James J. Calder (JC-8095)
Steven Shiffman (SS-3630)
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, New York 10022-2585
(212) 940-8800

Charles R. Krikorian (pending admission *pro hac vice*)
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, Illinois 60661-3693
(312) 902-5200

*Attorneys for Plaintiff*



**JUDGE KARAS**

**05 CV 7799**

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIOVAIL LABORATORIES INTERNATIONAL SRL, a corporation of Barbados,

Plaintiff,

vs.

WATSON LABORATORIES, INC., a corporation of New York,

Defendant.

No.

**COMPLAINT FOR PATENT INFRINGEMENT**

**JURY TRIAL DEMANDED**

Plaintiff Biovail Laboratories International SRL ("Biovail"), by its attorneys Katten Muchin Rosenman LLP, for its complaint against Watson Laboratories, Inc. ("Watson"), alleges as follows:

## JURISDICTION, VENUE, AND PARTIES

1. This is an action for infringement of U.S. Patent Nos. 6,096,341 and 6,143,327 pursuant to 35 U.S.C. §271(e)(2). Defendant Watson has filed an Abbreviated New Drug Application ("ANDA") Number 77-715 with the United States Food and Drug

Administration ("FDA") for a generic version of Wellbutrin XL®, an antidepressant which may be administered once daily. Each of the foregoing patents is listed in the FDA's book of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") as covering Wellbutrin XL®. Watson has mailed a written notice to Biovail ("the Notice letter"), informing it that pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Watson has certified to FDA that each of the foregoing patents will not be infringed by the manufacture, use, or sale of the new drug for which ANDA No. 77-715 is submitted. The Notice letter states that Watson seeks approval from FDA to market its proposed ANDA product prior to the expiration of the above-identified patents. Under 35 U.S.C. §271(e)(2), "[i]t shall be an act of infringement to submit an [ANDA] application under [21 U.S.C. §355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent."

2. Plaintiff Biovail Laboratories International SRL ("Biovail") is a corporation organized and existing under the laws of Barbados, and has a place of business in Carolina, Puerto Rico.

3. After an opportunity for further investigation or discovery, there is likely to be evidence that Watson is a corporation organized and existing under the laws of the State of New York, having a place of business at 1033 Stoneleigh Avenue, Carmel, New York 10512.

4. This Court has jurisdiction under 28 U.S.C. §1338(a). Watson resides in this District. This Court has personal jurisdiction over Watson and venue is proper in this

Court under 28 U.S.C. §§1391(c) and 1400(b).

5. New Drug Application ("NDA") 021515 was approved by the United States Food and Drug Administration ("FDA") on August 28, 2003 for the manufacture, marketing and sale of a drug product having the active ingredient bupropion hydrochloride, used in the treatment of depression. Since that time a drug product has been sold, pursuant to NDA 021515, under the trademark Wellbutrin XL®. NDA 021515 and the Wellbutrin XL® drug product is listed in the FDA's book of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"), under its active ingredient, bupropion hydrochloride. The following United States patents are also listed in the Orange Book as covering the drug product of NDA 021515: U.S. Patent Nos. 6,096,341 and 6,143,327.

6. U.S. Patent No. 6,096,341 ("the '341 patent") was duly and legally issued on August 1, 2000. Biovail is the owner of the '341 patent, and has the right to sue for infringement and recover damages.

7. U.S. Patent No. 6,143,327 ("the '327 patent") was duly and legally issued on November 7, 2000. Biovail is the owner of the '327 patent, and has the right to sue for infringement and recover damages.

**COUNT I**
**WATSON'S ACT OF INFRINGEMENT OF THE '341 PATENT UNDER 35 U.S.C. §271(e)(2)**

8. Biovail incorporates paragraphs 1-7 by reference.

9. Watson advised Biovail by a written instrument dated July 21, 2005 ("the Notice letter"), that it had filed ANDA No. 77-715, seeking approval from the FDA to market a generic version of Wellbutrin XL®, and that it had certified to the FDA pursuant

to 21 U.S.C. §355(j)(2)(A)(vii)(IV) that its proposed ANDA product would not infringe the '341 patent. The Notice letter states that Watson seeks approval from the FDA to market its proposed generic product before the expiration of the '341 patent.

10. Biovail has served written requests on counsel for Watson for information necessary to determine whether the product Watson is likely to market if the FDA approves ANDA No. 77-715 is within the scope of one or more claims of the '341 patent. Watson has not provided this information. All of the information relating to the issue of infringement is in Watson's possession or is on file with the FDA on a confidential basis. Biovail does not have access to such information.

11. In the absence of the information Biovail has requested, Biovail must resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Watson infringes one or more claims of the '341 patent.

12. After a reasonable opportunity for further investigation or discovery, there is likely to be evidence that Watson has infringed the '341 patent under 35 U.S.C.§271(e)(2), by seeking approval under its ANDA No. 77-715 to engage in the commercial manufacture, use, sale or offer for sale of its proposed ANDA product prior to the expiration of the '341 patent.

13. After a reasonable opportunity for further investigation or discovery, and by the time this case goes to trial, there is likely to be evidence that Watson has damaged Biovail by publicizing the fact that Watson has filed its ANDA, and by offering to sell its proposed ANDA product within the United States to distributors or pharmacies for distribution to physicians after the effective date of any FDA approval.

## COUNT II
## WATSON'S ACT OF INFRINGEMENT OF THE '327 PATENT UNDER 35 U.S.C. §271(e)(2)

14. Biovail incorporates paragraphs 1-13 by reference.

15. Watson advised Plaintiff by the Notice letter, that it had filed ANDA No. 77-715, seeking approval from the FDA to market a generic version of Wellbutrin XL®, and that it had certified to the FDA pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) that its proposed ANDA product would not infringe the '327 patent. Watson seeks approval from the FDA to market its proposed generic product before the expiration of the '327 patent.

16. Biovail has served written requests on counsel for Watson for information necessary to determine whether the product Watson is likely to market if the FDA approves ANDA No. 77-715 is within the scope of one or more claims of the '327 patent. Watson has not provided this information. All of the information relating to the issue of infringement is in Watson's possession or is on file with the FDA on a confidential basis. Biovai does not have access to such information.

17. In the absence of the information Biovail has requested, Biovail must resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Biovail infringes one or more claims of the '327 patent.

18. After a reasonable opportunity for further investigation or discovery, there is likely to be evidence that Watson has infringed the '327 patent under 35 U.S.C.§271(e)(2), by seeking approval under its ANDA No. 77-715 to engage in the commercial manufacture, use, sale or offer for sale of its proposed ANDA product prior

to the expiration of the '327 patent.

19. After a reasonable opportunity for further investigation or discovery, and by the time this case goes to trial, there is likely to be evidence that Watson has damaged Biovail by publicizing the fact that Watson has filed its ANDA, and by offering to sell its proposed ANDA product within the United States to distributors or pharmacies for distribution to physicians after the effective date of any FDA approval.

## RELIEF REQUESTED

**WHEREFORE**, Biovail requests the following relief:

A. A judgment that Watson Laboratories, Inc. has infringed valid U.S. Patent Nos. 6,096,341 and 6,143,327 under 35 U.S.C. §271(e)(2);

B. An order that the earliest effective approval date of ANDA No. 77-715, if any, shall not be earlier than the last expiration date of U.S. Patent Nos. 6,096,341 or 6,143,327;

C. An injunction against the commercial manufacture, use, offer to sell or sale within the United States of any product made pursuant to the specification of ANDA No. 77-715;

D. An award of damages;

E. An award of costs and expenses in this action; and,

F. For such further and other relief as this Court may deem just and proper.

**DEMAND FOR JURY**

Plaintiff demands a jury trial for all issues triable to a jury.

Dated: September 6, 2005

James J. Calder (JC-8095)
Steven Shiffman (SS-3630)
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, New York 10022-2585
(212) 940-8800

Charles R. Krikorian (pending admission *pro hac vice)*
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, Illinois 60661-3693

Attorneys for Plaintiff