

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BIOVAIL LABORATORIES, INC.,	:	
a corporation of Barbados,	:	
	:	
Plaintiff,	:	No. 05-cv-1085
	:	
v.	:	
	:	
IMPAX LABORATORIES, INC.,	:	
a corporation of Delaware,	:	
	:	
Defendant.	:	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Biovail Laboratories, Inc. (“Biovail”), by and through its undersigned counsel, Fox Rothschild LLP, hereby asserts this amended complaint for patent infringement against defendant, Impax Laboratories, Inc. (“Impax”), and respectfully alleges as follows:

JURISDICTION, VENUE, AND PARTIES

1. This is an action by Biovail against Impax for infringement of U.S. Patent No. 6,096,341, pursuant to 35 U.S.C. § 271(e) (2). This infringement action arises under the patent laws of the United States because Impax has filed, pursuant to 21 U.S.C. §355(j), an Abbreviated New Drug Application (“ANDA”) Number 77-415 and amendments thereto with the Federal Food and Drug Administration (“FDA”) for Bupropion Hydrochloride 150 mg and 300 mg extended release tablets (Impax’s 150 mg Bupropion XL tablets and Impax’s 300 mg Bupropion XL tablets). Impax has mailed written notice to Biovail (the “Notice Letters”) informing it that, pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), it has certified to the FDA that the foregoing patent will not be infringed by the manufacture, use or sale of the new drug for which ANDA No. 77-415 is submitted. 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.”

2. Biovail is a corporation organized and existing under the laws of Barbados and has a place of business located at #34B Street Iturregui Avenue, Carolina, Puerto Rico 00646.

3. Impax is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 30832 Huntwood Avenue, Hayward, California 94544, as well as at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124.

4. This Court has jurisdiction under 28 U.S.C. § 1338(a).

5. This action arises under the patent laws of the United States, and specifically under 35 U.S.C. §§271(a) and 271(e)(2).

6. Impax has an office located in this district and, therefore, this Court has personal jurisdiction over Impax.

7. Venue is proper in this Court under 28 U.S.C. §§1391(c) and 1400(b).

BIOVAIL’S NEW DRUG APPLICATION – WELLBUTRIN XL[®]

8. SmithKline Beecham Corp. (“SmithKline”) is the owner of the rights under New Drug Application (“NDA”) 021515, under which it sought and received approval from the FDA on August 28, 2003 to manufacture, market and sell a drug having the active ingredient, Bupropion Hydrochloride, used in the treatment of depression. Since that time, under NDA 021515, SmithKline has sold a drug under the trademark Wellbutrin XL[®].

SmithKline has listed NDA 021515 and its Wellbutrin XL[®] drug in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), under its active ingredient, Bupropion Hydrochloride. SmithKline has an exclusive license under U.S. Patent No. 6,096,341 (hereinafter "the '341 patent"), and has listed that patent in the Orange Book as covering its NDA product.

9. U.S. Patent No. 6,096,341 (the '341 patent) was duly and legally issued on August 1, 2000.

10. Biovail is the owner by assignment of the '341 patent, has the right to sue for patent infringement and to recover any damages associated with the infringement.

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

11. Biovail hereby incorporates by reference paragraphs 1 through 10, inclusive, of plaintiff's amended complaint by reference.

12. Impax advised Biovail by Notice Letters dated January 20, 2004 [sic 2005] and January 24, 2004 [sic 2005], that it had filed ANDA No. 77-415 with the FDA for Bupropion Hydrochloride 150 mg and 300 mg extended release tablets (Impax's 150 mg Bupropion XL tablets and Impax's 300 mg Bupropion XL tablets). The Notice Letters stated that Impax had certified to the FDA (pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification")), that its proposed ANDA product will not infringe the '341 patent. The Notice Letters stated that Impax seeks approval from the FDA to market its proposed generic product before the expiration of the '341 patent.

13. Biovail has reviewed ANDA No. 77-415 and believe that it infringes the '341 patent based upon the information provided, but Biovail will need additional information to determine the extent of Impax's infringement.

14. Most of that information concerning the issue of infringement is within Impax's possession or is on file with the FDA on a confidential basis. As such, Biovail does not have access to that additional information.

15. In the absence of such information, Biovail must resort to the judicial process and the aid of discovery in order to obtain, under appropriate judicial safeguards, such information as is required to confirm their belief and to present to the Court evidence that Impax infringes one or more claims of the '341 patent.

16. After a reasonable opportunity for further investigation or discovery, there is likely to be evidence that Impax has infringed the '341 patent under 35 U.S.C. § 271(e)(2), by seeking approval under its ANDA No. 77-415 with a Paragraph IV certification 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.

17. After a reasonable opportunity for further investigation or discovery, and by the time that this case goes to trial, there is likely to be evidence that Impax has damaged plaintiffs by publicizing the fact that Impax has filed its ANDA, and by offering to sell or import into the United States its proposed ANDA No. 77-415 to distributors or pharmacies for distribution to physicians after the effective date of any FDA approval.

DEMAND FOR JURY

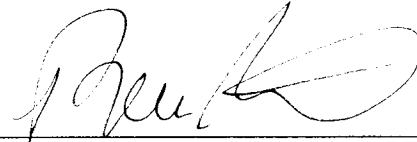
Biovail hereby demands a trial by jury.

RELIEF REQUESTED

WHEREFORE, plaintiff, Biovail Laboratories, Inc., prays for judgment in its favor as follows:

- A. For a judgment that defendant, Impax Laboratories, Inc., has infringed valid U.S. Patent No. 6,096,341;
- B. For an Order that the earliest effective approval date of ANDA No. 77-415, if any, shall not be earlier than the last expiration of U.S. Patent No. 6,096,341;
- C. For an injunction prohibiting the commercial manufacture, use, offer to sell or sale within the United States any product made pursuant to specifications of ANDA No. 77-415;
- D. For an award of damages for Impax's offer to sell or import an approved drug under ANDA No. 77-415;
- E. For an award of the costs and expenses in this action; and,
- F. For such further and other relief as this Court may deem just and proper.

Respectfully submitted,



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**Attorneys for Plaintiff
BIOVAIL LABORATORIES, INC.**

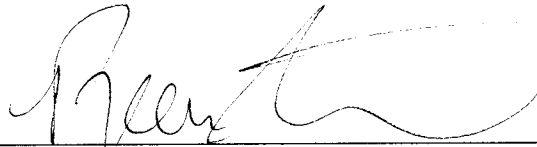
Dated: April 7, 2005

CERTIFICATE OF SERVICE

I, Robert S. Tintner, Esquire, do hereby certify that the foregoing Amended Complaint for Patent Infringement was served this 7th day of April, 2005, by United States First-Class Mail, postage pre-paid, upon the following:

Frederick H. Rein, Esquire
Annemarie Hassett, Esquire
Goodwin Procter LLP
599 Lexington Avenue
New York, NY 10022

**Attorneys for Defendant
IMPAX LABORATORIES, INC.**

A handwritten signature in black ink, appearing to read 'Robert S. Tintner', written over a horizontal line.

ROBERT S. TINTNER, ESQUIRE