hatch-Waxman Act contains provisions that allow a branded-drug company to delay the entry of a generic drug for which a Paragraph IV Certification has been filed, depending on whether a patent infringement suit is initiated. If neither the patent holder nor the branded-drug company files a patent infringement suit against the generic drug applicant within forty-

Complaint

five days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed. Upon final FDA approval of the ANDA, the generic applicant is free to market its product. If, however, a patent infringement suit is filed against the generic drug applicant within the forty-five day period, then final FDA approval of the ANDA is automatically stayed until the earliest of: (a) patent expiration; (b) a final determination by a court of non-infringement or patent invalidity; or (c) the expiration of a thirty month period from the time the patent holder receives the Paragraph IV Certification. This thirty month period, which effectively is an automatic statutory injunction, is commonly referred to as the “30-month stay.”

VI. Tiazac Sold in the United States is the Relevant Market in which to Assess Biovail’s Conduct

18. The relevant antitrust product market in which to assess the anticompetitive effects of Biovail’s conduct is Tiazac and generic bioequivalent versions of Tiazac. Tiazac is a diltiazem-based prescription drug taken once a day. It is used to treat high blood pressure (hypertension) and chronic chest pain (angina).

19. In addition to Tiazac, other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several branded and generic formulations of once-a-day diltiazem, but these other therapeutic agents do not significantly constrain Tiazac’s pricing.

20. In contrast, entry of a generic bioequivalent version of Tiazac likely would result in a significant, immediate decrease in the sales of branded Tiazac, and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents.

21. The relevant antitrust geographic market in which to assess the anticompetitive effects of Biovail’s conduct is the United States. This is so given the FDA’s elaborate regulatory process for approving drugs for sale in the United States, and the

Complaint

fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis.

VII. Biovail Has Monopoly Power in the Relevant Market

22. At all times germane to this complaint, Biovail, through its U.S. distributor Forest Laboratories, Inc., of New York, has had 100 percent of the sales in the Tiazac market in the United States.

VIII. The Threat of Generic Tiazac Entry

23. The FDA approved Tiazac for sale in the United States in September 1995. Shortly thereafter, Biovail, through Forest Laboratories, Inc., began marketing Tiazac in the United States.

24. Tiazac is an important product for Biovail. In 2000, Tiazac's U.S. sales reached almost \$200 million, accounting for approximately 38 percent of the total gross sales of products owned by Biovail.

25. On or about June 22, 1998, Andrx Pharmaceuticals, Inc. ("Andrx"), a Florida-based company that develops generic versions of extended-release, branded pharmaceuticals, submitted an ANDA to the FDA to market a generic version of Tiazac. Andrx's application included a Paragraph IV Certification asserting that its generic product would not infringe any patent claiming Tiazac. At the time, the only patent listed in the Orange Book as claiming Tiazac was U.S. Patent Number 5,529,791 ("the '791 patent"), which covers aspects of the extended-release formulation of Tiazac. The basic patent on diltiazem, Tiazac's active pharmaceutical ingredient, expired long before any date relevant to this complaint.

26. On October 7, 1998, Biovail filed a patent infringement lawsuit against Andrx in the U.S. District Court for the Southern District of Florida, alleging that Andrx's proposed generic bioequivalent version of Tiazac would infringe the '791 patent.

Complaint

By filing this lawsuit, Biovail triggered a provision under the Hatch-Waxman Act preventing the FDA from granting final approval of Andrx's ANDA for up to thirty months.

27. On March 6, 2000, the federal district court ruled in Andrx's favor, finding that its generic bioequivalent version of Tiazac did not infringe the '791 patent. Biovail appealed this decision, and the United States Court of Appeals for the Federal Circuit affirmed the district court's ruling on February 13, 2001.

28. The FDA tentatively approved Andrx's ANDA for generic Tiazac on September 29, 2000, and informed Andrx that the ANDA would be eligible for final approval upon expiration of the 30-month stay, which, because of the decision of the Court of Appeals for the Federal Circuit, would have ended around February 13, 2001. Final FDA approval of Andrx's ANDA, however, was not granted on February 13 or at any other time as of the date of this complaint.

IX. Biovail's Anticompetitive Conduct

a. Biovail Acquired an Exclusive License to the '463 Patent

29. On December 19, 2000, the U.S. Patent and Trademark Office issued the '463 patent to its inventor, Dr. Arnold Lippa, the founder and CEO of DOV Pharmaceuticals, Inc. Dr. Lippa subsequently assigned the patent to DOV.

30. The product described in the '463 patent is a unique formulation of diltiazem (the same active pharmaceutical ingredient as in Biovail's Tiazac), which combines both an immediate-release and an extended-release form of diltiazem.

31. Within days of the patent's issuance, Biovail approached and met with Dr. Lippa in order to negotiate an exclusive license to the '463 patent.

Complaint

32. Biovail insisted on completing the license agreement with DOV by no later than January 19, 2001. A patent claiming a pharmaceutical product must be listed in the FDA's Orange Book within thirty days of issuance by the U.S. Patent and Trademark Office in order to trigger Hatch-Waxman Act provisions that could result in a 30-month stay. As a result, January 19 was the last day on which Biovail could list the '463 patent and still be eligible to obtain a second 30-month stay, precluding the FDA from granting final approval of Andrx's application to sell a generic version of Tiazac.

33. On January 12, 2001, Biovail and DOV executed the exclusive license agreement for the '463 patent.

b. Biovail Listed the '463 Patent in the FDA's Orange Book

34. On January 8, 2001, Biovail listed the '463 patent in the Orange Book. In its certification to the FDA supporting the listing, Biovail attested that the '463 patent covers the currently approved formulation of Tiazac.

35. On January 30, 2001, Biovail publicly disclosed that it had listed the '463 patent in the Orange Book. Biovail's press release stated that as a result of this listing, FDA approval of any generic version of Tiazac could be delayed for up to thirty months:

The effect of Biovail's listing of this Patent in the Orange Book is that the FDA will require every filer of an ANDA for a generic version of Tiazac to also submit a Notice of Certification to Biovail on this Patent. As a result, Biovail will consider whether such ANDA formulation infringes on its listed Patent and will have the legal right to commence a lawsuit against the owner of such ANDA. If Biovail determines to commence such suit within 45 days from receipt of the Notice of Certification, the Hatch Waxman provisions of the [FDCA] will be triggered

Complaint

and the ANDA owner will not be able to obtain final approval for up to 30 months.

36. At the time of listing, Biovail was aware that the ‘463 patent did not cover the formulation of Tiazac it was marketing. Further, Biovail knew that absent its exclusive license with DOV, it would not have listed the ‘463 patent in the Orange Book. The product described in the ‘463 patent contains at least 1 percent of uncoated or “free” immediate-release diltiazem in addition to extended-release diltiazem in the form of coated beads. By contrast, the only Tiazac formulation that Biovail has ever sold contains only negligible amounts – that is, less than 1 percent – of uncoated immediate-release diltiazem outside the extended-release coated beads. Accordingly, Biovail did not need the ‘463 patent in order to manufacture and sell its existing FDA-approved formulation of Tiazac, and it could have continued to do so without infringing the ‘463 patent.

37. Because Biovail listed the ‘463 patent in January 2001, the FDA was no longer permitted to grant Andrx final approval to launch its generic Tiazac product in February 2001. Instead, Andrx was required to make a new certification to the FDA concerning the ‘463 patent, potentially further delaying Andrx’s entry into the Tiazac market.

**c. Andrx Challenged – and the FDA Questioned –
the Propriety of Biovail’s Listing of the ‘463 Patent**

38. After Biovail’s January 30, 2001, press release announcing that it had listed the ‘463 patent in the Orange Book, Andrx contacted DOV in order to seek a license for the patent. Citing its exclusive agreement with Biovail, DOV refused to discuss such an arrangement with Andrx.

39. On February 1, 2001, Andrx petitioned the FDA to require Biovail to de-list the ‘463 patent, alleging, among other things, that the ‘463 patent did not cover the Tiazac product Biovail currently marketed.

Complaint

40. On February 7, 2001, and again on February 22, 2001, the FDA, consistent with its limited “ministerial role” in listing patents in the Orange Book, sought confirmation from Biovail that the ‘463 patent was properly listed for Tiazac.

41. On February 26, 2001, as the result of a court filing by Biovail in a federal lawsuit by Andrx to force Biovail to de-list the ‘463 patent, the FDA learned that Biovail’s position was that the ‘463 patent covered a new formulation of Tiazac that Biovail developed only after it acquired the exclusive license to, and listed, the ‘463 patent, rather than covering the version of Tiazac that Biovail had been marketing.

42. On March 20, 2001, the FDA notified Biovail that its new formulation of Tiazac was not approved by the FDA under the Tiazac NDA, and that the FDA would de-list the ‘463 patent from the Orange Book unless Biovail amended its certification to indicate that the ‘463 patent claimed the version of Tiazac that the FDA had approved.

43. On March 26, 2001, Biovail submitted a signed declaration to the FDA stating that “Biovail hereby confirms its belief that the ‘463 patent is eligible for listing in the FDA’s Orange Book in connection with Biovail’s drug product Tiazac.” This declaration did not clarify whether the term “Tiazac” as used by Biovail meant FDA-approved Tiazac (as the FDA required) or Biovail’s revised form of the product, which practices the ‘463 patent.

44. As revealed in papers filed by the FDA in the federal lawsuit by Andrx to force Biovail to de-list the ‘463 patent, it is clear that the FDA understood Biovail’s March 26, 2001, declaration as “affirming the ‘463 patent covers the *currently approved* Tiazac product” (emphasis added), and, on that basis, decided not to de-list the ‘463 patent from the Orange Book. Biovail, however, continued to assert that listing the ‘463 patent in the Orange Book was justified because it covers a revised form of

Complaint

Tiazac that Biovail believes falls within the Tiazac NDA, but which the FDA does not.

**d. Biovail Initiated a Patent Infringement
Lawsuit against Andrx Based on the ‘463 Patent**

45. On February 16, 2001, Andrx filed a Paragraph IV certification with the FDA, certifying either that its generic Tiazac product does not infringe the ‘463 patent or that the patent is not valid. Sometime thereafter, Andrx notified Biovail of this certification.

46. On April 5, 2001, Biovail filed a lawsuit against Andrx alleging infringement of the ‘463 patent, thereby triggering a second 30-month stay under the Hatch-Waxman Act, and precluding the FDA from granting final approval to Andrx’s ANDA for generic Tiazac.

X. The Anticompetitive Effects of Biovail’s Conduct

47. As a result of Biovail’s conduct as alleged herein, consumers have been deprived of the benefits of lower-priced generic competition that might have occurred had the FDA granted final approval to Andrx’s generic Tiazac in February 2001. Andrx’s generic Tiazac was expected to enter the market at a substantial discount to branded Tiazac, and it was expected to take almost all of its market share from branded Tiazac. In fact, Biovail’s own forecasts projected that generic Tiazac would capture 40 percent of branded Tiazac sales within the first year.

48. The purpose or effect of Biovail’s actions was to block Andrx or any other manufacturer of generic Tiazac from entering the relevant market and thereby lowering the price consumers pay for the drug.

49. Biovail’s anticompetitive actions are not justified by any countervailing efficiencies.

Complaint

XI. Violations Alleged

Count 1 – Unlawful Asset Acquisition in Violation of Clayton Act § 7 and FTC Act § 5

50. Biovail's acquisition of an exclusive license to the '463 patent constitutes an asset acquisition within the meaning of Section 7 of the Clayton Act, 15 U.S.C. § 18.

51. Prior to Biovail's acquisition of an exclusive license to the '463 patent, Biovail had monopoly power in the relevant market.

52. Biovail did not need a license – much less an exclusive license – to the '463 patent in order to make and sell its FDA-approved Tiazac product.

53. Biovail's acquisition of the exclusive license to the '463 patent raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition, thereby protecting Biovail's monopoly in the relevant market, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

Count 2 – Unlawful Monopolization in Violation of FTC Act § 5

54. Biovail has, and at all times relevant to this complaint has had, monopoly power in the market for Tiazac and generic bioequivalent versions of Tiazac in the United States.

55. Biovail engaged in acts to willfully maintain its Tiazac monopoly. These acts included, but were not limited to: (a) acquiring an exclusive license to the '463 patent for the purpose of listing it in the Orange Book; (b) wrongfully listing the '463 patent in the Orange Book as claiming Tiazac, in order to be eligible for an automatic 30-month stay of FDA approval for any generic Tiazac product; and (c) giving non-responsive answers to

Complaint

questions raised by the FDA about the propriety of listing the '463 patent in the Orange Book so as to avoid de-listing.

56. Biovail's monopolization raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition, thereby depriving consumers of the benefits of lower-priced generic competition that might have occurred had the FDA not been precluded from granting final approval to Andrx's generic Tiazac.

57. Biovail's acts and practices described above are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this second day of October, 2002, issues its complaint against said respondent.

By the Commission.

Decision and Order

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”):

Decision and 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**I.**

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.

Decision and Order

- 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.

Decision and Order

- 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.).

II.**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.

Decision and Order

- 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.).

III.

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

Decision and Order

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.

Decision and Order

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

Decision and Order

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.

Decision and Order

IV.

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.

V.

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.

VI.

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.

VII.

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,

Decision and Order

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.

VIII.

IT IS FURTHER ORDERED that:

Decision and Order

- 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.

IX.

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.

Decision and Order

X.

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.

XI.

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

By the Commission.

Analysis

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Biovail Corporation, settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent with the U.S. Food and Drug Administration. The Commission has placed the proposed consent order on the public record for thirty days in order to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by Biovail Corporation that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Biovail Corporation is a Canadian manufacturer of branded and generic pharmaceutical products, including Tiazac. Tiazac, a once-a-day diltiazem-based prescription drug that is at issue in this case, is used to treat high blood pressure and to decrease the occurrence of chronic chest pain. In 2000, Tiazac's sales reached almost \$200 million, accounting for 38 percent of Biovail's gross sales.

Andrx Pharmaceuticals, Inc., a Florida-based company that develops generic versions of branded pharmaceuticals, was the first company to submit an application to the U.S. Food and Drug Administration ("FDA") to make and sell a generic version of Tiazac. Andrx's application to the FDA included a certification asserting that its generic product would not infringe any patent claiming Tiazac. At that time, the only patent known to claim Tiazac was U.S. Patent Number 5,529,791 ("the '791 patent"), which covers aspects of Tiazac's once-a-day formulation.

As in several recent Commission matters, the facts of this case are set against the backdrop of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as "the Hatch-Waxman Act." Congress enacted the Hatch-Waxman Act

Analysis

to facilitate the entry of lower priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs. In particular, the Hatch-Waxman Act established certain rights and procedures in situations where a company seeks approval from the FDA to market a generic product prior to the expiration of a patent or patents relating to the branded drug upon which the generic is based.

A generic drug is a pharmaceutical product that the FDA has determined to be bioequivalent to a branded drug. Generic drugs are chemically identical to their branded counterparts, but they typically are sold at substantial discounts from the branded drug's price. A Congressional Budget Office Report estimates that U.S. consumers saved an estimated \$8-10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the branded product.¹

Under the provisions of the Hatch-Waxman Act, a company seeking approval from the FDA to market a new drug must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product. As part of this process, the NDA applicant also is required to submit to the FDA information on any patent claiming the approved drug and for which a claim of patent infringement could reasonably be asserted against another party. The FDA then lists the approved drug and its related patents in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

¹Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii & 13 (July 1998).

Analysis

The Hatch-Waxman Act also allows the listing of patents that are issued by the U.S. Patent and Trademark Office after an NDA has been approved.²

In order to receive FDA approval to market a generic version of a branded drug, a company must file an Abbreviated New Drug Application (“ANDA”) demonstrating that its product is bioequivalent to its branded counterpart. As part of the ANDA application process, the ANDA applicant also must provide a certification to the FDA regarding its generic product and any patents listed in the Orange Book that claim the reference branded drug. Under one form of certification, known as a “Paragraph IV certification,” the ANDA applicant certifies that the patents listed in the Orange Book either are invalid or will not be infringed by the manufacture, use, or sale of the drug products for which the ANDA is submitted.

The Hatch-Waxman Act further provides that notice of the Paragraph IV certification must be provided to each patent owner and the NDA holder for the listed drug. After receiving notice of a Paragraph IV certification, if the branded drug owner does not initiate a patent infringement suit within forty-five days, then the FDA’s review and generic approval process may proceed according to the FDA’s schedule. If, however, a patent infringement suit is filed within the forty-five day window, the FDA’s approval of the ANDA is automatically stayed until the earliest of: (1) the date the patents expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of thirty months from the receipt of notice of the Paragraph IV certification (the “30-month stay”).

Andrx filed the first ANDA for a generic version of Tiazac in June 1998. At that time, it provided a Paragraph IV certification to the FDA regarding the only patent then claiming Tiazac, the ‘791 patent. Within forty-five days of receiving Andrx’s notice of

²21 U.S.C. § 355(c)(2).

Analysis

certification, Biovail filed a patent infringement lawsuit, alleging that Andrx's generic Tiazac product would infringe the '791 patent. This lawsuit triggered a 30-month stay of final regulatory approval of Andrx's ANDA, which was to expire on February 26, 2001 (or earlier, if an appellate court decision was granted in Andrx's favor before that date).

On March 6, 2000, the U.S. District Court presiding over the patent infringement suit found that Andrx's product did not infringe the '791 patent.³ Biovail appealed this decision to the U.S. Court of Appeals for the Federal Circuit. On September 29, 2000, while the appeal was still pending, the FDA tentatively approved Andrx's ANDA and informed Andrx that it would be eligible to receive final FDA approval upon expiration of the 30-month stay. This stay would have expired on February 13, 2001, the day the Federal Circuit affirmed the district court's ruling that Andrx's product did not infringe Biovail's '791 patent.

Before the Federal Circuit issued its decision, however, Biovail, on January 8, 2001, listed a second patent in the Orange Book as claiming Tiazac. Biovail acquired this patent, U.S. Patent No. 6,162,463 ("the '463 patent"), from DOV Pharmaceuticals, Inc., of New Jersey, through an exclusive licensing arrangement that also included plans to jointly develop new diltiazem products using the '463 patent. Because of this listing, Andrx was required to submit a second Paragraph IV certification asserting non-infringement of the '463 patent. After receiving Andrx's certification, Biovail filed a second patent infringement suit, triggering a second 30-month stay of the final approval of Andrx's ANDA, and further delaying the potential entry of Andrx's generic Tiazac product.

³*Biovail Corp. Int'l v. Andrx Pharm. Inc.*, 2000 WL 33354427 (S.D. Fla. March 6, 2000).

Analysis

The Challenged Conduct

The Commission's complaint alleges that Biovail acquired exclusive rights to the '463 patent from DOV Pharmaceuticals, Inc., for the purpose of listing it in the FDA's Orange Book and thereby blocking Andrx's entry into the Tiazac market.

Two days after the U.S. Patent and Trademark Office issued the '463 patent, Biovail met with DOV to discuss a potential licensing agreement. Biovail sought to complete an exclusive licensing agreement with DOV by no later than January 19, 2001, the last date on which it could list the patent in the Orange Book and still be eligible to trigger Hatch-Waxman provisions that could result in a 30-month stay. Biovail listed the '463 patent in the Orange Book on January 8, four days before it actually completed the exclusive license agreement with DOV.

In its certification to the FDA supporting the listing of the patent, Biovail attested that the '463 patent claimed FDA-approved Tiazac. According to the complaint, however, Biovail was aware that the '463 patent did not claim the formulation of Tiazac that it had been marketing. The product described in the '463 patent contains at least 1 percent of uncoated or "free" immediate-release diltiazem, in addition to extended-release diltiazem in the form of coated beads. By contrast, the only form of Tiazac that Biovail has ever sold contains only negligible amounts – that is, well below 1 percent – of uncoated immediate-release diltiazem. Accordingly, Biovail did not need the '463 patent in order to make or sell its existing FDA-approved formulation of Tiazac, and it could have continued to do so without infringing the '463 patent. Moreover, in prosecuting the patent before the U.S. Patent and Trademark Office, Dr. Lippa of DOV was required to distinguish the '463 patent from the prior art – including Biovail's Tiazac – before the patent examiner approved the patent. This suggests that the '463 patent could not simultaneously be valid and properly listed in the Orange Book for Tiazac.

Analysis

After learning that DOV was unable to give it a license to the ‘463 patent because of Biovail’s exclusive license, Andrx petitioned the FDA to require Biovail to de-list the ‘463 patent from the Orange Book. Although the FDA has publicly stated that it lacks the resources and the expertise to review patents submitted with NDAs and that it has only a limited “ministerial role” in listing patents,⁴ a party may dispute the propriety of a patent listing, as Andrx did, by notifying the FDA. The FDA will then request that the NDA holder confirm that the listed patent information is correct. Unless the NDA holder voluntarily withdraws or amends its listing, however, the FDA will not change the patent information in the Orange Book. As one court has observed, the FDA’s listing of a patent does “not create any presumption that [a] patent was correctly listed” in the Orange Book.⁵

On February 7, 2001, and again on February 22, 2001, the FDA, consistent with its limited “ministerial role” in listing patents in the Orange Book, sought confirmation from Biovail that the ‘463 patent was properly listed. The complaint alleges that on February 26, 2001, as a result of a court filing by Biovail in a federal lawsuit brought by Andrx to force Biovail to de-list the ‘463 patent,⁶ the FDA learned that Biovail’s position was that the ‘463 patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the ‘463 patent, rather than the version of Tiazac that the FDA had approved and that

⁴59 Fed. Reg. 50338, 50345 (Oct. 3, 1994).

⁵*Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 456 (D.N.J. 1998).

⁶The federal district court eventually ruled that there is no private right of action under the Food, Drug, and Cosmetic Act for one company to require another to de-list a patent from the Orange Book. *Andrx Pharm., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1373 (S.D. Fla. 2001).

Analysis

Biovail had been marketing. The FDA notified Biovail on March 20, 2001, that its new formulation of Tiazac was not approved by the FDA under the Tiazac NDA. Accordingly, the FDA would de-list the '463 patent from the Orange Book unless Biovail amended its certification to indicate that the patent claimed the version of Tiazac the FDA had approved.

In response to the FDA's inquiries, Biovail submitted a signed declaration stating that the '463 patent was eligible for listing in the FDA's Orange Book as claiming Tiazac. The complaint alleges that this declaration was misleading because it did not clarify whether the term "Tiazac" as used by Biovail meant the form of Tiazac the FDA had approved for marketing (as the FDA intended) or Biovail's revised form of the product. The FDA understood Biovail's March 26, 2001, declaration as affirming that the '463 patent covers the currently approved Tiazac product. On that basis, the FDA decided not to de-list the '463 patent from the Orange Book. According to the complaint, however, Biovail continued to assert that listing the '463 patent in the Orange Book was justified because it covers a revised form of Tiazac that Biovail believed fell within the Tiazac NDA, but which the FDA did not.

The complaint concludes that as a result of Biovail's conduct, consumers of Tiazac have been deprived of the benefits of lower-priced generic competition that might have been possible had Biovail not acquired exclusive rights to, and then listed, the '463 patent, thereby precluding the FDA from granting final approval to Andrx's generic Tiazac in February 2001.

Competitive Analysis

The complaint alleges that the relevant product market in which to assess the anticompetitive effects of Biovail's conduct is Tiazac and generic bioequivalent versions of Tiazac. Although other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several other branded and generic formulations of once-a-day diltiazem, these other

Analysis

therapeutic agents do not significantly constrain Tiazac's pricing. In contrast, entry of a generic bioequivalent version of Tiazac likely would result in a significant, immediate decrease in the sales of branded Tiazac, and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents. In fact, Biovail's own sales forecasts projected that generic Tiazac would have captured 40 percent of branded Tiazac sales within the first year alone.

The relevant geographic market in which to assess the competitive effects of Biovail's conduct is the United States, given the FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals, like Tiazac, occur on a nationwide basis.

The complaint thus alleges that, at all times relevant to this case, Biovail's market share of the relevant antitrust market has been 100 percent.

Biovail's conduct as described above, and as alleged in the complaint, violated the antitrust laws in two ways. First, Biovail's acquisition of an exclusive license to the '463 patent substantially lessened competition in the U.S. market for Tiazac and its generic equivalents. As stated in the complaint, Biovail's acquisition of the exclusive license to the '463 patent raised substantial barriers to Andrx's entry into the relevant market and gave Biovail the power to exclude competition, thereby protecting Biovail's monopoly in the Tiazac market, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

The complaint also alleges that Biovail violated Section 5 of the FTC Act by engaging in acts that willfully maintained its Tiazac monopoly. These acts included: (a) acquiring an exclusive license to the '463 patent for the purpose of listing it in the Orange Book; (b) wrongfully listing the '463 patent in the Orange Book as claiming Tiazac, in order to be eligible for an automatic 30-

Analysis

month stay of FDA approval for any generic Tiazac product; and (c) giving non-responsive answers to questions raised by the FDA about the propriety of listing the '463 patent in the Orange Book, so as to avoid the possibility of de-listing. As the complaint states, Biovail's illegal monopolization raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition. Biovail thereby deprived consumers of the benefits of lower-priced generic competition that might have been possible had the FDA not been precluded from granting final approval to Andrx's generic Tiazac. These acts and practices are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

The Proposed Order

The proposed order is designed to address the anticompetitive effects of Biovail's illegal conduct charged above, by requiring Biovail to divest part of its exclusive rights to the '463 patent and by providing other relief, on a prospective basis, to prevent or discourage recurrence of such conduct in the future. In essence, the proposed order:

- Requires that Biovail divest to DOV the exclusive rights to the '463 patent, as it applies for use in making any form of the currently marketed and FDA-approved Tiazac product.
- Prevents Biovail from taking any actions that would result in an additional 30-month stay of final FDA approval for a generic form of Tiazac.
- Prohibits Biovail from wrongfully listing any patents in the Orange Book in violation of applicable law.
- Requires that Biovail give the Commission prior written notice before it acquires an exclusive license to any patent that it plans to list in the Orange Book for a product for which Biovail already has an FDA-approved NDA.

Analysis

By requiring that Biovail divest its exclusive rights in the ‘463 patent in the “Tiazac Field,” that is, for use in making any form of the currently FDA-approved Tiazac, Paragraph II returns the market for Tiazac products to the status quo as it existed before the patent acquisition occurred. Paragraph II.A requires that Biovail divest to DOV its exclusive interest in the ‘463 patent as it relates to the Tiazac Field. Paragraph II.B prevents Biovail from structuring the divestiture in such a way that it would be able to continue reaping the benefits of its acquisition of the patent. Paragraph II.C proscribes the creation of a confidentiality agreement that could hinder future Commission enforcement actions against Biovail under the order or the antitrust laws. Paragraph II.D prohibits Biovail from having any input into the future utilization of the patent in the Tiazac Field. Paragraph II.E prevents Biovail from participating in any lawsuits to enforce the ‘463 patent in the Tiazac Field. Paragraph II.F requires Biovail to dismiss its patent infringement claim against Andrx.

Taken as a whole, Paragraph II removes Biovail’s possession of exclusive rights in the ‘463 patent (through which it was able to erect barriers to Andrx’s potential entry), while preserving Biovail’s and DOV’s ability to innovate and develop new products using that same patent. Paragraph II allows Biovail to continue to use the ‘463 patent, on an exclusive basis, to develop new diltiazem products that may result in the filing of an NDA with the FDA. Moreover, nothing in the paragraph prevents Biovail from holding non-exclusive rights to the ‘463 patent to develop improved forms of the currently marketed Tiazac product.

If Biovail fails to complete the divestiture required in Paragraph II.A within ninety days of signing the Agreement Containing Consent Order in this matter, Paragraph III of the Proposed Order requires Biovail to enter into a trust agreement and transfer the assets set forth in Paragraph II.A to a trustee appointed by the Commission. The trustee will then have the sole and exclusive power to divest the assets required in Paragraph II.A, subject to the prior approval of the Commission. The trustee

Analysis

will have twelve months to accomplish the divestiture, at no minimum price, to a buyer or buyers approved by the Commission.

Paragraph IV is intended to remedy Biovail's allegedly illegal monopolization. By preventing Biovail from engaging in strategies that pharmaceutical companies have used to exploit the Hatch-Waxman Act to thwart generic entry, Paragraph IV seeks to ensure the entry of a generic Tiazac product at the earliest possible moment.

Paragraph V is intended to deter Biovail from listing patents in the Orange Book that do not actually claim the drug product at issue, and thus prevent the triggering of procedures under the Hatch-Waxman Act that could improperly block generic entry. The Commission is concerned that improper patent listings may be a recurring problem in the pharmaceutical industry, and that such listings have a significant potential to affect competition and harm consumers. NDA holders have the ability unilaterally to list patents in the Orange Book – and thus exclude potential generic competitors from entering the market and competing for up to thirty months – whether or not the patent they list actually claims the product approved under the NDA. Because the FDA views its role in listing patents as “purely ministerial,” and because there is no private right of action to challenge a patent listing under the Food, Drug, and Cosmetic Act,⁷ it is possible for NDA holders, such as Biovail in this case, to obtain an additional thirty months free from generic competition by listing inappropriate patents in the Orange Book.

The Commission believes that the operative provisions in Paragraphs II through V of the proposed order strike an appropriate balance between Biovail's interests in acquiring

⁷*Mylan v. Bristol-Myers Squibb Co.*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001). *See also Andrx Pharm., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1373 (S.D. Fla. 2001).

Analysis

patents for legitimate business purposes, such as developing new products using that intellectual property, and the Commission's intention to remedy an NDA holder's creation of barriers to generic competition through strategic patent acquisitions and the misuse of the Hatch-Waxman regulatory framework. By not imposing broad prohibitions on Biovail's ability to develop new products based on the '463 patent, and by not preventing Biovail from legitimately acquiring and listing patents for other NDAs it may hold, the order maintains Biovail's incentive to develop and sell new drug products, while curbing the potential for Hatch-Waxman Act abuse.

Paragraph VI requires that Biovail submit written notification to the Commission before acquiring any patent or exclusive license on a patent, if Biovail also intends to seek the patent's listing in the Orange Book. Biovail will thus be free to continue acquiring intellectual property for legitimate business purposes, but the Commission will be notified in situations where there is a possibility that the acquisition of an exclusive license may serve to protect Biovail's dominant position in a relevant pharmaceutical market.

Paragraph VII sets forth the form of notice that Biovail must provide to the Commission under Paragraph VI of the order. In addition to supplying a copy of the patents to be acquired, Paragraph VII requires Biovail to provide certain other information to assist the Commission in assessing the potential competitive effect of the patent acquisition. Accordingly, the order requires Biovail to identify, among other things, the parties participating in the acquisition, the approved NDA(s) with respect to which the acquired patent will be submitted for listing in the Orange Book, and all persons who have filed an ANDA referencing the identified NDAs. In addition, Biovail must provide the Commission with copies of all transactional documents and other documents that evaluate the proposed licensing agreement.

Analysis

Paragraphs VIII, IX, and X of the proposed order contain certain reporting and other standard Commission order provisions designed to assist the Commission in monitoring compliance with the order.

The order will expire in ten years.

Opportunity for Public Comment

The proposed order has been placed on the public record for thirty days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed order and the comments received and will decide whether it should withdraw from the agreement containing the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be addressed. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

Complaint

IN THE MATTER OF

LIBBEY INC., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket 9301; File No. 0110194**Complaint, May 9, 2002--Decision, October 7, 2002*

This consent order addresses the acquisition by Respondent Libbey Inc. – the largest maker and seller of food service glassware in the United States – of Anchor Hocking Corporation, the third largest maker and seller of food service glassware in the United States, and a wholly-owned subsidiary of Respondent Newell Rubbermaid Inc. The order, among other things, requires the respondents to provide the Commission with prior notice of the acquisition, sale, transfer, or other conveyance of all or part of Anchor or Anchor’s Food Service Business. The order also requires Respondent Libbey to provide the Commission with prior notice of its acquisition of any interest in Anchor’s stock or in the assets of Anchor’s Food Service Business. In addition, the order requires Respondent Newell, for ten years, to provide the Commission with prior notice if it sells, transfers, or otherwise conveys any part of Anchor’s Food Service Business to Libbey or Vitrocrisa, and to provide such prior notice for five years with respect to such transactions in all other circumstances.

Participants

For the Commission: *Richard Liebeskind, Chul Pak, Rhett Krulla, Morris Bloom, Brian Burgess, William Diaz, Lisa A. Rosenthal, April Tabor, Robert Tovsky, Robert Williams, Mary Forster, Art Strong, Elizabeth A. Piotrowski, Debra J. Holt, Christopher Garmon, Joseph Breedlove, Leslie Farber, and Mary T. Coleman.*

For the Respondents: *Bruce J. Prager and E. Marcellus Williamson, Latham & Watkins, Richard C. Weisberg, Libbey, and William S. D’Amico, Chadbourne & Parke.*