IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BIOVAIL CORPORATION
7150 Mississauga Road
Mississauga, Ontario
Canada L5N 8M5

and

BIOVAIL LABORATORIES INTERNATIONAL SRL,
Chelston Park, Building 2, Ground Floor
Collymore Rock, St. Michael
Barbados, West Indies

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20857

and

ANDREW C. VON ESCHENBACH, M.D.,
In His Official Capacity as
Acting Commissioner of Food and Drugs,
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Defendants.

COMPLAINT FOR INJUNCTIVE AND
DECLARATORY RELIEF AND WRIT OF MANDAMUS

INTRODUCTION

1. Plaintiffs Biovail Corporation and Biovail Laboratories International SRL (collectively, "Biovail") have brought this action for injunctive, declaratory and mandamus relief

challenging the failure of the defendants, the U.S. Food and Drug Administration and its Acting Commissioner of Food and Drugs (collectively, "FDA"), to respond substantively to a Citizen Petition ("Biovail's Citizen Petition") filed by Biovail. Defendants' failure to decide the issues raised by Biovail's Citizen Petition violates the Administrative Procedure Act (the "APA") and Biovail's due process rights.

2. Biovail's Citizen Petition seeks to protect the public by ensuring that FDA applies appropriate standards when determining whether or not to approve an application to market a generic version of WELLBUTRIN XL®, a prescription drug product. FDA by regulation ordinarily has 180 days to determine the issues raised in a Citizen Petition—but more than 180 days have passed without any ruling from FDA on Biovail's petition. Biovail asks for a writ of mandamus to compel FDA to perform its duty and rule on the Citizen Petition.

3. Biovail also asks that FDA be required to rule on the Citizen Petition at least one calendar week prior to granting any application for approval of generic WELLBUTRIN XL®, so that if the Citizen Petition is denied there is a meaningful opportunity to seek judicial review of the denial. Therefore, Biovail also seeks temporary, preliminary and permanent injunctive relief to preserve the *status quo* by ordering FDA not to grant any such approval for generic WELLBUTRIN XL® without having decided Biovail's Citizen Petition at least one calendar week in advance.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 5 U.S.C. §§ 555, 702 and 706 (the APA); 28 U.S.C. § 1331 (federal question); and 28 U.S.C. § 1361 (mandamus).

5. The relief requested is authorized pursuant to 28 U.S.C. § 1651 (all writs act); 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. § 2202 (further relief). Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. §§ 701-706.

6. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

PARTIES

7. Plaintiff Biovail Corporation is a corporation with its head office at 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5. Biovail, together with its subsidiaries, is a fully integrated pharmaceutical company that, among other things, tests, develops, manufactures, and sells prescription drugs, either directly or to other pharmaceutical companies for marketing and distribution primarily in the U.S. and Canadian markets. The company is listed and publicly traded on the New York and Toronto Stock Exchanges.

8. Plaintiff Biovail Laboratories International SRL is a wholly owned subsidiary of Biovail Corporation, with its offices located at Chelston Park, Building 2, Collymore Rock, St. Michael, Barbados, West Indies. Biovail Laboratories International SRL is the assigned owner of the patents to WELLBUTRIN XL®.

9. Defendant U.S. Food and Drug Administration, which has its principal office at 5600 Fishers Lane, Rockville, Maryland 20857, regulates prescription drugs under authority delegated by Congress and the Secretary of Health and Human Services of the U.S. Department of Health and Human Services, a federal agency headquartered in the District of Columbia. Defendant Andrew C. von Eschenbach, M.D., is sued in his official capacity as Acting Commissioner of Food and Drugs. As Acting Commissioner, Dr. von Eschenbach has the ultimate responsibility for the activities of FDA, including those actions complained of herein.

STATEMENT OF FACTS

Biovail's WELLBUTRIN XL®

10. Biovail developed and manufactures WELLBUTRIN XL®. WELLBUTRIN XL® is an FDA-approved "innovator" prescription drug (sometimes referred to as a "pioneer," "brand-name" or "branded" drug) used to treat Major Depressive Disorder ("MDD"), a common and severe psychiatric disorder.

11. Biovail manufactures and supplies WELLBUTRIN XL® for the U.S. market exclusively to GlaxoSmithKline, Inc., one of the largest pharmaceutical companies in the world.

12. WELLBUTRIN XL® represents a substantial asset and cash flow stream for Biovail, generating hundreds of millions of dollars a year in revenue.

13. Chemically, WELLBUTRIN XL® is bupropion hydrochloride in extended-release tablets for once-a-day-administration.

14. Under relevant provisions of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 321, *et seq.* ("FDCA"), parties are permitted to file Abbreviated New Drug Applications ("ANDAs") for generic forms of FDA-approved innovator drugs such as WELLBUTRIN XL®. A generic version of an innovator drug may be approved under an ANDA that relies upon the findings of safety and effectiveness for the innovator drug.

15. However, because a generic is marketed as a substitute for an innovator drug, FDA may not approve an ANDA unless the applicant proves that its generic version is "bioequivalent" to the innovator drug.

16. It is not uncommon for those with rights to, and scientific knowledge about, an innovator drug to provide FDA with technical information during the ANDA review process to ensure an accurate determination of bioequivalence. The process for submitting such

information is by filing a "Citizen Petition" under applicable regulations. Under those regulations, FDA must consider and take action on the petition within 180 days of filing unless unable to do so.

17. Although a number of companies have filed ANDAs for generic versions of WELLBUTRIN XL®, there is currently no approved generic version. The first such ANDA deemed by FDA acceptable for review was filed by Anchen Pharmaceuticals, Inc. ("Anchen"). FDA granted a "tentative approval" of Anchen's ANDA on November 14, 2005.

18. Pursuant to the applicable regulations, after the filing of Anchen's ANDA, Biovail filed a Citizen Petition on December 20, 2005, concerning ANDAs for generic versions of WELLBUTRIN XL®. In its Citizen Petition, Biovail requested that FDA apply certain criteria in the approval process to any ANDA for a generic version of WELLBUTRIN XL®. Application of those criteria was and is necessary to ensure protection against potentially serious risks relating to high levels of buproprion hydrochloride, the active drug in WELLBUTRIN XL®.

19. In a June 7, 2006 notice, FDA stated that it would be unable to decide the Biovail Citizen Petition within the 180-day regulatory response deadline and indefinitely delayed such action. This tentative response stated without further explanation that "FDA has been unable to reach a decision on [Biovail's] petition because it raised complex issues requiring extensive review and analysis by Agency officials."

20. The issues raised in Biovail's Citizen Petition are extremely important to public health and safety and should have been acted upon by FDA within the required 180-day timetable.

21. On June 29, 2006, Biovail sent a letter to FDA requesting that FDA take immediate action on its Citizen Petition. FDA has yet to respond to Biovail's June 2006 letter.

22. FDA's failure to decide Biovail's Citizen Petition within the required 180 days is consistent with FDA's actions with respect to other Citizen Petitions relating to ANDAs. Upon information and belief, in the last six years, FDA has consistently disregarded the 180-day requirement and has never decided a Citizen Petition prior to its decision to approve the related ANDA.

23. Rather, it is FDA's pattern and practice to render a decision on a Citizen Petition relating to an ANDA on the same day that FDA issues its approval of an ANDA, without regard to the 180-day requirement.

24. FDA's aforementioned pattern and practice with respect to Citizen Petitions, including the Biovail Citizen Petition that is the subject of this Complaint, threatens public safety and harms the rights of those interested in Citizen Petitions.

25. Here, the express purpose of the Biovail Citizen Petition is to ensure that FDA applies proper criteria to verify that any generic version of WELLBUTRIN XL® is bioequivalent to the innovator drug. Any FDA approval of a generic version of WELLBUTRIN XL® that is not bioequivalent to the innovator drug will present a potential health risk to patients who would use the generic product.

26. By not deciding Citizen Petitions until the same time as issuing the approval of ANDAs, FDA has ignored its own regulations and harmed interested parties and the public. This practice effectively precludes any opportunity for effective judicial review of the denial of a Citizen Petition. Upon approval of an ANDA, the approved generic is almost immediately on

the market and the innovator is therefore harmed irreparably before there is any possibility of judicial review.

27. The substantial harm to Biovail that would be caused by the premature FDA approval of a generic version of WELLBUTRIN XL®, without adequate notice prior to FDA's decision on Biovail's Citizen Petition, would be irreparable.

CLAIM

28. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 27 of this Complaint.

29. Pursuant to the APA, plaintiffs have presented a Citizen Petition to the FDA. To date, FDA has failed to rule on the petition.

30. The APA requires FDA within a reasonable time to proceed to conclude a matter that has been presented to it.

31. The relevant regulation (21 C.F.R. § 10.30) provides that the "Commissioner shall furnish a response to each petitioner within 180 days of the receipt of the petition."

32. The APA provides that a reviewing court shall compel agency action unlawfully withheld or unreasonably delayed.

33. FDA's failure to decide the issues raised in Biovail's Citizen Petition is a violation of the APA and plaintiffs' due process rights under the Fifth Amendment to the U.S. Constitution.

34. As a result of FDA's action, Biovail has suffered and will continue to suffer, absent injunctive relief, irreparable harm for which there is no adequate remedy at law.

RELIEF REQUESTED

WHEREFORE, plaintiffs respectfully request that this Court enter an order:

A. Declaring that FDA's unreasonable delay in responding to the Biovail Citizen Petition is a violation of the APA and Biovail's due process rights;

B. Requiring FDA, by writ of mandamus or injunction, to provide a substantive determination of the Biovail Citizen Petition within a reasonable period to be determined by the Court, and in any event at least one week prior to granting approval of any ANDA respecting generic WELLBUTRIN XL®;

C. Temporarily, preliminary and permanently enjoining FDA from deciding any ANDA application with respect to generic versions of WELLBUTRIN XL® without having decided Biovail's Citizen Petition at least one calendar week in advance;

D. Awarding plaintiffs' attorneys' fees and reasonable expenses incurred in connection with this action; and

E. Such other relief as the Court deems just and proper.

Dated: August 23, 2006

Respectfully submitted,

By: */s/ James F. Segroves*
James F. Segroves (DC Bar No. 480360)
PROSKAUER ROSE LLP
1001 Pennsylvania Avenue, NW
Suite 400 South
Washington, DC 20004-2533
202.416.6800
202.416.6899 (fax)

Ronald S. Rauchberg (not admitted in DC)
Kevin J. Perra (not admitted in DC)
PROSKAUER ROSE LLP
1585 Broadway

New York, NY 10036-8299
212.969.3000
212.969.2900 (fax)

John B. Dubeck (DC Bar No. 238287)
KELLER AND HECKMAN LLP
1001 G Street, NW
Washington, DC 20001
(202) 434-4200
(202) 434-4646 (fax)

Attorneys for Plaintiffs Biovail Corporation and Biovail Laboratories International SRL