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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of **BIOVAIL CORPORATION,** a corporation.	**Docket No. C-4060**

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 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.

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 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-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 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. 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.

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 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.

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 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.

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 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.

Donald S. Clark
Secretary

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